



Transcript of Proceedings:

Grievance of First Officer Michael Danford, ATL 18-14

AIR LINE PILOTS ASSOCIATION, INT'L
and
DELTA AIR LINES CO.

Volume One
October 28, 2020

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VIRTUAL ARBITRATION

GRIEVANCE OF FIRST OFFICER MICHAEL DANFORD

CASE NO. 18-14

BETWEEN

AIR LINE PILOTS ASSOCIATION, INT'L

AND

DELTA AIR LINES CO.

VOLUME ONE

OCTOBER 28, 2020

REPORTED BY:

DAMIEN STONEBERGER

STORYCLOUD

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APPEARANCES

ARBITRATOR:

Mark Burdette

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Mike J. Doyle, Company Board Member
Patrick Burns, Company Representative

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APPEARANCES, CON'T

Also Present for the Union:

- Emilio Marcos, Contract Administration
Committee Chairman
- Kevin Morris, Union Board Member
- Steve Mayer, Union Board Member

Also Present:

- Michael Danford, Grievant
- Emily Zavis, Remote Technician

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TRANSCRIPT OF PROCEEDINGS, VOLUME ONE
OCTOBER 28, 2020

THE ARBITRATOR: This is Mark Burdette. I've been selected as the arbitrator under the Delta-ALPA Collective Bargaining Agreement to be the neutral chair of the system board in the matter of the discharge of Michael Danford. And so with this, we're going to proceed today. Are there any items, Mr. Kassin or Mr. Seham, that we need to deal with before we get into opening statements and --

MR. SEHAM: I don't know when it is appropriate to bring this up, but probably -- probably now, is that the parties have stipulated that we will handle this proceeding on a bifurcated basis. In other word, determine first -- we'll have the board determine first whether reinstatement is appropriate and we will defer any issue in terms of the make whole relief.

MR. KASSIN: That is correct.

THE ARBITRATOR: Okay. That's fine. I'm comfortable with that. All right with -- with that on the record, this is a discharge case, so the company will bear the burden of proof. Mr. Kassin, are you prepared to go forward with an opening statement?

MR. KASSIN: Yes, sir, I am.

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1 THE ARBITRATOR: Okay. Thank you. Go ahead.

2 MR. KASSIN: Sure. Good morning, Arbitrator
3 Burdette and members of the System Board of Adjustment.
4 Like other major airlines, Delta has a HIMS Program for
5 its pilots who are alcohol-dependent. We talked about
6 that in a number of the pre-hearing conferences, but
7 the whole board has not heard this, so I'm going to
8 give a quick summary. I mean, the Delta HIMS program
9 is called the Delta Pilot's -- Pilot Assistance
10 Committee or HIMS, and it's administered both by Delta
11 and ALPA. The other stakeholder in the Delta HIMS
12 program is the Federal Aviation Administration.

13 Pilots can enter DPAC thru various avenues. As a
14 general rule when a pilot enters DPAC as a volunteer or
15 through an off-duty alcohol incident, they complete
16 initial treatment, they're placed on what's called a
17 Contract A. Pilots on a Contract A are required to
18 maintain complete abstinence, attend meetings,
19 participate in aftercare program, and they're subject
20 to random unannounced alcohol testing. All of this is
21 agreed to in their Contract A. Pilots who enter DPAC
22 through on-duty positive test, but who do not operate
23 an aircraft with alcohol in their system are placed on
24 what we call a Contract B. Contract B incorporates
25 Contract A, but it also includes a last chance

1 provision.

2 We have a lot of testimony to cover in the time we
3 have allotted so I'm going to keep my opening remarks
4 rather brief. I'm going to refer everybody to what
5 we've identified as Company Exhibit 1, which is Michael
6 Danford chronology. And kind of give an overview is
7 where we are and how we got here.

8 (Company Exhibit 1 marked for identification)

9 On January 5, 2017, Mr. Danford was operating a
10 Dodge pickup truck in the township of Black Wolf,
11 Wisconsin. At approximately 5:30 pm. Mr. Danford
12 rear-ended a Ford Explorer at a stop sign. Believing
13 that Mr. Danford was impaired, the investigating
14 officer did a field sobriety test and then transported
15 Mr. Danford to a hospital for what the State of
16 Wisconsin calls, an evidentiary chemical test in his
17 blood. The test was conducted approximately an
18 hour-and-a-half after the accident and Mr. Danford's
19 blood alcohol was measured at .229. From that point
20 forward there was no notice to Delta from Mr. Danford
21 of his DUI. He continued to fly. In June of 2017, he
22 was unable to get his FAA medical renewed because of
23 the DUI or Wisconsin calls it an OWI. In July, he
24 called in sick for his flight. On July 31st, 2017, he
25 had an assessment and this is something the FAA

1 required. And following that assessment, on the day of
2 August 1st, 2017, he entered the Talbot Recovery Center
3 for treatment. On September 13, 2017, he signed his
4 Contract A as part of the DPAC program and the Delta
5 Substance Abuse Policy.

6 He completed his treatment at the Talbot Recovery
7 Center on September 14th, 2017, and he was admitted or
8 entered into the DPAC program on September 17th. So
9 once Mr. Danford completed his treatment at the Talbot
10 Recovery Center on September 14 and enter DPAC on
11 September 17, he was subject to DPAC's Random Testing
12 Protocol, which is essentially 14 tests a year. Delta
13 uses urine test to measure ethyl glucuronide or you're
14 going to hear us referred to ethyl glucuronide as ETG
15 and ethyl sulfate and you'll hear us refer to it as
16 ETS. It also uses phosphatidylethanol or PEth or
17 P-E-T-H. And you're going to hear references to all
18 three of those, but they're the same thing. Testing
19 either as a stand alone, random test or when there is a
20 question about a urine test that has EPG in it and
21 we're looking to see whether or not alcohol was present
22 through ingestion drinking alcoholic beverages.

23 Over the next several months, he had several random
24 tests. November 28th, 2017 he was tested random --
25 tested negative on a random alcohol test. Tested

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1 negative on December 14th, 2017. Tested random on --
2 I'm sorry, negative on January 4th on a random test,
3 tested negative on February 12th on a random test. He
4 received his FAA special issuance on February 26, 2018.
5 Started the process to come back to flying at Delta.
6 He had another random test on March the 9th, 2018 and
7 tested negative. March 27, 2018 another random test
8 and he was negative. April 26, 2018 another test -- a
9 random test and he tested negative. May 1st is one of
10 those extra tests that they throw in as part of the
11 DPAC program through Choice Laboratories. He tested
12 positive for ETG on a random test. His EPS was
13 negative and in accordance with the protocol at Delta
14 and used by DPAC, he was given a PEth test. They used
15 dried blood spot on May 9th, 2018. The initial tests
16 on that came back at a 69, the cut-off is 20 nanograms
17 per milliliter. In his initial presumptive positive
18 was 69 nanograms per milliliter. His confirmatory test
19 on the PEth was 98 nanograms per milliliter.

20 And this established a failure to maintain complete
21 abstinence. He was at that point in violation of his
22 Contract A. Mr. Danford was given the opportunity to
23 obtain re-treatment at a facility mutually agreed upon
24 by Delta and ALPA. Claiming he was not drinking, he
25 refused re-treatment. At that point, his HIMS AME, Dr.

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1 Harper Junior withdrew on May 18th, 2018 and the FAA
2 revoked his special issuance the same day, May 18th
3 2018. Delta issued what is referred to as a Notice of
4 Intent to Terminate or NOI on July 12th, 2018. A
5 grievance was filed on his behalf by ALPA on July 20th
6 2018. There was an initial hearing with -- on July
7 30th 2018 with Captain Graham and Captain Burns.
8 Following the initial hearing, his grievance was denied
9 and he was issued a letter of termination on August 6th
10 2018.

11 Delta's opinion was that having violated his
12 Contract A by failing to complete -- maintain complete
13 abstinence as he was required to do, and then being
14 offered re-treatment, but refusing to do it, he was an
15 untenable safety risk. I mean, Delta just simply
16 couldn't put him back into the cockpit without him
17 successfully completing re-treatment and going onto a
18 Contract B. Accordingly, his employment with Delta was
19 terminated. As part of our presentation in this case,
20 we'll have testimony from the decision-maker for Delta
21 Airlines that was Captain Jim Graham and -- Captain
22 Graham will explain in detail the basis of his
23 decision. So at this point, what I would ask of the
24 system board members and the arbitrator is that once we
25 complete the hearing in this matter, the evidence is

1 admitted, the board and arbitrator have the opportunity
2 to consider our post-hearing briefs, we'll ask you to
3 reaffirm the company's decision to terminate Mr.
4 Danford's employment and deny the grievance in this
5 case. Thank you.

6 THE ARBITRATOR: Thank you. Mr. Seham, do you want
7 to give an opening statement? You're muted. Mr.
8 Seham, you're muted.

9 MR. SEHAM: Yes. Good morning to all, including
10 the board and Arbitrator Burdette. Mr. Michael
11 Danford's entire life has been built around being a
12 professional pilot. First over 10 years as a Navy
13 pilot serving our country, then as a Delta pilot for
14 nearly 20 years. In all that time, he never had an
15 incident, never had an accident, never failed a
16 training event of any kind, never received discipline
17 of any kind. Mr. Danford was a model servicemen and a
18 model employee. He had and continues to have a
19 spotless record as a professional pilot. His
20 participation in the HIMS program was not triggered by a
21 workplace incident or FAA mandated random or reasonable
22 cause test. Rather, he had an off-duty DUI incident
23 and subsequently volunteered to enter the HIMS program
24 which included an inpatient program at the Talbott
25 Recovery campus.

1 The experience at Talbott's was both harsh and
2 ugly. Mr. Danford was housed with a racist profane
3 ex-convict. His requests for alternative
4 accommodations were summarily rejected. Nonetheless,
5 he satisfied Talbott's review process and he was
6 reinstated to the flight line. His flights were
7 performed without incident and you will hear from his
8 peer monitor that he wasn't an exemplary and proactive
9 HIMS participant. On May one, he received a text from
10 program administrator Michelle Gable instructing him to
11 provide a urine specimen for alcohol testing. His
12 urine was tested at Quest Diagnostics laboratory using
13 two different methodologies referred to by Mr. Kassin,
14 neither of which is FDA approved, neither of which has
15 been vetted via Notice of Proposed rulemaking process
16 by either DHHS or the Department of Transportation.

17 These methodologies were the following as alluded
18 to by Mr. Kassin, Ethyl Sulfate or ETS and Ethyl
19 Glucuronide or ETG. Notably, ETG is considered such a
20 highly sensitive test that leading laboratories warn
21 that a positive can be triggered by incidental exposure
22 to alcohol, which is via a hand sanitizer. Indeed, and
23 we find this ironic, even USDTL takes the position that
24 positive ETG results can be produced by certain agents
25 like hand sanitizers and even mouthwash. On May 9th,

1 Michelle Gable called Mr. Danford and told him the ETS
2 test was negative, but the ETG was supposedly positive.
3 The board members should already be scratching their
4 respective heads. How can a single specimen tested by
5 the same laboratory yield a positive and a negative?

6 How can a man's career rest on such vagaries?
7 Under fundamental forensic toxicological principles,
8 the overall results should be treated as a negative.
9 That's the approach demanded by the Department of
10 Transportation and the National Transportation Safety
11 Board in the context of drug testing. If the amino
12 acid screen test and the gas chromatography mass
13 Spectrometry test, in the context of drug testing,
14 failed to yield a uniform result, then the final result
15 is deemed a negative. End of story. There is no
16 continuation of testing in order to ring a bell that
17 will end the man's career. Moreover, we'll provide
18 expert testimony that the ETG result should actually be
19 deemed a negative based on a review of the Quest
20 Diagnostics litigation package. So in fact, Mr.
21 Danford's May 1 collection produced two negative test
22 results. Nevertheless, Ms. Gable, the program
23 administrator for Delta, instructed Mr. Danford to
24 provide dried blood spots or DBS to be tested by USDTL.
25 Here again, we're dealing with a non FDA test -- yes?

1 THE REPORTER: Can you go back? You broke up for a
2 moment.

3 MR. SEHAM: Okay. So its, about five seconds you
4 need or?

5 THE REPORTER: About 10.

6 MR. SEHAM: About 10, Okay. So let me go back to
7 here. We will provide expert testimony that the ETG
8 tests should actually be deemed a negative based on a
9 review of the Quest Diagnostics litigation package. So
10 in fact, Mr. Danford's May 1 collection produced two
11 negative test results. Nevertheless, Ms. Gable
12 instructed Mr. Danford to provide drug blood drug --
13 excuse me, dried blood spots, DBS to be tested by USDTL
14 using a methodology referred to as PEth. We're dealing
15 with a non FDA testing process using an experimental
16 matrix. What we mean by matrix is the substance being
17 tested, such as urine, saliva, breath, venous blood or
18 whole blood, or in this instance, dry blood. As USDTL
19 has posted, "There are no other labs that do commercial
20 dried blood spot PEth testing, so there are no labs for
21 comparison."

22 Other laboratories utilizing PEth with whole blood
23 warn the recipient of the test results. That, "Results
24 should be interpreted in the context of all available
25 clinical and behavioral information." Significantly, in

1 this case, every other piece of clinical and behavioral
2 information supports the conclusion that Mr. Danford
3 was abstinent, including psychiatric reports, polygraph
4 examinations, peer monitor testimony, and professional
5 piloting performance. Now that were not enough, the
6 minute Mr. Danford received news of the false PEth test
7 result, he rushed out and submitted to numerous
8 additional tests, all of which produced negative
9 results with a time frame and a look-back period that
10 preclude giving credit to the USDTL test result that
11 arose from the May 9th collection.

12 Now, notwithstanding this welter of countervailing
13 evidence, Delta demands that the single PEth test
14 should be considered dispositive. We will present
15 evidence, however, that USDTL that -- excuse me, that
16 USDTL's own protocols were violated in a manner that
17 precludes consideration of the May 9th PEth test
18 result. We will also present evidence that USDTL PEth
19 testing has produced inconsistent results and false
20 positives in the recent past. A violation of Contract
21 A is premised on a violation of the commitment to
22 abstinence. There is insufficient evidence to
23 establish that Mr. Danford breached Contract A in this
24 respect. Even if he did suffer a relapse, our position
25 is that termination would not have been warranted under

1 all the circumstances.

2 As Mr. Kassin pointed out in his opening, this is
3 not a Contract B case which provides for a last chance
4 arrangement. This is Contract A, which is based on a
5 premise of a return -- return of the employee to
6 employment. Now, Delta presents, it's offered to Mr.
7 Danford that he return to Talbott or some similar
8 inpatient program as an act of magnanimity. In another
9 context, maybe it would be. We consider Mr. Danford's
10 rejection of the offer as an act of courage. Yes. It
11 would have been the certain way out to jump through the
12 hoops he so recently had successfully leaped through.
13 However, putting to one side the dreadful conditions
14 that that he was subjected to at Talbotts, he would
15 have been required to make a false confession that he
16 had suffered a relapse.

17 Mr. Danford decided that he would rather suffer
18 termination and present his case to this board rather
19 than lie. For this, he should be commended. In the
20 eyes of the FAA, Mr. Danford is medically qualified and
21 fit to fly. This board should reach the same
22 conclusion. We request that Mr. Danford be reinstated
23 with full make whole relief and seniority, assist on
24 full compliance with the monitoring process that was in
25 place at the time of his termination. Thank you.

1 THE ARBITRATOR: Thank you. Mr. Kassin, are you
2 prepared to call your first witness?

3 MR. KASSIN: We are and this is where I normally
4 the witness would be here. The first witness will be
5 Dr. Joe Jones from US Drug Testing Laboratory. And I
6 guess my question is how do we, Emily and others, how
7 do we get him on board?

8 REMOTE TECH: Is he signed in as USDTL WebEx?

9 MR. KASSIN: Yes.

10 REMOTE TECH: Okay. I will let him in now.

11 MR. KASSIN: Okay.

12 MR. SEHAM: While we're waiting, Arbitrator
13 Burdette, just for the record, and I presume you've
14 already ruled on this, but based on Union Exhibit 77,
15 we are objecting to any testimony from this next
16 witness that goes beyond factual testimony based on the
17 failure to previously disclose what his testimony would
18 consist of. I don't -- I don't mean to burn the record
19 any further other than to refer to Union Exhibit 77.

20 THE ARBITRATOR: That's fine. My understanding is
21 that we -- I previously ruled on the union's request to
22 have a report issued from him and there is no such
23 report so is -- clarification that was the ruling I
24 think that I made was that I could not compel to
25 produce a report that didn't exist. Your objection is

1 noted on the record, Mr. Seham.

2 MR. SEHAM: Thank you.

3 THE ARBITRATOR: Mr. Kassin, proceed with the
4 witness.

5 MR. KASSIN: Is Dr. Jones, here?

6 THE ARBITRATOR: He's here, I can see him.

7 MR. KASSIN: Okay. There -- I do. Okay. I do see
8 him now. Thank you very much. Okay. Good morning.
9 Dr. Jones, this is Tom Kassin. I'm having a technical
10 glitch here in Atlanta and am using Dr. Taylor's
11 computer. So that's where I'll be speaking to you from
12 today. And then we're going to work through that
13 technical glitch later. Generally, the process would
14 be to have witnesses sworn by the court reporter. Are
15 we able to do that, Damien?

16 THE ARBITRATOR: I can do it. Mr. Kassin, I've
17 done it.

18 MR. KASSIN: Thank you, sir.

19 THE ARBITRATOR: All right. Would you raise your
20 right hand, please? Do you swear or affirm that the
21 testimony you're about to give in this case will be the
22 truth, the whole truth, and nothing but the truth?

23 THE WITNESS: I do.

24 THE ARBITRATOR: Thank you very much. Would you
25 also please affirm to us that you are in the room by

1 yourself?

2 THE WITNESS: I am.

3 THE ARBITRATOR: Okay. And that you don't have any
4 documents that are not a part of the Exhibits in this
5 case in front of you?

6 THE WITNESS: I do.

7 THE ARBITRATOR: Thank you very much. Mr. Kassin,
8 you may proceed.

9 JOE JONES,
10 having been first duly sworn, testifies as follows:

11 DIRECT EXAMINATION

12 BY MR. KASSIN:.

13 (Company Exhibit 9-10 marked for identification)

14 Q. Sure. And before doing a quick introduction
15 through the testimony, Dr. Jones, we're going to be
16 asking you about two particular documents. One is
17 identified as Company Exhibit 10, the US Drug Testing
18 Lab litigation packet on May 9, 2018, sample from Mr.
19 Danford. And the other document we're going to be
20 asking you about is identified as Company Exhibit 9.
21 And do you have those present?

22 A. I do.

23 MR. KASSIN: Okay. You have been sworn in. Let me
24 ask you to state your full name for the record.

25 THE REPORTER: Can we hold on just a minute.

1 Please. It's a lawn mower or something? Mr. Jones is
2 there a lawn mower outside?

3 THE WITNESS: Yes, they have come, but they're next
4 door and they should be done on a few minutes. Okay.

5 THE REPORTER: It's a little hard to hear Mr.
6 Kassin over it, but I'll -- I'll let you know if I
7 don't hear anything.

8 THE WITNESS: Okay.

9 MR. SEHAM: I was going to mention it. I can
10 barely hear Mr. Kassin. So Tom, if you could just
11 speak up a little bit. I'd appreciate it.

12 MR. KASSIN: I will and I'm going to move the
13 microphone a little bit closer to me.

14 BY MR. KASSIN:

15 Q. Dr. Jones, I'm probably showing up on your
16 screen as call-in user number 5. Okay. Let's try this
17 again. Please state your full name.

18 A. Joseph Timothy Jones.

19 Q. Who are you employed by?

20 A. United States Drug Testing Laboratories.

21 Q. What is your position with US DTL?

22 A. I am the Chief Operating Officer and
23 Executive Vice President.

24 Q. Please tell the Arbitrator and board members
25 what your duties and responsibilities are in that

1 position?

2 A. My responsibilities are the management of the
3 day-to-day operations of the laboratory. And to ensure
4 that the laboratory director has all of the tools and
5 resources such as staff equipment, and training to
6 operate a forensic toxicology lab report.

7 Q. How long have you held that position as Chief
8 Operating Officer?

9 A. Three years.

10 Q. And what previous positions, if any of you
11 had with US DTL?

12 A. I was a Senior Vice President for a few
13 years. I was the Vice President of Laboratory
14 Operations for 10 years and I was the Laboratory
15 Management for four years. All included I've been at
16 US DTL for 20 years.

17 Q. Right. Have you worked for any other
18 laboratories by chance?

19 A. Yes. I started with a laboratory called
20 Coffey Kim Laboratories in 1987. They were one of the
21 first NIDA certified laboratories before NIDA became
22 SAMHSA. Back in 1987 one of the first six or so labs
23 in the country certified to do federal drug-free
24 testing. We were also one of the two labs that did
25 testing for the Army. That lab was bought out by Roche

1 Biomedical Laboratories. And we existed as Roche for
2 about four or five years. And then in '92, that Roche
3 Biomedical Laboratories merged with National Health
4 Laboratories to become LabCorp. And I stayed there.
5 It was at the same address with three different names
6 over about 14 years. And then I left from there and
7 came to US DTL in 2000.

8 Q. How do you describe your professional
9 specialty?

10 A. Forensic Toxicologist.

11 Q. And can you briefly tell the board members
12 and Arbitrator, what your educational background is?

13 A. Yes. I have a BS in Chemistry from the
14 University of North Carolina at Chapel Hill. I have a
15 Masters in Chemistry from North Carolina Central
16 University in Durham. I have a PhD in Public Health,
17 specializing in epidemiology from Walden University.

18 (Company Exhibit 12 marked for identification)

19 Q. All right. If you will look at Company
20 Exhibit 12, which is your curriculum vitae. And if you
21 will, just kind of briefly summarize because I know
22 there's a lot involved, just your professional
23 qualifications that allow you to serve in the position
24 you serve.

25 A. Yeah. So the first would be 30 years

1 experience in the industry. The other significant
2 accreditation I have is I'm accredited by the NRCC.
3 It's a Clinical Chemistry -- the National Registry of
4 Clinical Chemistry -- of Certified Chemist. Excuse me,
5 National Registry of Certified Chemist, as a
6 Toxicological Chemist. That's kind of a mouthful. So
7 let me say it again. The National Registry of
8 Certified Chemists as a Toxicological Chemist. It's an
9 exam based accreditation and I've had that for seven or
10 eight years.

11 I have served as a College of American Pathologist
12 Inspector. Due to my recent duties, I have not done
13 that for a few years. But it's part and parcel of
14 being a College of American Pathologists Laboratory.
15 Each lab has to pass to also offer peer review of other
16 laboratories. I've served as a peer reviewer for a
17 number of scientific journals where articles are
18 submitted for review and you comment and either suggest
19 that the articles published or amended or revised
20 before publication.

21 Q. Okay. And Arbitrator Burdette at this point,
22 what I'd like to do is just move for admission of
23 Company Exhibit 12, which is Dr. Jones' curriculum
24 vitae.

25 THE ARBITRATOR: Okay. Mr. Seham. Any objection?

1 MR. SEHAM: No objection.

2 THE ARBITRATOR: Thank you. It's admitted.

3 Q. Dr. Jones, I'm going to ask you some
4 questions now about USDTL. What type of laboratory is
5 USDTL?

6 A. USDTL is a forensic toxicology laboratory.

7 Q. Okay. Exactly what does that mean?

8 A. That means that we accept specimens from
9 around the country, biological specimens, blood, dried
10 blood spots, urine, hair, fingernail clippings, newborn
11 meconium, which is the first fecal matter passed by a
12 newborn, umbilical cord, tissue segments. And we
13 analyze those specimens for the presence of drugs
14 and/or their metabolites and long-term alcohol
15 biomarkers. And we conduct those analyses under
16 forensic environment because we have to expect that at
17 any given day, any one of the specimens may be
18 litigated like this one today.

19 Q. Okay. What types of credentials or
20 certifications does USDTL have?

21 A. We have several that are pertinent to this
22 case today. We have the -- the -- the ground work, the
23 CLIA, our certificate that we operate under. CLIA is
24 required for a laboratory to do business across state
25 lines with biological specimens. They also have the --

1 the rules and regulations for conducting what's called
2 a laboratory develop test. And -- and it's got the
3 baseline accreditations that a lab in good standing
4 should operate under. Those regulations are posted in
5 the federal registry. The CLIA is -- is a -- is a
6 federal deal and they mandate that each state execute
7 the CLIA. So what most states will do, instead they --
8 they -- we will have their own CLIA inspectors. But
9 they will have a deeming organization that if you have
10 the certificate from the -- from the deeming
11 organization, then you fully satisfy the CLIA
12 requirements.

13 In Illinois, the deeming body is the College of
14 American Pathologists, like many states. And so the
15 College of American Pathologists, offer a laboratory
16 general accreditation and they also offer an additional
17 accreditation called the forensic drug testing program.
18 So we have both certificates from the College of
19 American Pathologists. For states -- most states just
20 require you to register and pay for registration,
21 supply a copy of the CLIA or the CAP certificate that
22 you have on file and you receive a certificate or
23 you're placed on a list. Like the state of Iowa, you
24 -- you don't get -- you're just put on this list.
25 Never seen the list. They just tell you that you're on

1 the list. But that's the way most states deal with it.

2 The state of New York is a little different in that
3 they actually have their own separate checklists that
4 are extremely similar to the College of American
5 Pathologists' checklists. The terms they use are a
6 little different, but they're the same. But they will
7 bring out people to do onsite inspections just like the
8 College of American Pathologists. So that's why I say
9 that that was -- even though this state -- this test
10 did not originate out of the State of New York, it's an
11 important certification because they do bring in
12 colleagues and peers in the field to inspect the
13 laboratory.

14 Last but not least is the ISO 17025 accreditation
15 of forensic laboratories. Again, we are inspected by a
16 group of peer inspectors and they -- they conduct two
17 types reviews. They come in on site, in-person. And
18 in the interim periods of time, we have to do what's
19 called a desk review and so they have this checklist.
20 We go through the checklist who provide evidence that
21 we are operating under the guidelines and -- and submit
22 that. And of course, this is what they go by when they
23 come in for their on-site inspections. So all
24 together, those make up a list of accreditations that I
25 -- that I feel are pertinent for this -- for this

1 hearing.

2 Q. Right. And once you have those
3 accreditations and certifications, what does USDTL have
4 to do to maintain it?

5 A. So -- so each one of those accreditations
6 that I mentioned have guidelines, checklists. And so
7 it is our responsibility to stay up-to-date with those
8 checklists and to ensure that the laboratory is
9 operating within the scope of -- of the requirements
10 that they have. We have to re-apply either every year,
11 every two years, or every three years, depending on --
12 on the organization, we have to reapply and demonstrate
13 that we are in good standing. And -- and then they
14 will schedule the inspection. Then we go from there.

15 Q. Okay. Just in general, if you can give us an
16 idea, how often are you subject to inspections from
17 these different entities?

18 A. We receive at least one inspection each year
19 from someone. In most cases, in most years, we have at
20 least two. And so -- and since kind of some are every
21 year some are every other year, some are every three
22 years. They kind of, you know, it's like the senators,
23 you know, they're 2, 4, and 6 elections.

24 Q. I see. Does USDTL have what is generally
25 referred to as standard operating procedures?

1 A. Yes. This is a critical element in the
2 regulatory process. A regulated laboratory must have a
3 standard operating procedure manual or SOP. You know,
4 like an academic research lab, you're given maybe a
5 sample or problem or a question, you go away and do a
6 literature search and maybe you follow the directions
7 from the paper and all of that. And you can then
8 publish a paper. In the -- in the commercial world,
9 very different rules we have to abide by. So we have
10 to have a standard operating procedure that is approved
11 by our laboratory director of record. And this
12 standard operating procedure is the official procedure
13 for any tests that we do or for any functions that we
14 perform, such as our quality control, quality
15 assurance, quality improvement management.

16 All of those processes are outlined in detail in
17 the standard operating procedure manual and we must
18 follow them each time. We are not allowed any variance
19 from that SOP. All of our employees are trained.
20 That's part of the training is to follow the SOP and
21 that's the one of the things that the inspectors will
22 inspect us on. When they review the data they will be
23 looking for breaches of the SOP. And so this is a very
24 important factor in a regulated forensic toxicology
25 laboratory.

1 Q. Okay. Additionally does USDTL have to
2 conduct and maintain data on the validation of its
3 testing procedures and protocols?

4 A. Yes. And so there's a number of layers to
5 that. So number 1 in the CLIA regulations, most of the
6 assays that we offer since there are, you know, they're
7 really kind of non standard tests like a 5-panel urine
8 screen, and that they are not FDA cleared and they
9 don't have to be. The laboratory developed tests are
10 tests that are designed to be executed in a specific
11 laboratory, as opposed to a device or kit that was out
12 for sale to be used by either like laboratories or
13 people. And -- however, the caveat on that is -- is
14 that the -- the CLIA accredited laboratory must have on
15 record, a set of experiments to determine the
16 performance characteristics of an assay. And as a
17 group that sort of experiments is called the
18 validation.

19 So we have to validate these assays before we are
20 allowed to offer this test up to the public and report
21 out the first test. So it's in the CLIA regulations,
22 this is also in the College of American Pathologists
23 checklist. It's also in the New York State Department
24 of Health checklist and the ISO checklist. So we've
25 got a number of people that when a new test is offered,

1 they may or may not, but they -- it's made available to
2 them that they can come in and review the validation
3 package. Now they give some very loose guidelines on
4 what needs to be done in the -- in set of experiments.

5 A lot of the common elements of a validation are
6 precision and accuracy, the linear range, the limited
7 protection, the limit of quantitation, upper limit of
8 quantitation, matrix effects, ion suppression, ion
9 enhancement, carryover, and -- and a few others. And
10 so the very baseline of the requirements that are
11 required by CLIA, it's a little bit more, there's a
12 little more detail in the CAP, and then there's a
13 little bit more detail in the New York.

14 And as far as our industry is concerned, the
15 Department of Justice set up a -- a working group
16 several years ago called SWGTOX, the Scientific Working
17 Group of Forensic Toxicology. And as a group of
18 toxicologists across the country, maybe even
19 international, they came up with like even more
20 stringent requirements and guidelines for validating a
21 new test with the purposes of forensic toxicology. And
22 so at this time and at the time of the validation of
23 this test, we were following the SWGTOX guidelines.
24 Their name has changed now, it's ODAC, O-D-A-C. I'm
25 not sure what that stands for, I just know there was a

1 name change. But these are the criteria that are
2 expected in a validation prior to release to the
3 public.

4 Q. Okay. Earlier, I asked you to provide us
5 some information that would be helpful in explaining
6 phosphatidylethanol or PEth. And you provided us a
7 PowerPoint with some slides. And for the board members
8 and Arbitrator, those slides are in Company Exhibit 13.
9 Dr. Jones, I'd like you to refer to something in
10 Exhibit 13. And just explain to all of us, what is
11 PEth or P-E-T-H?

12 (Company Exhibit 13 marked for identification)

13 A. Excellent. Phosphatidylethanol -- if we're
14 looking at slide number 1 is a series of abnormal
15 phospholipids, that are formed only in the presence of
16 ethanol. And as a -- as a group, we call this a long
17 term direct, ethanol biomarker. What do I mean by long
18 term? It means that last more than a few hours or few
19 days. And by direct alcohol biomarker, if you look at
20 slide number 2 -- before we go to slide 2, let's finish
21 up slide 1. The Phosphatidylethanol has a couple of
22 components that we need to understand to kind of see
23 where the nomenclature or how we name these components.
24 Slide number 1, there's three red circles, and the
25 circle on the right is showing the phosphoethanol head

1 group. And so this is like the base group, for all of
2 these different homologues of PEth.

3 The two smaller circles on the left are where two
4 different fatty acids are attached to this compound.
5 Now in -- in the body you have a number of fatty acids
6 that are available for this -- to form this compound.
7 You have myristic acid, lauric acid, palmitic acid,
8 stearic acid, all the way up to probably the biggest
9 one, that's readily available is arachidonic acid, this
10 is a long fatty acid. And you know, we could remember
11 all of these names, palmitic, stearic, oleic and all
12 that, but there's also an easier way to denote these
13 and this is with the numbering system. So fatty acid
14 is a chain of carbon atoms with a carboxylic acid group
15 at the end. It can also be named by the number of
16 carbons in the chain with a colon, and then the number
17 of double bonds that exist in that chain.

18 So for instance, for palmitic acid, it's referred
19 to as 16:0. And that means that it's 16 carbons long
20 and there's no double bonds. Oleic acid is 18 carbons
21 long with 1 double bond. So it's routinely referred to
22 as 18:1. So obviously that's a lot shorter way to talk
23 about these than these long names and I'll have to
24 remember the spelling. So the -- the -- the specific
25 homologue or isoform of this group of compounds is

1 determined by which two fatty acids is attached to this
2 phosphoethanol head, and then you get the name of the
3 fatty acid. Now the direct alcohol biomarker, what
4 that means on slide 2 is that if the ethanol itself is
5 attached to the marker that we're looking at, that's
6 called a direct alcohol biomarker.

7 Similar to Ethyl glucuronide, the ethyl come from
8 the ethanol. Ethyl sulfide, the ethyl came from the
9 ethanol, which is in comparison to an indirect
10 biomarker such as CDT, Carbohydrate-deficient
11 transferrin, and what that is doing, it's measuring
12 the damage that's done from excessive alcohol
13 consumption. The interesting with those are is that
14 alcohol may not be the only process that does the
15 damage that is measured. So for instance, a woman
16 going through menopause may have an abnormal CDT.
17 Someone with an HIV infection may have an abnormal C --
18 CDT. There's a couple of others, but that's a good
19 example and, but that's the reason that these indirect
20 biomarkers fall interesting. And they do have a good
21 amount of information.

22 They're not -- they don't have the same specificity
23 as a direct alcohol biomarker like Phosphatidylethanol
24 or PEth. So slide number 3, once the -- once the PEth
25 is formed, it is incorporated in the -- to the

1 phospholipid membrane, the blood cells. And it remains
2 there until either number one, naturally decomposes, or
3 number 2, you shed that blood cell. So we cycle
4 through blood cells over a period of time, many weeks
5 to a couple of months. And you rollover these red
6 blood cells, you make them and get rid of them all the
7 time. And so those processes slowly eliminate the PEth
8 from your -- from your blood, because your blood
9 contains these blood cells.

10 Most humans do not have a mechanism to repair that.
11 There's current work with an enzyme called
12 phospholipase C, which may be involved in a rapid
13 hydrolysis of the -- of the PEth in various tissues
14 around the body. And so the -- there's still a lot to
15 be understood about that. So at this time we
16 understand there's elimination, a half-life and that
17 there's a wide variety that a wide range of the
18 half-life. And by half-life, I mean that, over a
19 period of time, the concentration drops in half. Now
20 this is very different than like blood ethanol, which
21 is a straight line, zero or kinetic elimination of one
22 drink per hour all the way down to zero. Most other
23 drugs that we study have a half-life, and PEth is one
24 of them.

25 So how is this incorporated in if we go to the next

1 slide? Ethanol interrupts a natural metabolic pathway
2 that we have that's going on in basically every cell in
3 our body. And that is the -- the transformation of
4 phosphatidylcholine into more starting products in
5 these different metabolic cycles that we have going on
6 all the time. So in the absence of ethanol, we have
7 phosphatidylcholine, which is this -- this reaction is
8 catalyzed by an enzyme called Phospholipase D. And when
9 you have water, which you've got a lot of water in the
10 body, that hydrolyzes to phosphatidic acid and choline.
11 And then those are products for other processes
12 elsewhere in the body.

13 If we introduce the -- go to the next page, if we
14 introduce ethanol into this equation, the ethanol is
15 actually preferred to the water. And it interferes
16 with this reaction such that instead of forming
17 phosphatidic acid plus water, it forms phosphatidyl
18 ethanol plus the choline. So this -- this is -- this
19 is an interruption of the natural pathway and it's
20 incorporated into the membrane where it's sort of
21 protected from the environment set at constant
22 temperature. So this is a little different than a
23 blood test in which like in most blood drug tests or in
24 like a blood alcohol test, we think of blood is this
25 dynamic specimen type where what's going on with the

1 concentration of an analyte in the blood is kind of
2 what's going on in the system. So this is why you do
3 blood alcohol or breath alcohol for road side safety.

4 If someone has you know, .15 blood alcohol, that
5 has meaning as to their mental state at that time, or
6 their inebriation or -- or their intoxication. In the
7 case of this test, although it's blood, it behaves more
8 like a reservoir specimen type. So more like hair,
9 fingernails, tissues, meconium, umbilical cord tissue,
10 et cetera. In that it's behaving more like a reservoir
11 where things tend to accumulate. So we're are not able
12 to backtrack and determine time, dosage or frequency.

13 The answer is really a binary. So its either
14 detected or not detected which is why we were
15 interested in this compound for our clients in that
16 under this circumstance, and with the detection window
17 that it offers, it offers a really good measure of
18 abstinence compliance of people that are in programs.
19 Doesn't tell us how much they've been drinking or
20 exactly when they did it, but if they're abstinent, it
21 should be negative and if they're not abstinent we'll
22 find some PEth. That's kind of where PEth comes from
23 and where it ends up.

24 Q. And just to follow up on what you said. So
25 what is generally the window of determining whether

1 PEth is present?

2 A. For most people following chronic excessive
3 drinking, you have a detection window that's up to
4 approximately two to four weeks.

5 Q. Okay. And there was a lot of scientific
6 information that you presented. Which of the -- hope
7 I'm saying this right, which of the homologues is it
8 that you are looking to test when you do a test on
9 somebody's dried blood spot or whole blood to determine
10 whether or not they've maintained abstinence?

11 A. Yeah. We zero in on the most prevalent
12 homologue, which is the 16-0-18-1.

13 Q. I believe you may have covered this or at
14 least alluded to it, but what -- what is it that your
15 clients are looking for when they ask you to do PEth
16 testing? What type of programs are they running?

17 A. Typically the tests are part of a substance
18 use disorder treatment program and these are subjects
19 that are in treatment and are required to be abstinent.
20 And so this test is used to verify that abstinence. So
21 we're looking for negative results on an ongoing basis
22 with these individuals.

23 Q. In addition to airlines like Delta Airlines
24 that uses USDTL for PEth testing, what other types of
25 professions also use your services for PEth testing?

1 A. We received specimens from pretty much every
2 state. There's -- there's a few that we don't do
3 business with. There's medical boards for each state.
4 We'll set up a not-for-profit to monitor their medical
5 professionals for substance use disorders. And at any
6 given time, the number of people with alcohol use
7 disorder is four or more times more than the number of
8 people with other drugs all put together and even half
9 of them also have an alcohol use disorder. So the
10 state physician health programs around the country.
11 Many times a physician is referred to the state medical
12 board for disciplinary action because of evidence of
13 maybe an opioid use issue. Paradigm, you know, pick
14 your drug, cocaine, methane.

15 But in many instances there's this underlying
16 alcohol use disorder and you cannot really treat them
17 for opioid use disorder unless you're dealing with the
18 alcohol too. And so they use these tests on the -- on
19 the intake to kind of get a big picture of the drug
20 history of their participants and then we monitor them
21 over time to make sure or to confirm or verify that
22 when they say they're abstinent that they are truly
23 being abstinent. There's a number of what's called
24 third-party administrators around the country. And
25 there's four that specialize in this specific

1 demographic. Affinity E-health, Recovery Truck,
2 Professional Wellness, PPW, and FSS Risks Solutions.
3 They specialize in working with it because there's a
4 lot of date of this kept up with, a lot of random
5 testing.

6 With the medical professionals, there's just lots
7 of special circumstances from anesthesiologists to
8 nurses crushing up volume, all kinds of special
9 circumstances that you just, you don't see this with a
10 non-medical professional environment so there's
11 specialists in this area. We do business with all four
12 of those and through those four people, we pretty much
13 have samples coming in from all 50 states. There's,
14 like I said, a few that we don't -- a few states we
15 don't receive specimens from, but the vast majority of
16 them we do.

17 Q. Could you provide the arbitrator and board
18 members with some background information as to how and
19 when PEth testing first came about?

20 A. Yes. So for 50 years, the wholly grail of
21 newborn toxicology has been trying to identify every
22 baby born that has been exposed to ethanol in utero.
23 In the substance use disorder community -- treatment
24 community, they've been looking for objective
25 biomarkers to confirm abstinence, to verify abstinence

1 among the patient population. For many decades, the
2 tools that they had at their disposal were self-report,
3 which has obvious limitations, and the direct detection
4 of ethanol itself, which has a major limitation in
5 that, it's only detected for like one hour per drink
6 consumed. It's a very, very short detection method,
7 but it was better than nothing. The first markers at
8 least that I'm aware of that came out were these
9 indirect biomarkers, CDT, MCV, GGT, and some others.

10 They were better, but because of the non
11 specificity of the result it had very limited use in
12 application in these markets. The first long-term
13 alcohol biomarker that was commercially available in
14 this country, was Ethyl Glucuronide or ETG in urine.
15 And around the year 1999 to 2001, this became a very
16 prevalent test as it was gaining steam, popularity in
17 this particular demographic. In the first three to
18 five years of labs beginning to offer ETG, a number of
19 limitations of that test came to bare. So number one,
20 the big advantage was is you had a detection window of
21 two to five days, which is much improved over two to
22 five hours. So this was why everybody was excited
23 about this. It helped confirm the abstinence of their
24 participants.

25 But there's some limitations that we have to be

1 aware of is that number one, especially with the
2 medical professional folks, they use a lot of waterless
3 hand sanitizer, Purell. So that contains a large
4 amount of ethanol and it's not unusual for a nurse to
5 use Purell, well over 100 times a day. Because she's
6 doing Purell before patients, doing Purell after a
7 patient, that's a lot of exposure day in and day out.
8 And what we found quickly was that we were finding ETG
9 at very low levels in these medical professionals. So
10 a lot of work went back-and-forth on choosing the right
11 cut offs and when to do the testing and making sure
12 that they don't use products, but use the isopropanol
13 version instead of ethanol version. And so kind of
14 took them a little bit to figure that out and so off we
15 go.

16 Another limitation of ETG testing in urine is:
17 Number one, post collection symphysis, and number two,
18 post collection decomposition. So it turns out that if
19 you have certain bacteria in your urine, those urine
20 secreted enzyme that actively hydrolyze ETG in the
21 urine. So by the time you get it to the lab it may
22 have been fully decomposed or by the time you do the
23 initial test and get to the confirmation test it's
24 gone. In other cases, you'll have a low level, you
25 come back in three months and test it and it's gone.

1 Even in the freezer, those bacteria will still work.

2 Equally troublesome, was post-collection formation.
3 So if you have someone that is not actively controlling
4 their sugar and they have certain bacterial infections,
5 it can make ETG in transit to the laboratory. So
6 between 2000 and 2005 as effective as ETG and ETS in
7 urine were, there was a lot of limitations so people
8 continued looking for what's the best way to monitor
9 this population. The next assay that was made
10 available was ETG in hair. And so originally we looked
11 for some compounds called fatty acid ethyl esters,
12 which is kind of similar to PEth, but not. The fatty
13 acids ethyl esters really never got off the ground.
14 They use it a lot in Italy under certain circumstances,
15 but the real drawback to fatty acid ethyl esters in the
16 hair is that even in clipped hair, if you exposed that
17 hair to ethanol vapor, it will form fatty acids ethyl
18 esters.

19 So when -- when this is made known, that just
20 totally takes that test off -- it's not a feasible test
21 anymore. The ETG, with all of this information about
22 post -- post collection symphysis and post collection
23 formation, right off the bat people were checking and
24 publishing, you know, the ethanol contained in air
25 sprays or ethanol contained in hair gels, do they put

1 ETG in the hair, does the skin around the hair or the
2 scalp, does that form ETG when you saturate that skin
3 with ethanol? And we found out quickly that it did
4 not, but the limitation there is cosmetic treatment,
5 bleaching, permanent dying, chemical strengthening, et
6 cetera. Those processes destroyed the ETG. So again,
7 a better test, much longer detection would have three
8 months, but limitations. We develop that test in
9 fingernail still a little better, still similar
10 limitations.

11 During the same period of time, a lot of work was
12 coming out of Europe concerning this compound called
13 Phosphatidylethanol. You know, you spent six weeks
14 trying to learn how to pronounce this thing and figure
15 out how to draw the structure, and you start learning
16 about it in reading these papers, and it looks like
17 it's a biomarker that has a lot of promise. And the
18 first development of these tests coming out of Europe,
19 the scientists that were involved in that development
20 were not familiar with liquid chromatography tandem
21 mass spectrometry, but were more familiar with
22 something called evaporative light scattering detection
23 which has a real serious limitation of sensitivity. On
24 alcohol withdrawal patients they were able to detect as
25 a group, the entire group of 48 homologues, as, you

1 know, a single curve and -- and do their work on that.

2 Monitoring people as they're withdrawing from
3 alcohol is not interesting -- is not a very useful of
4 service of -- of -- for the market that we're operating
5 in. And so but we are liquid chromatography, mass
6 spectrometrists. This is what we do, and when we look
7 at this problem, we're like, well, number one, we're
8 going to get away from the evaporator -- evaporative
9 light scattering detector, we will move into tandem
10 mass spectrometry. Number two, is we're going to pick
11 the most prevalent of those compounds, that will zero
12 -- zero in on that and not worry about the others
13 because the presence of this 1 of 48 is going to be
14 representative of the other group. And so we developed
15 this assay looking for the 16, 0, 18, 1 because it's the
16 most prevalent, it's approximately 40-45 percent of the
17 total and so it's by far the most prevalent.

18 The next most prevalent is the 16, 0, 18, 2 and
19 then the 16, 0, 20 4. There's interesting research
20 being done with those three markers and that they're
21 looking at the relative amounts of those three trying
22 to predict is this the trail of a big binge a long time
23 ago or is this like on a upper slope that's coming back
24 down? A lot of work being done there, but not ready
25 for prime time, but -- but it -- it's interesting. But

1 for the purpose of abstinence detection or abstinence
2 verification, picking the most prevalent one, it should
3 not be there. And if it's not there the rest of them
4 are not there. If it's there, then that is consistent
5 with relapse or consumption and if it's there, the rest
6 of them there. So we pick that one.

7 Q. How long has USDTL been doing PEth testing?

8 A. Since 2007, we started with whole blood, and
9 our clients gave us the feedback that in many
10 instances, it was inconvenient for the donors to find a
11 clinical setting with a phlebotomist to pop a vein and
12 get a blood drawn. And -- and plus it's expensive.
13 Phlebotomists are expensive. And so we also have many
14 areas of the country where these people may have to
15 travel two hours to -- to get a drug test. And so we
16 -- we needed we -- we looked for a mechanism such that
17 a specimen could be collected in a nonclinical
18 environment aka it could be done in the field without a
19 phlebotomist.

20 Blood spot cards have been used since the 60s,
21 since Guthrie started looking at PKU with newborns and
22 -- and the -- the Whatman 903 paper that is used in the
23 dried blood spot collection is an excellent mechanism
24 to collect the dried blood spot. You can do it with a
25 fingerprint or you can get the tube of blood and spot

1 it yourself, either way. You can do it a number of
2 different ways, but you get the dried blood on the
3 blood spot, and with the fingerprint, just like every
4 diabetic pricks their finger and checks their glucose
5 at their home, we could allow people to collect their
6 own blood spots at home and they'd have to send them to
7 their program to come to us because we can't take a
8 specimen without professional intervention. But if
9 offered an opportunity to get access and convenience of
10 -- for these donors.

11 So around 2010-2013, we developed and published a
12 method on PEth and dried blood spots. The groups in
13 Europe did some matched studies with us where they
14 looked at the whole blood, we looked at the dried blood
15 spots and we found some other studies where the
16 comparison between venous blood and capillary finger
17 stick blood were evaluated. They're not identical, but
18 they're very similar and in -- and so that has been a
19 standard offering with USDTL since around 20 -- 2011,
20 2013 and it's been getting traction and the feedback
21 and the outcomes that they -- that our clients get.

22 Q. Okay. Is the PEth testing that you do at
23 USDTL considered a forensic test? And if so, why?

24 A. It's a forensic test because it's a
25 laboratory developed test and it was developed under

1 the guidelines offered by Laboratory Develop Test.
2 It's a forensic test, because we're not -- we're not
3 doing therapeutic drug monitoring. We are not
4 determining if the donor is taking his ethanol as
5 prescribed by his doctor. That's not the purpose of
6 this test. The purpose of this test is to verify the
7 abstinence. Obviously you -- you have a participant,
8 the self-report is I have been abstinent. So we
9 collect the sample under chain of custody as analyzed
10 under chain of custody. It goes through an initial
11 test, it goes through a confirmation test under chain
12 of custody and is released up. The documentation is
13 kept such that we anticipate that any given sample on
14 any given day could be litigated, we have to reproduce
15 all of that data. And so for those reasons, we are a
16 forensic laboratory and this test is a forensic test.

17 Q. So forensic tests may be used in the
18 litigation setting?

19 A. Absolutely. That -- they are -- they are
20 executed with that in mind, as opposed to when you go
21 to the hospital and they do a blood draw, that data can
22 be subpoenaed the court, and you have to bring people
23 in and testify yeah, I touched it, it was over there
24 and there. When you do it under forensic conditions in
25 a forensic laboratory, all of that is documented as if

1 we know that sample is going to court, even though less
2 than one percent of them go to court or litigated. We
3 conduct the assay as if that sample is going to be
4 litigated.

5 Q. Dr. Jones, you alluded to clinical testing
6 and just to distinguish between forensic testing. Is
7 clinical testing done in a medical study for diagnosing
8 -- diagnostic purposes? Is my understanding correct?

9 A. Yeah. A -- a -- a clinical test is used for
10 diagnostic purposes and a forensic test is not.

11 Q. You also made reference to something called a
12 laboratory developed test. I also hear it sometimes be
13 referred to as LDT. But can you tell us what the
14 difference is between a laboratory developed test and
15 an FDA approved test?

16 A. Yeah. So the main differences between a FDA
17 cleared test and a -- and a laboratory developed test
18 is an FDA cleared test is when the manufacturer is
19 manufacturing reagents or kits or a system for sale out
20 to other laboratories to use or for use in the general
21 public. So I mentioned the -- I mentioned the blood
22 glucose test, so that's a little gadget you can go down
23 to Walgreens and buy, you may or may not need a
24 prescription. But you get the little strips, you stick
25 your finger, you do the test yourself, and from that

1 result you go, oops I need to watch my sugar or okay,
2 great, I'm -- I'm staying in glyceimic control. The
3 hemoglobin Alc that your physician may order on you as
4 a diabetic, the result from that hemoglobin Alc may
5 direct that physician as to further intervention that
6 he may need to conduct with regard to your glyceimic
7 control.

8 Laboratory developed tests are a little different
9 animal in that, these are not tests that are going to
10 be distributed to other individuals. These are tests
11 that are developed for use at a single site, okay? And
12 so just from the logistics of it, with many thousands
13 of laboratories across the country, and with each
14 laboratory may have hundreds of laboratory developed
15 tests. Just the sheer number, FDA would not be able to
16 come into the laboratory, inspect the laboratory, and
17 -- and -- and look at each laboratory developed test.
18 So just on the face of it, it's just not feasible for
19 all laboratory developed tests to be FDA cleared. FDA
20 does not come in and inspect laboratories. So you
21 produce documentation and send it to them and -- and
22 then off you go.

23 CLIA is in charge of laboratory developed tests.
24 So like the test that we have at USDTL, that's of
25 significant shares, the PEth. It's run on a piece of

1 equipment that cost a half a million dollars, and we've
2 got two of them because if you've got one, you've got
3 to at least have one for backup. So we got a million
4 dollars in equipment. So it's not like we can go and
5 place the system in another lab, you know, and sell
6 them the system, so to speak, to test the PETH. That
7 -- that's not feasible. So the laboratory developed
8 tests setup is -- is such that it's in the CLIA
9 regulations, and in order to offer a test to the
10 public, we have to do the validation and it has to be
11 made available on -- on -- on demand to the inspectors
12 when they come or if they call, we have to make it
13 available to the inspectors. As in many instances,
14 it's part and parcel of the inspection.

15 So that's -- those are the main differences between
16 an FDA cleared test and a laboratory developed test.
17 One last caveat is that a laboratory may choose, for
18 marketing reasons, to take their laboratory developed
19 test and submit it for FDA clearance. And so there's
20 no requirement to do that, it's a choice, but it gives
21 them a marketing perspective of, you know, that's an
22 FDA cleared test, but it is not necessary.

23 Q. Okay. Do all forensic laboratories use
24 laboratory developed tests?

25 A. Absolutely.

1 Q. Okay. And you mentioned the expense of the
2 equipment involved. The GC-MS -- I didn't get all the
3 initials of all your equipment, --

4 A. Sure.

5 Q. -- but are those considered the gold standard
6 for accuracy when you're measuring the specifics which
7 you're looking for in different laboratory developed
8 tests?

9 A. That is correct. For these types of assays,
10 mass spectrometry is the gold standard because of its,
11 not only sensitivity, but more importantly it's
12 specificity.

13 Q. We got an ad at our house last night for a
14 test you can go buy down at Costco to see if you have
15 COVID. Is that an example of a FDA approved test?

16 A. Yes. To put something on the shelf at
17 Walgreens, you have to go through the FDA clearance
18 because you're selling that to the general public, as
19 opposed to selling it to professionals like an LBT.

20 Q. Dr. Jones, you mentioned two terms that are
21 going to become important and we've had some reference
22 to them already in some opening comments, but you
23 mentioned the concept of specificity, and you also
24 mentioned the concept of sensitivity. Just so we have
25 the right appropriate toxicology background, can you

1 explain to the arbitrator and board members what those
2 terms mean?

3 A. Sure. Sensitivity is how low you can go, and
4 so the lower you drop the cut off the more sensitive it
5 is. And so that's sensitivity, kind of a simple
6 concept. Specificity is how specific is the assay. A
7 good example of this is that the FDA cleared reagent
8 used for opiate urine screens, okay? It's a reagent
9 that we purchase from a manufacturer, a vendor if you
10 will. They send us a box that's got these liquids in
11 it. You put it on our chemistry analyzer, you send the
12 tube of urine through -- squirt, squirt, squirt. It
13 takes a reading and it gives you a reading for opiates,
14 right? So that's -- it's pretty sensitive because it's
15 using, like, microliters of urine. But it's not very
16 specific.

17 Now it's specific with regard to opiates. In other
18 words, cocaine does not cause it to react. Marijuana
19 does not cause it to react, but an opiate will. Some
20 opiates will. Well, what I mean by the specificity
21 here, is that several different opiates could be
22 causing that reaction on the instrument. It could be
23 heroin, it could be morphine, it could be codeine, it
24 could be hydrocodone, it could be hydromorphone, and if
25 there's enough, it could be oxycodone. And so since we

1 can't, from that result, tell you which one of these
2 opiates it was, that's not very specific. When you go
3 to mass spectrometry, all of those opiates come out at
4 different times, and they each have different mass
5 spectral compositions, and so we are able to take that
6 same urine, and test it by liquid chromatography tandem
7 mass spectrometry, or gas chromatography-mass
8 spectrometry, it depends on what's in the lab, and
9 we're able to say, yeah, that sample was positive for
10 hydrocodone, but not the other ones or it had
11 hydrocodone and morphine in there, but not the other
12 ones or it had all of them. And we can quantitate and
13 tell you specifically which opiate was in there. So
14 that's -- that's what specificity is. How specific is
15 the identification of the -- of the components that
16 we're looking for.

17 Q. Does specificity, sorry, give you the ability
18 to detect true negatives?

19 A. Yes.

20 Q. Okay. And maybe on the other side of the
21 coin on sensitivity, does that give you the ability to
22 detect true positives?

23 A. Yes.

24 Q. I want to ask you some questions about the
25 USDTL PEth testing. And is your PEth test -- and I

1 think we covered this, but I want to be real clear as
2 we look back in our record, is that considered a
3 laboratory developed test?

4 A. Yes.

5 Q. All right. And has your laboratory developed
6 test been reviewed and approved by any particular
7 entity?

8 A. All of the entities that I mentioned before.
9 CLIA, College of American Pathologists, College of
10 American Pathologists Forensic Drug Testing program,
11 New York State Department of Health, ISO 17025, all of
12 the validation records have been made available to
13 them. When they come to us, they ask for a lot of
14 stuff and they go behind closed doors and review the
15 data. So I don't know specifically what they've looked
16 at, but they've been made available to them, and if
17 there's a problem, they'd find it, and I've not heard
18 of any problem. But it's been made available to them
19 to review at their wish.

20 Q. Has USDTL satisfied all the regulatory
21 requirements to do PEth testing of DBS as well as whole
22 blood?

23 A. Yes.

24 Q. And is there any regulatory requirement that
25 you submit your standard operating procedures for your

1 PEth testing to the FDA in order to get its approval?

2 A. None.

3 Q. Okay. We're going to start getting into some
4 specifics about PEth testing and just to set a
5 framework. What are the units of measurement that are
6 used when you're looking for PEth in either a DBS or
7 whole blood?

8 A. The units of measurement that are used for
9 PEth in this country are -- are nanograms per
10 milliliter, and that stands for the weight or nanograms
11 of the compound itself and one milliliter of the
12 specimen type, like blood. So our cutoff is 20
13 nanograms of PEth per one milliliter of blood.

14 Q. Okay. And is that cutoff at 20 nanograms per
15 milliliter the most commonly accepted cutoff for
16 forensic testing of PEth?

17 A. Yeah. Right now there's a handful of labs in
18 this country that offer PEth testing and -- and all of
19 those labs have adopted the 20 nanogram per mil cutoff.

20 Q. Okay. Does USDTL have a standard operating
21 procedure for the collection of a DBS sample?

22 A. Yes.

23 Q. And could you summarize what those procedures
24 are and what type of paper's used for that? And I
25 think you've already alluded to the paper.

1 A. Yeah. So the -- the collection procedure is
2 you have an identification of the subject, and then you
3 -- both the collector and the donor wash their hands.
4 And you are not supposed to use any ethanol containing
5 products in or around the collection just because
6 that's poor laboratory practice if you do an alcohol
7 testing. So like, if you're doing a -- a blood draw,
8 they don't clean your venipuncture with -- with an
9 ethanol pad, they use betadine or -- or isopropanol,
10 just to make sure that there's no ethanol anywhere
11 around the collection site. So once they wash their
12 hands and -- and we've got the individual identified,
13 we then use a -- a lancet -- sterilize the fingertip
14 with an isopropyl alcohol pad and then you puncture the
15 skin with the lancet.

16 The first drop of blood is wiped away with a piece
17 of gauze and that encourages blood flow, it kind of
18 rags open the puncture wound, and it allows for the
19 blood to flow a little easier. And so without touching
20 the paper, you take your -- your -- your drop of blood
21 and you drop it onto the Whatman 903 collection paper.
22 Now, the Whatman 903 collection paper is a special kind
23 of paper for doing dried blood spots. That paper is
24 impregnated with guanidinium salts. Guanidinium salts
25 are important here because when the blood hits the

1 impregnated paper, the guanidinium salts lyse open all
2 of the blood cells, so they bust open and everything
3 spreads out. Number 2, the guanidinium salts fix any
4 blood-borne pathogens that may be in there. It also
5 fixes any hormones or enzymes that may be still active.

6 So the advantage of this is that whatever is there
7 is locked in, it discourages any further reaction or
8 decomposition, and the specimens are not a biohazard
9 once they're dry. And then they can be packaged up,
10 you can put a lot in a big package and ship overseas,
11 they're not considered infectious material, so a lot of
12 advantages. They can be sent through the US mail at
13 that point and so -- so it -- it has a big advantage of
14 them. So once you collect your -- your -- your blood
15 spots on the Whatman 903 paper, the -- the little -- it
16 looks like a -- a -- a long matchbook -- book of
17 matches. And so you don't flip that back in, you kind
18 of leave it open, it acts like a little spring inside
19 of a little drawing box. And so the drawing box was
20 selected because it's not airtight, and it allows the
21 specimen to dry while it's -- after it's been sealed
22 with a tamper evidence seal.

23 And this box was brought into play because the
24 donors did not want to wait for one to three hours for
25 the blood spots to thoroughly dry before you put the

1 seal on the little book of match, Whatman 903 paper
2 collection device. And so this is a convenience factor
3 that was added for the donors like early on. And so we
4 can place the collection card inside the drawing box.
5 We can put a tamper evidence seal around both ends, set
6 it to the side. It can dry and -- and then be shipped
7 to the laboratory in the afternoon Fed-Ex shipment
8 while it's in a secure tamper evidence environment.
9 You fill out the paperwork, we have a standard
10 requisition form like any other lab that accompanies
11 the sample. You put it in an envelope and off to the
12 lab it goes.

13 Q. You may have alluded to this earlier. Are
14 there other laboratories in the United States that do
15 PEth testing?

16 A. Yes, there's -- there's a handful. Drugscan
17 near Philadelphia, MedTox in Minneapolis, CRL has now
18 gotten into this and Associated Regional Pathologist
19 out in Salt Lake City, a large clinical laboratory.
20 They're ARUP is -- is kind of what they go by. They're
21 -- they're getting into it, but right now the
22 commercial laboratories that are doing whole blood is
23 MedTox in Minneapolis, Drugscan in Philadelphia --
24 outside of Philadelphia, and there's a research lab at
25 the University of Texas Medical School that -- that

1 does both whole blood and dried blood spots. And so
2 right now, that laboratory is the retest lab. If
3 someone contests or refutes the result, we send the
4 specimens down to University of Texas or we can retest
5 it ourselves if -- if they want us to do, we can do
6 that too, we do that routinely. But if they want a
7 second laboratory to take a look at it, we can send it
8 to University of Texas. University of Texas Medical
9 School is the only other lab right now that's doing
10 dried blood spots. ARUP is looking at it, CRL is
11 looking at it.

12 Q. And each of those laboratories use a
13 laboratory developed test?

14 A. Yes. If you go to the ARUP website and go to
15 their test index, they call it phoshatidylethanol. If
16 you scroll down just a few inches, you'll see where it
17 -- it calls PEth, that they're currently doing the
18 whole blood. It's a laboratory developed test.

19 Q. Okay. Next one I'd like to turn to is the
20 process and procedures that you use, at USDTL for once
21 you accept -- once a drug blood spot sample arrives and
22 take us through how it is handled at USDTL from receipt
23 through the completion of confirmatory testing?

24 A. Certainly. So most of our packages come to
25 us by major courier first thing in the morning, FedEx,

1 UPS. We have some late shipments later in the day. US
2 Mail trickles in at some point during the day. But the
3 packages hit the receiving floor early in the morning.
4 We scan in the -- the -- the shipment tracking numbers
5 and through the requisition form, we scan the bar-code
6 number and that ties that sample to that shipping. We
7 then accept -- we open the package with an accession
8 that specimen into our -- our laboratory. We scan the
9 barcode on the sample, we scan the barcode on the
10 paperwork. That has to agree or we're not allowed to
11 receive the specimen.

12 Once it is received into the system, we denote who
13 the client and what tests they've ordered in the system
14 and then the computer spits out barcode labels with a
15 laboratory ID number. So those seals or stickers are
16 fixed to the -- to the paperwork and to the specimen
17 itself. The specimen is then forwarded under chain of
18 custody over to what we call an aliquot station.
19 Aliquot is a portion of a -- of a larger sample, and
20 the paperwork goes across the hall to the order entry
21 area where they enter in so while we're working on the
22 sample, order entry can then focus on entering in the
23 specimen and the donor and the client specific
24 information like, you know, Social Security number or
25 -- and/or maybe temperature of the urine if it was

1 collected at -- at that -- at that point in time. So
2 they're entering in that information.

3 Aliquot is now over -- excuse me, the specimen is
4 over in aliquot station and they are batched in a group
5 of anywhere from 20 to 40 specimens in a batch. And in
6 that batch of screening batch or initial testing batch,
7 there will be a calibrator and some controls, low,
8 medium, high and negative control. And we -- 3 punches
9 are from the specimen, we have what's called a
10 pneumatic hole puncture. When we first started, you
11 know, like the old days you -- you do it with the hole
12 puncture with your hand. But we have a nice little
13 pneumatic puncture, it has got a nice light and
14 everything and you can slip the paper in, select where
15 you to punch it and you get a little foot pedal and it
16 knocks a hole in holding the paper. And the -- the
17 test tube that's labeled sitting under there captures
18 the little dot or the little punch. And so we collect
19 three of those for each patient. You put the next tube
20 in. And so we collect them. It is then extracted
21 liquid -- liquid extraction primarily in methanol and
22 that is evaporated, is reconstituted in a mobile phase
23 buffer, specific to the LC-MS analysis. And then the
24 batch is analyzed by liquid chromatography and mass
25 spectrometry .

1 Now, this first batch of the initial testing is --
2 has two fundamental purposes. It needs to be fast. It
3 needs to be precise around the cutoff so that we can
4 quickly eliminate the negatives and report them out so
5 people can go about their lives. Go about your
6 business. If it's above the cutoff, we're not so
7 concerned about the quantitation. Number one the
8 quantitation is irrelevant anyway, you know, as a
9 laboratory, we want to make sure that the number that
10 goes out is a good number. But in the initial it's all
11 about was it above 20 or below 20, negatives report
12 amount. Now we can focus on the presumptive positive.
13 It's not positive at this point. It's a presumptive
14 positive.

15 So now that information reflexes back into the
16 receiving laboratory. That specimen is retrieved, it's
17 re-identified. And then we prepare another portion or
18 aliquot of that for analysis. It goes through a
19 similar extraction procedure except this time the
20 controls that are part of the batch. They send a
21 confirmation batch have a very specific quantitative
22 criteria because now we are interested in exactly how
23 this thing quantitates. So it goes to extractions,
24 this extracted methanol over to mass spec. It's in the
25 buffer local phase. And then it's analyzed again by

1 LC-MS/MS under slightly different rules, that's more
2 geared towards quantitative results.

3 So following that analysis, all of the data ends up
4 in a data certification office. And we have multiple
5 layers of review there. And at the end of the day, we
6 have a, what we call a positive certifying scientist,
7 which is kind of a end game position in a forensic lab.
8 They review the initial tests, they review the
9 confirmation tests, and those results must agree. And
10 they have to review the chain of custody internal and
11 external, and then the positive can be released out to
12 the client. Only that point is it called a positive.
13 And so that process is kind of the cornerstone of a
14 forensically defensible result. You get two analytical
15 passes of a sample. In an ideal world, you'd want two
16 completely different analytical methodologies, but that
17 doesn't exist and so there's accommodations made for
18 that in the CLIA guidelines and the CAP guidelines, et
19 cetera. But we do have different rules. It's two
20 different teams of people that are doing the screen and
21 the confirm and they have to agree and they're
22 performed under chain of custody.

23 Q. Okay. What type of laboratory equipment did
24 you specifically -- do you specifically use for you're
25 dried blood spot testing that you just described to us?

1 A. Yes. We use a liquid chromatography tandem
2 mass spectrometer. And the liquid chromatography
3 component is an Agilent 1200 HPLC system. And the
4 detector is a Sciex tandem mass spectrometry system.
5 Specifically, it's the 6500 tandem mass spectrometer

6 Q. Is that type of equipment commonly used in
7 forensic laboratories?

8 A. Yes.

9 Q. What procedures does USDTL use to ensure the
10 accuracy of the equipment that's doing the PEth
11 testing?

12 A. So there's a number of layers there. All
13 right. So number one, we have the validation that
14 we've talked about at length earlier, so that's number
15 one. Number two, is that these -- these equipment are
16 very sophisticated, expensive pieces of equipment. The
17 individuals that operate these equipment have
18 specialized training to operate the equipment and to
19 perform routine maintenance of the equipment. There is
20 a maintenance plan or protocol procedure that's part of
21 the standard operating procedures that these
22 instruments go through on a daily, weekly, monthly,
23 quarterly, depending on the instrument and the
24 recommendations of the manufacturer.

25 Routinely and again, this depends on the

1 manufacturer. There will be a preventative maintenance
2 visit by the manufacturer. So they'll come in either
3 every six months or once every 12 months and they will
4 tear the equipment down, examine all the different
5 components and clean things, put it back together and
6 put it through a series of checks and -- and it -- it
7 gets a clean bill of health and placed back in the
8 service. So that's kind of from an overall -- a high
9 level review. On a lower closer to the bench review,
10 each batch that a sample is analyzed has a set of
11 calibrators and controls. And the performance of those
12 calibrators and controls, determines whether or not the
13 batch is acceptable or not.

14 If they're unacceptable, the batch fails, we kick
15 it back to receiving. We start all over again. If the
16 batch passes, there's a set of criteria for each
17 individual specimen. So things like chromatic graphic
18 appearance, or things like signal-to-noise
19 requirements, things like mass ratio, relative
20 retention time. So all of these characteristics have
21 to be acceptable for each individual injection and then
22 that sample can be accepted. So it's a multi-layer
23 deal. And again, going back to the 35,000 foot view,
24 you know, we have the inspections and all of that. But
25 part and parcel of this regulatory oversight is the

1 notion of proficiency testing -- proficiency testing,
2 so that means that samples are entered into the
3 laboratory process blindly and we have to kick out the
4 expected result.

5 The CLIA checklist and the CAP checklist, they all
6 have provisions where it's preferred that you obtain
7 commercially available high-quality proficiency tests
8 through a program such as CAP of New York or what have
9 you. But for many, many tests, those don't exist
10 because it's just not enough of them being done in the
11 petri. So they outline in their guidelines, procedures
12 and processes for developing an in-house proficiency
13 testing program was called the alternative proficiency
14 testing program. And that is closely scrutinized by
15 CLIA, CAP New York and ISO when they inspect the
16 laboratory. Because you know, that they understand
17 that these aren't coming from outside. And they have a
18 number of ways that you can accomplish that.

19 MR. SEHAM: For the record, I'm going to object to
20 any testimony as to what the CLIA inspectors look at
21 and what they don't look at because the witness already
22 testified that any review of documentations is done
23 behind closed doors. So that's speculation what the --
24 what the witness is testifying to now. Okay.

25 MR. KASSIN: I think the witness is describing

1 what's made available to them.

2 MR. SEHAM: If that is the limit of the testimony,
3 then I withdraw my objection.

4 Q. Dr. Jones, can you clarify?

5 A. Yes. These -- these documents are made
6 available to them.

7 Q. Okay. Dr. Jones, can you just describe for
8 us what is referred to in your industry as the method
9 validation process?

10 A. So method validation is a series of
11 experiments that must be conducted prior to offering a
12 test for release to the public. They include
13 experiments that evaluate the accuracy and precision
14 around the cutoff and various other concentration
15 levels. You have to determine your limit of detection,
16 your limit of quantitation, your upper limit of
17 linearity. You have to determine your matrix effects.
18 And there's -- there's ways to do that. Matrix effects
19 basically are looking at a phenomenon called ion
20 suppression or ion enhancement, so we have to evaluate
21 for that. We have to evaluate the potential for
22 carryover from one specimen to the next. And as a
23 group, this body of experiments is called the
24 validation.

25 Q. You mentioned earlier that USDTL has the

1 ability to do PEth testing both on DBS, as well as,
2 whole blood. What is your view of the pros and cons of
3 each?

4 A. So the pros and cons. If you've got someone
5 that's already got an open vein, for instance, if
6 you're doing a medical examine and you're already
7 collecting four or five tubes of blood. Adding one
8 more tube, one more great talk tube the collection.
9 Easy peasy. Logistically, that would be an advantage.
10 The second advantage would be that, there's more
11 laboratories that offer whole blood testing. So that's
12 an advantage depending on your -- your perspective on
13 that.

14 But the disadvantage of -- of doing whole blood is
15 number 1, access to all of your donors in a feasible
16 scenario. In other words, can you get them to a
17 clinical scenario, or do you have to do the collection
18 in the field. So blood spots has an obvious advantage
19 there. Secondly, is that, PEth in the whole blood can
20 be formed if the donor is currently under the influence
21 of alcohol. So in other words, if you collect the
22 blood in a tube and the donor has a measurable blood
23 alcohol in transit to the laboratory, the PEth will
24 continue rising because it's making PEth, in the tube.
25 So that's a disadvantage -- In this environment that's

1 kind of a moot point, but like in a research
2 environment where they're trying to look at the levels
3 and categorize their -- their patients, that has an
4 obvious disadvantage there. Another disadvantage is
5 that the PEth will degrade or decompose over time when
6 stored in whole blood. And so that's an obvious
7 disadvantage and that if you call back weeks, months,
8 or a year later to re analyze the specimen for the
9 PEth, it may be known, or it may be severely
10 diminished.

11 The advantage of -- and shipping whole blood has a
12 lot of blood-borne pathogen issues with regard to
13 shipping and how it shipped in protective environment
14 so that the tubes don't crack in transit, and all that.
15 So a lot of logistics, a couple of chemistry reasons
16 why the whole blood is a disadvantage. The blood spot,
17 once it's on the paper is not a bio-hazard. And number
18 two, everything is fixed so you don't have the creation
19 and the decomposition is, much, much, much slower, over
20 time with the dried blood spot than with the whole
21 blood.

22 So, you know, depending on your circumstances one
23 may be better than the other, or easier than the other.
24 But all taken together, it's my opinion that the dried
25 blood spot is a -- is a -- is a more convenient, better

1 service than the whole blood.

2 Q. Since 2007 when USDTL started doing PEth
3 testing, can you give us an idea of approximately how
4 many PEth tests that USDTL has conducted?

5 A. Between 120 and 150,000.

6 Q. Okay. And to your knowledge, has USDTL ever
7 had a positive test result, scientifically determined
8 to be a false positive?

9 A. No.

10 Q. You mentioned the possibility of with DBS
11 samples sending them to the University of Texas,
12 medical laboratory. Have you ever --

13 A. Yes.

14 Q. -- done that with tests that you found
15 positive?

16 A. Yeah. So far, knock on wood, between 50 to
17 60 samples, I believe, have been sent to, the
18 University of Texas for retest and all of them have
19 reconfirmed. We've had a couple, I believe, go to
20 Drugs Scan. I don't think we've had any go to Med Tox
21 yet, but so far all the re-tests have confirmed --
22 reconfirmed.

23 Q. Are you aware of any scientific studies that
24 have found there to be false positive PEth test?

25 A. Yes and no. There was one poster

1 presentation at the Society of Hair Testing, a couple
2 of years ago. People wash their hands immediately
3 before selecting a -- a dried blood spot were
4 generating PEth in those dried blood spots. To the
5 best of my knowledge that has not been peer reviewed
6 and published yet. The reason I say yes and no is
7 that, who would wash their hands with Everclear prior
8 to a PEth collection? That wouldn't make sense. And
9 the collection instructions say do not use any ethanol
10 containing substances in or around the collection event
11 so yes and no. But it's only one -- it was a post or
12 platform presentation and I've not seen it published
13 yet.

14 Q. I'm not sure what Everclear is, is that some
15 sort of a alcohol hand sanitizer?

16 A. Yeah -- well, Everclear is the purest alcohol
17 that you can buy at the liquor store. So it's used in
18 Harry Buffalo and PJ.

19 Q. Setting aside that, have there been any
20 scientific studies that have shown there to be false
21 positives?

22 A. I just saw a couple of people smiling when I
23 said PJ, I saw them.

24 Q. Yeah, I think that a lot of people --

25 A. I'm sorry, could you repeat the question,

1 please?

2 Q. Yeah. Was that a peer-reviewed study?

3 A. It was -- it was a presentation at a
4 conference and those are not classified as peer
5 reviewed.

6 Q. Okay. Are you aware of any scientific
7 studies that have been peer-reviewed that had found
8 there to be false positives?

9 A. No, quite the opposite.

10 Q. Okay. I think we're ready to look at company
11 -- one second. Are you aware of any other laboratories
12 that have had false positives on PEth testing?

13 A. No, I'm not. Good question. I have not
14 heard of any.

15 Q. Okay. I think we're ready to turn to Company
16 Exhibit 10, which we've identified as the USDTL
17 litigation package on the PEth testing that was
18 conducted on a dried blood spot sample, taken by Mr.
19 Danford, on May 9, 2018. Dr. Jones, I'm just going to
20 ask you to take us through and show us the key sections
21 of this. It's a rather long document, and fortunately
22 the pages are numbered in different sequences,
23 somewhat, as you work through the bottom up -- we're
24 all going to have to be -- you have to be patient with
25 us as we make sure we're all on the same page. And it

1 looks like you -- you put a screen on for us. Is that
2 what you just did?

3 A. That was not me.

4 Q. Okay. Arbitrator Burdette, was that you? I
5 bet that was StoryCloud. There we go. Okay. Here we
6 go. So Dr. Jones, just take us through it and tell us,
7 starting with the summary of results, explain what
8 information is provided, and as well the processes that
9 are being used.

10 A. Okay. So, the first page there was a cover
11 letter and then identification on the next page of the
12 specimen contained in this litigation package. The
13 next page is a table of contents.

14 Q. Okay. Before you go there, I do have a
15 question for clarification purposes.

16 A. Yeah, sir.

17 Q. On the second page, where it says "Litigation
18 package for Account: Choice Labs Inc." At the very
19 bottom it says, "Matrix: Whole Blood."

20 A. Yeah.

21 Q. If this was a dried blood spot, what's the
22 reference to the, "Matrix: Whole Blood" there?

23 A. Yeah. You can do other specimen types on the
24 Whatman 903 paper. In the blood line, you can do whole
25 blood, you can do serum, you can do plasma, you can do

1 pack cells. You can do urine blood spots. There's
2 papers out there about -- you know, about that now,
3 again, with the shipping convenience of doing blood
4 spots. You can do breast milk in dried blood spots,
5 you can do cerebrospinal fluid, and -- and so in this
6 instance here we're pointing out that the blood spot
7 that we had, it was a whole blood specimen, not a
8 plasma, not a pack cells.

9 Q. Thank you. You go ahead and continue,
10 please.

11 A. Okay. So the next page, I believe, it was
12 the table of contents. We have five sections. We have
13 a summary of results, just for convenience, at the very
14 beginning. We then have the chain of custody documents
15 associated with that specimen. We then have initial
16 test documents, followed by the confirmation test
17 documents, followed by a one-pager with our licensures
18 and registrations, that we have current in the
19 laboratory. So on the next page --

20 Q. Well, let's start with the summary of
21 results, Dr. Jones, and if you could explain to the
22 arbitrator and board members, what information is
23 provided on that summary of results page?

24 A. We're just giving a quick reference in a more
25 textual, and not a lab report-looking format of -- of

1 what was the initial test result, what was the
2 confirmation test result and a place for signature
3 where someone can say, yeah, I've reviewed all of this
4 data and I -- I certify to that.

5 Q. As long as you are looking at this page,
6 could you tell us what the initial result was and what
7 the cutoff was that was used?

8 A. Yes. The -- the cutoff that was used for the
9 initial test is 20ng/mL, and -- and the instrument, we
10 received a result back of 69, and so that was positive,
11 and it went back for confirmation. Again, the cutoff
12 was 20, and on this batch, well, we received a
13 quantitation of 98. It was positive. We can see that
14 Liaqat Ali Abbas has reviewed the lit pack that follows
15 this summary, and he's attesting.

16 Q. Okay. And in both instances, the test was
17 run on the 16:0/18:1?

18 A. That is correct.

19 Q. Okay. If you would -- take us through the
20 chain of custody documentation.

21 A. So this right here is the report that was
22 issued to Choice Lab, and -- and that has the official
23 results that you saw on the summary. So if we go to
24 the next page, we'll get into the chain of custody.

25 Q. Okay.

1 A. So this is what we call the requisition form,
2 and this information has the client specific
3 information, and the donor specific information, and
4 the test requested specific information that is filled
5 out at the collection site, typically signed by the
6 donor, but it's not mandatory, because in many
7 instances we may have donors who are not being
8 cooperative, but are mandated for collection. So
9 you'll see fictitious names written down, or just a X.
10 But anyway, that's optional, but it -- it appears that
11 it was signed here and there's a place for the
12 collector to sign where they are attesting that they
13 collected the specimen and affix the seals and send it
14 in for collection. They have a date and a time. And
15 midway through this form, we can see the collection
16 site, where this was physically carried out, and this
17 is -- this is a standard form that is -- that is used
18 in our industry.

19 Q. Okay. And if you can, I notice where it has
20 Mr. Danford's name listed, there is a box that says
21 "Picture ID Verified," what's the purpose of that?

22 A. Yeah, this is to verify that -- that it's
23 actually the person showing up. So in -- in many
24 instances we have people that -- that, you know,
25 perhaps they have an agenda. They will send in people

1 with fake IDs, or just show up for the test. And so
2 this is to make sure that we've got some sort of a
3 government-issued picture ID to -- to verify the
4 identity of the person providing the specimen.

5 Q. Okay. And as to Letter H Collection Site
6 Information, who does that show the collection site to
7 be?

8 A. This is Any Lab Test Now. This is a
9 third-party administrator that is a client of USDTLs.

10 Q. Okay. Go ahead and continue, please.

11 A. And so this -- this -- this is the beginning
12 of the chain of custody, and the specimen is then
13 packaged up. If you can go to the bottom of the page,
14 you can see where there's some blank spaces there, but
15 there's one little barcode number on the bottom right.
16 That is one of four barcode seals that are tampered
17 evidence once they're placed on the specimen or the --
18 or the package, you can't lift them without it being
19 obvious. So we can see that the two were removed and
20 they were used to seal the ends of the box. And so
21 that's the -- that's the primary number that we use to
22 connect that specimen with this paperwork, is we'll
23 scan the barcode up at the top right of this document,
24 if you can scroll back up to the top.

25 Q. Okay. And I also notice that there is a

1 laboratory certification at the bottom. What is the
2 purpose of that?

3 A. Yeah. That is a statement that Shanita
4 Certain has made. She is a specimen technician for
5 USDTL in our receiving department where she is saying
6 that I received the specimen, seals were intact and she
7 accepts chain of custody of that specimen, and then she
8 eventually forwards the specimen over to -- to the
9 aliquoting area.

10 Q. Okay.

11 A. So again, this is the beginning of chain of
12 custody.

13 Q. Okay. Then what happens next to this
14 particular sample?

15 A. The next thing that happens with this
16 specimen is that it goes in for initial testing. So if
17 we scroll down, this document here is kind of at the
18 very end of the procedure. This shows that in May 30,
19 this specimen was selected for long-term storage and it
20 was put into long-term storage to be kept for one year.
21 This little section here is like the beginning of the
22 chain of custody and the end of chain of custody.

23 Q. Okay.

24 A. So next page. Now we're into the initial
25 test documents. Next page. This is what we call the

1 worklist and we can find the specimen in question.
2 Hold on. So the lab ID for this specimen is 2337764.
3 In this batch of worklist, it's the second from the
4 bottom on this page. There you go. Thank you. And so
5 this sample was placed into this batch. And if we go
6 to the next two pages, we can see where in the box down
7 at the bottom, we can see where Sarah Spanraft received
8 the specimen from the temporary storage area, and she
9 prepared an aliquot of it, and returned the original
10 specimen back over to temporary storage.

11 Up in the top half, these are all the different lot
12 numbers of the calibrator and control materials, and
13 the amount of the internal standard that was used, and
14 the lot number for the internal standard. There's a
15 lot of batch information here. We go to the next page
16 since there -- on the next page, since Sarah created
17 this aliquot, the aliquot comes to existence under her
18 custody. And then she turns the batch over as a -- as
19 a whole, into temporary storage pending the extraction
20 procedure. And Katie Lea picks up this batch, she
21 performs the extraction procedure, and then she places
22 it into another temporary storage, depending analy --
23 pending analysis. And then later on on the next shift,
24 Graham Kennedy receives this batch from temporary
25 storage, and he transfers it to the custody of LCMSMS,

1 number 23.

2 The analysis occurs. It takes in -- depending on
3 the size of the batch, it can take anywhere from two to
4 eight hours for a batch to load on the instrument, and
5 so Lesley Stolp come in on the -- at the end of the
6 shift or the next shift because it's the next day. She
7 come in on third shift, and she reviewed the data, and
8 printed it out, verified the samples and the sample
9 tray where -- in the correct position, and then she
10 placed the those aliquots or extracts into temporary
11 storage, pending data review. And so the data follows
12 this. And on the next page -- all right. On -- on the
13 next page, this is the calibrator. It's a -- the
14 calibrator is a specimen that has been fortified with
15 20 nanograms per ml of PEth160181. So going forward
16 when I refer to PEth, I'm referring to 16:0/18:1. If
17 not I'll refer to others specifically, but now it's
18 just PEth.

19 So the calibrator is a sample that or a certified
20 negative specimen that has been fortified with 20
21 nanograms per ml of PEth. We're going to take that
22 specimen and spot -- spot cards, and then we punch
23 holes out of that spots card. And the response is
24 proportional to that concentration, and the
25 concentration either found or not found in the patient

1 sample itself. So this is the first page of data with
2 regard to the calibrator. You can see at the top the
3 sample name is called Cal for calibrator. You can see
4 in the results of summary that the calculated
5 concentration is 20. So what the computer is doing at
6 this point is that when you analyze a calibrator, you
7 tell the computer that the calibrator is the
8 calibrator, and it's at a certain level, in this case,
9 20 nanograms per ml.

10 So it calculates this variable called the response
11 factor. And then using that response factor, it will
12 calculate the concentration of the controls and the
13 patients based on that. The next block down shows the
14 specific mass weights that we're looking at for PEth 1.
15 It gives you the retention time of 4 -- 1.489 minutes.
16 The area of 11,684 area accounts. The actual
17 acquisition date and time. And then the on column
18 value is set at 20 because it's the calibrator. The
19 bottom block on this page is information related to the
20 internal standard. The internal standard is a compound
21 that's added across the entire batch prior to analysis.
22 And it's the relative amounts of the analog to this
23 internal standard, that is used in the calculation of
24 the response factor, which is then used in the
25 calculation of the concentration of the controls in the

1 patients.

2 But we can see here that the retention time was
3 1.474, area account is 42,000 -- area counts 42,091,
4 and the specific acquisition date and time, and the
5 concentration of the internal standard is set at 80.
6 Eight, zero. On page 2, these are the actual
7 chromatograms for the quantitation ions of PEth. And
8 per-deutero PEth, which is the internal standard. The
9 Palmitic species, has 31 deuteriums replace --
10 replacing hydrogens.

11 Q. I'm sorry to interrupt, but has the page
12 you're referencing, has that moved because --

13 A. Yeah, next page, I'm sorry. I was looking
14 down. Thank you.

15 Q. All right. .

16 A. So here we go, we have the chromatograms. And
17 so the top chromatogram is the response that we saw
18 from the PEth, and the bottom chromatogram is the
19 response that we got from the internal standard. And
20 it's from the relative abundances that it calculated, I
21 got big gray box on my screen. There we go. And so
22 from that response, we -- we set this relative response
23 to be equal to the calibration amount of 20. So if we
24 move to the next page, right. So this is the --

25 MR. SEHAM: Sir, I'm sorry to interrupt. Tom, I

1 was going to ask if we're coming to a logical break
2 point for a call of nature, rest period?

3 MR. KASSIN: I think this is a good point right now
4 if it's acceptable with everybody and the arbitrator.

5 MR. SEHAM: Mr. Burdette, is it okay we take a 5 to
6 10 minute break to wash hands? Oh, he is on mute.

7 MR. KASSIN: Yeah.

8 MR. SEHAM: You're on mute. I think Mr. Burdette.

9 THE ARBITRATOR: Sorry, I was in the wrong spot
10 trying to unmute. Yeah. Let's come back in 10 minutes
11 at 11:14 my time, 12:14 your time.

12 MR. SEHAM: Okay. Thank you.

13 THE ARBITRATOR: And Damien, we'll go off the
14 record.

15 (OFF THE RECORD)

16 BY MR. KASSIN:

17 Q. Dr. Jones, if you could pick up where you
18 left off, please.

19 A. So the next page is what we call the mid
20 control. And this control is targeted to be 25
21 nanograms per ml, plus or minus 30 percent. And -- and
22 in -- in the middle of -- well, up at the top, you can
23 see where it says mid under sample name. And then drop
24 down to results summary. We can see that the
25 calculated concentration is 23.72 and that's within the

1 expected quantitation of that. The analog retention
2 time was 1.489. We're looking at 1 ion. So at this
3 point there is no ion ratio. So those two fields are
4 blank. The next block down gives us the data for PEth
5 1. With the retention time of 1.489, area count
6 14,890, with the acquisition date and time. Then the
7 on column calculation was 23.72 and then the bottom box
8 is the internal standard. It is always set at 80. So
9 going forward, I will not mention that in the interest
10 of time.

11 On the page following that, the next page, are the
12 chromatograms associated with the mid control. The top
13 chromatogram is the PEth. The bottom chromatogram is
14 the internal standard. Passes all appearance
15 criterias. Next page. So this is the low control. Up
16 at the top table where you can see where it's called
17 the low. Result summary. PEth 1, the calculated
18 amount was 5.74, and so the targeted amount, there was
19 eight nanograms per ml. The result for this control
20 has a limit of -- It must be less than 20. Since we're
21 just concerned with positive, negative, is it less or
22 more than 20? 5 is less than 20, off we go.

23 The next box is the PEth 1 data retention time of
24 1.489, area count of 3,486. The acquisition date and
25 time. Again, the on column calculation of 5.74

1 nanograms per ml. On the next page, are the
2 chromatograms for the low control. Okay. And so the
3 top chromatogram is the response that we saw from the
4 PEth in the low control and the lower chromatogram is
5 the response that we saw from the internal standard.
6 This passes all appearance criterias. Okay. Next
7 page. This is the high control. This is targeted to
8 be at 80. And the criteria for passing the batch here,
9 is it has to be greater than the cut off of 20. Again,
10 because the screening batch is more concerned with is
11 it there, is it not there versus calculation. At any
12 rate, you can see at the top of the table it says high.

13 This is the high control. The PEth, then the
14 results summary. Calculated concentration was 105.
15 Retention time was 1.489. The second block is the data
16 associated with the PEth, with the retention time of
17 1.489, area counts of 66,946, and that calculated
18 amount was 105. The next page, are the chromatograms
19 for the high control, with the upper chromatogram being
20 response of the PEth, the lower chromatogram being the
21 response for the internal standard.

22 Next page. I only have a negative control. On the
23 next page. Up at the top, we can see where it says neg
24 for negative control. Here we have a calculated
25 concentration and the results summary of 0.24. Now our

1 limit of detection, depending on which year we -- we
2 update that. Each year we look at it again, is
3 anywhere between two and three nanograms per ml.

4 So any result that we say less than the limit of
5 detection, we say it's not detected. Then anything
6 less than the limit of quantitation, which in most
7 years is eight, anything less than that, we can say,
8 like, between 3 and 8, we can say we detect it, but we
9 can't tell you exactly what the number is. If it's
10 above 8, then we can say we're certain -- with a
11 limited amount of certainty -- of the actual
12 quantitation. But if we look at the calculated
13 concentration here at .24, when we look at the
14 chromatogram on the next page, you can see that all of
15 this has been normalized so that the largest peak is
16 the full size of it, but we can see that you can start
17 to see all of this noise in the background, which tells
18 you that we've really zeroed in on this and we're
19 looking at the baseline really, really closely because
20 that little highlighted peak, that quantitated at .24
21 is just a noise peak and we're down on the noise here.
22 So what that tells us is that the negative control is
23 indeed negative and the retention time is not at the
24 right places. It's too far to the right to be PEth,
25 it's more in line with the deuterate. So, the negative

1 control is negative and passes the criteria that we
2 have established. Next, we have the patient sample
3 3337764 that we saw on the worklist. And so -- and you
4 can see that number at the top of the page. Under the
5 result summary for PEth 1, we see a calculated
6 concentration of 69.6756, 69.

7 By the way, in our field, we don't round up. We always
8 truncate down. So we would never -- it's not common
9 practice to call this a 70, although that would be your
10 -- your rules for rounding, because we'd never want
11 19.99 to be called a positive at 20. So we always
12 truncate. So at any rate, so this is a 69, retention
13 time 1.47. The middle table has the data for the PEth
14 retention time of 1.475. The area is 40,404.
15 Acquisition date and time and again, the calculated
16 concentration of 69.6756.

17 On the next page are the chromatograms associated
18 with this donor's specimen. In the upper chromatogram
19 -- we're missing one. Keep going. Next page. There
20 we go. And so the upper chromatogram is the response
21 that we got from the PEth. The lower chromatogram is
22 the response that we received from the internal
23 standard. In a screen batch, we have a requirement and
24 this is, like I said, from using chemistry analyses.
25 We have a legacy requirement -- next page, to include a

1 fortified control at the end of the batch. So you will
2 not see this in the confirmation batch because it's
3 operating under a different portion of the checklist.
4 But here, we -- we shoot a mid-control at the end.
5 Just to verify that the instrument was performing
6 throughout the entire assay during the screen batch.
7 So mid control -- you see at the top, mid. The results
8 summary. The target calculation was 25, this read
9 24.4765. The retention time was 1.484 minutes.

10 The middle box has the PEth data where we had
11 14,611 area counts, with the acquisition date and time.
12 And again, the on column calculation of 24.4765. The
13 last page of this section -- next page, again are the
14 chromatograms of the shot of the mid-control with the
15 upper chromatogram being the response that we saw from
16 the PEth and the lower chromatogram being the response
17 that we saw from the internal standard. So that's the
18 end of the screening batch. So now this sample gave us
19 a response that was greater than 20. So that's
20 presumptive positive and we're not done yet. So this
21 information reflexes back into the receiving lab. They
22 prepare a batch with -- with other positive samples.

23 Next page. And we can see our sample in question
24 as the last one on the page there. Nope -- nope --
25 nope -- next page. It's four from the bottom on the

1 second page of the worklist there, 2337764. So moving
2 two more pages deep in. Same deal with chain of
3 custody with the initial test and that Oksana retrieved
4 the specimen from temporary storage. She prepared an
5 aliquot. In the middle of the page we see the lot
6 numbers of the spiking controls that were used. For
7 the batch, we see the lot number for the internal
8 standard. And how much micro -- how many microliters
9 in internal standard. These are included for
10 troubleshooting purposes down the road. And so next
11 page, here's the chain of custody of the aliquots,
12 meaning that Oksana created the aliquot. It came into
13 existence under her custody and control.

14 So she put the batch into temp storage, temporary
15 storage, pending extraction. And so the following,
16 after midnight, Niranjan Patel retrieved that batch and
17 performed the extraction and placed it back into
18 temporary storage, pending analysis. Later on that
19 night, Samantha Fitzgerald retrieved that batch from
20 temporary storage and transferred it to LCMSMS number
21 27 for LCMSMS analysis. The next morning, lab tech
22 Joey Hua retrieved the batch off the instrument,
23 reviewed the data, printed it out, verified the sample
24 table that the specimen's in the correct position, and
25 set the batch back into temporary storage, pending data

1 review.

2 Next page. Off we go again with very similar
3 looking data, but there's some differences here, in
4 that you'll notice that there's this number called a
5 mass ratio in this results summary. And so this is a
6 feature that we add in the confirmation batch because
7 we're confirming a -- a positive screen. So we need to
8 make sure we've got everything accurately identified.
9 The mass ratio was -- is a standard practice in our
10 business. So again, this is the calibrator. We have a
11 calculated concentration of 20 nanograms per ml because
12 we fortified the calibrator at 20. We're telling the
13 computer that this is the calibrator and it has 20, so
14 it sets the batch up with these relative responses
15 equals 20. So that's the calibrator.

16 Next page. The chromatogra -- the -- pardon? The
17 next page are the chromatograms. Here we have two
18 chromatograms on top and two on the bottom. And so
19 this is what we're talking about with the mass ratio.
20 In that the first, the top -- looking at the top row,
21 we have them identified here as PEth 1 and PEth 2. The
22 first ion fragment is -- is the quantitative ion, so
23 the area from this response is used for calculating the
24 concentration. Second fragment is a different fragment
25 of PEth. And the relative amount of PEth 2 to PEth 1

1 has to be consistent with the calibrator throughout
2 this batch in order for the specimen to be identified
3 as PEth or confirmed as PEth.

4 So if we -- if we go back one page, we can go back
5 one page. We can see in the results summary under PEth
6 2 retention time of 1.294, we can see the -- the
7 calculated ion ratio and the expected value was 0.3150.
8 And the expected value was 0.3150 or 31-and-a-half
9 percent. Because it's the calibrator, everybody else
10 will be compared to that, so we'll reference that as we
11 go through the rest of this batch.

12 Next page, next page. Excellent. So now we're at
13 the mid control under results summary and we can see
14 that the calculated concentration is 26.6688. The
15 expected response was 25. And under the mass ratio,
16 you can see the calculated ion ratio of PEth 1 to PEth
17 2 was 0.3029. The expected ratio was 0.3150. So
18 there's an expected range of 20 percent there, plus or
19 minus. And so that's within the range so the computer
20 has put a checkmark under Ratio OK. We've got a
21 checkmark. And so it's passed quantitative criteria,
22 it's passed the mass ratio criteria. And onto the next
23 page we can look at the chromatograms and they're
24 symmetrical. They've got an 85 percent return to
25 baseline, were greater than 31 signal-to-noise . And

1 so all of these passed the individual chromatographic
2 criteria. I'll let that sink in for you. Now onto the
3 next page. Thank you. So this is the low, the target
4 value there is 8. And under results summary, we can
5 see that the calculated result -- okay.

6 So the calculated concentration in the middle of
7 the page was 7.7664, expected concentration was 8. So
8 this is very close. And the calculated ion ratio was
9 30.86 percent, which is within ratio. We've got
10 checkmark as being okay, it's within 20 percent.

11 Return to the next page for the chromatograms. Next
12 page, there we go. Inside the top row of this is the
13 PEth 1 and 2. The lower chromatograms are internal
14 standard, and they pass all peak appearance criteria.

15 Next page is the high control. It's expected
16 quantitation is 80. Plus or minus 30 percent, so we're
17 at 97. We're within the allowable quantitation, the
18 calculated ion ratio was .3180. Expected mass ratio
19 was 31.5 percent. So we see the checkmark in ratio
20 okay. And so this is a good quantitation, good
21 identification. Turn the page then we can see the
22 chromatograms, the responses for the high control. And
23 they're all symmetrical, peak appearance is acceptable
24 and off we go. So the last control that we shoot is
25 the negative control. And the calculated concentration

1 is well below the limit of detection. And you can see
2 also that a little bit of noise that it picked up, the
3 mass ratio was way out and so -- and the wrong
4 retention time. So -- so -- this is not PEth and even
5 if it was, it's below what we can claim as being
6 detected.

7 And if we turn to page, again we see like these
8 little noise tapes that are going -- going down. They
9 look large because the scale has been normalized to the
10 biggest signal, but if you look at it on the left,
11 you're in double digits, so this is like nothing.
12 You're looking at the noise. So the negative is indeed
13 negative. All of the controls, past are quantitative
14 and chromatographic criteria. And so now we can analyze
15 the subject specimen, and we can turn the page. And so
16 here we see the sample number 2337764. Under the
17 results summary, we've got calculated concentration of
18 98.8857 and the expected mass ratio is 31.5. And for
19 this specimen, the mass ratio was 33 and 38 -- .38.
20 Ion ratio was within acceptable limits.

21 We look at the next page with the chromatograms for
22 the subject specimen. And again, all of these peaks
23 passed forward. Next page, next page. There we go.
24 And so all of the chromatographic criteria passed for
25 this specimen here. So now we've got a presumptive

1 positive, we've got a confirmed positive. We have a
2 value that's been generated in a batch that has been
3 designed with the criteria needed to report on a
4 quantitative value. We got similar responses. When
5 we're comparing these two results, we think of the
6 screen in terms of low, medium and high. And so the
7 reviewer of this batch, we've looked at the initial
8 batch, it said 69 or whatever it is, this is a medium
9 response. And then we look at the 98 and that's --
10 that's a medium response. So they match and they go
11 out. Technically, if you look at those two values and
12 take the mean, these two points would be within plus or
13 minus 30 percent range of the mean. But nevertheless,
14 it's a low, medium, or high comparison to the first
15 because we don't have the same criteria quantitatively
16 on the initial.

17 Q. Dr. Jones, can you explain when you're
18 talking about this topic, why are the screening results
19 for the initial test results different from the
20 confirmatory results?

21 A. Yeah. So, the -- the -- the purpose of the
22 initial test, the confirmation tests are different.
23 The purpose of -- one of the purposes of the screen
24 test is to quickly identify the negatives and report
25 the amount as quickly as possible. And so quantitation

1 outside of the cutoff is really irrelevant at that
2 point. And so what we're trying to do is get a batch
3 and then get it in quick and have rules in place such
4 that we're targeting the cutoff and if it's less than
5 the cutoff, then it goes out as negative and people can
6 go on about their life. But if it's above the cutoff,
7 now we need to back up and focus in on that one. And
8 so we want to pay attention to those and give them more
9 strictly more detail than the negatives.

10 Once the negatives are out of the way, we can then
11 circle back and prepare a second aliquot of the sample
12 and do the confirmation test and the rules that we set
13 up for the confirmation in, you know, under the
14 guidance of our regulatory agencies. We have these
15 quantitative tolerances that are imposed on that second
16 batch that just aren't imposed on the first one. And
17 you see the same sort of deal with -- when you're
18 comparing amino acetate to a GCMS urine drug test.
19 It's the same kind of concept in that the initial test
20 is semi quantitative, you know, at best. And -- and
21 the -- the confirmation is a fully quantitative method,
22 but that's like the number 2, fully charged.

23 Q. Okay. And you may have alluded to this, but
24 when you're doing the PEth test and you've talked about
25 the initial and the confirmatory, what is your expected

1 reproducibility in the testing process?

2 A. Well, they have to match with regard to low,
3 medium, or high on the screen compared to the confirm.

4 Well, that's a very subjective thing. All right.

5 Well, at the -- at the end of the day, one of the
6 parameters that is calculated in a -- in a validation
7 package is -- is -- is this figure called the
8 uncertainty. And so the uncertainty is this procedure
9 that the quality management team goes through where
10 they evaluate all the different sources of uncertainty
11 or precision, if you will, accuracy and precision, all
12 the way from, you know, what's the uncertainty of the
13 pipettes that are being used to put in the -- in the
14 internal standard. What's the accuracy of the -- or
15 what's the precision and accuracy of the quantitation
16 of the controls over a period of time.

17 What's the accuracy and precision of -- of -- of --
18 of -- getting the punches of the exact same size. So
19 all of those have all of these little uncertainties and
20 during the whole process they add up. All right. And
21 as -- as -- as a cumulative number, that's called the
22 uncertainty of the final result. The uncertainty of
23 the final result, at this point in time, was
24 approximately 30 percent. And in the validation
25 package that you may or may not have in front of you,

1 it's like the second or third page on that package
2 where you can see where they did the -- the calculation
3 for the uncertainty.

4 Q. Okay. Well, how often is there a difference
5 between the results in the initial tests and the
6 confirmatory test?

7 A. You know, you see enough of it that, you
8 know, you have to confirm everything. All right. And
9 so I wouldn't call it exactly a rare occurrence, but
10 it's not all the time and so we expect to see
11 differences, you know, a couple of times at least in a
12 week or month. If you don't see these things, that
13 means people might be telling fibs about their data.
14 So you always want to have a small fraction of your
15 batches failing. You always want to have a small
16 fraction of your samples not passing and have to go
17 back. You get into a situation where everything's
18 passing, you got to -- you got to look at your team and
19 go, hey, are you guys really looking at this data? So
20 -- so again, that's kind of a subjective measure.

21 It's -- of course, we've got this competing thing
22 called turnaround time. Everybody wants their result
23 yesterday. You know, when you order a pizza, you don't
24 order 30 minutes before you get hungry, you're hungry
25 now. So you don't want your pizza tomorrow, you want

1 it right now. So -- so we have these competing things.
2 We have these rules and points, and -- and we monitor
3 the fail rates and -- and we make -- you don't know the
4 fail rates to be too high and you don't want the fail
5 rates to be zero either, to make sure that everybody's
6 doing their job.

7 Q. Okay. So as you evaluate the results of Mr.
8 Danford's testing of his dried blood spot sample from
9 May 9, 2018, initial test of 69 nanograms per
10 milliliter, confirmatory tests of 98 nanograms per
11 milliliter. What metrics does USDTL use to satisfy
12 itself that everything is in compliance and it's a
13 proper test result?

14 A. There's no specific that, like, it's got to
15 be within a certain percentage or it's got to be
16 specifically this or specifically that. It's a
17 subjective evaluation of low, medium and high. And so,
18 if it were 22 on the screen and 98 on the confirm, this
19 would raise a red flag. We need to do this again and
20 see what's up. If it came out at 1200 on the screen
21 and 98 on the confirm, wait a minute, something's wrong
22 here. But when you get like a 60 and a 90, that's all
23 in the same ballpark and we're looking at all the other
24 samples in the batch too. And so we can see if maybe a
25 sample got switched. Maybe they aliquoted the wrong

1 sample. Maybe there was a frame shift error in the
2 initial test. But we don't say that the initial test
3 and the final test have to be within 10 percent of each
4 other. Because we're comparing apples and oranges with
5 regard to quantitation. It really is low, medium,
6 high. Is it 20? Is it 60? Is it 600? Versus what do
7 we see on the confirm.

8 Q. Before I have a couple of final questions, I
9 noticed the next part of this particular exhibit,
10 Company Exhibit 10, has your licensures and
11 registrations. The documents will speak for
12 themselves, but essentially what is that?

13 A. That's a list of all of the different
14 organizations that either license or credit us. The
15 ones that we mentioned earlier today, the CLIA, the
16 CAP, the ISO, those are probably all there. But also
17 like the other states that require us to provide other
18 proof, such as Maryland, Oklahoma, Illinois Department
19 of Professional Regulation. They, like, require a
20 check and a copy of our CAP certificate. And 90
21 percent of the time, that's what we looking --

22 Q. Okay.

23 A. Except those -- those are the list of all the
24 different ones that we maintained. At that time, it
25 changes a little from time to time.

1 Q. Thank you for taking us through the
2 litigation package. I'd like to ask you, having done
3 that and if you could tell us what conclusion or
4 conclusions did you draw based on Mr. Danford's
5 positive PEth results from the DBS sample taken on May
6 9th of 2018?

7 A. All right. So based on the chain of custody
8 being intact, based on the outcome of the initial test
9 and based on the outcome of the confirmation test, it's
10 my conclusion that specimen that we received
11 identified, Michael Danford, contained PEth. And --
12 and that is consistent with someone who has not been
13 abstinent during the approximately two to four weeks
14 prior to the collection of this sample.

15 Q. Okay. Do you have any doubt at all that his
16 DBS sample taken on May 9, 2018, was positive?

17 A. No.

18 MR. KASSIN: Okay. Mr. Arbitrator, if I could just
19 have one moment, please.

20 THE ARBITRATOR: Sure.

21 MR. KASSIN: Mr. Arbitrator, so we are completed
22 with our direct examination of Dr. Jones.

23 THE ARBITRATOR: Okay.

24 MR. KASSIN: Maybe off the record we should talk.
25 This would be a good time for a lunch break and then we

1 could reconvene at your direction.

2 (OFF THE RECORD)

3 THE REPORTER: We're back on the record at 2:01
4 p.m.

5 THE ARBITRATOR: Okay. Thank you. Mr. Seham?

6 MR. SEHAM: Yes.

7 THE ARBITRATOR: Cross examination of Dr. Jones?

8 MR. SEHAM: Yes, sir. Trying to find which box
9 you're in. There you are at the bottom.

10 CROSS EXAMINATION

11 BY MR. SEHAM:

12 Q. Good morning, Doctor. In your direct
13 testimony, you referred to NIDA. That would be the
14 National Institute of Drug Abuse?

15 A. Yes.

16 Q. Okay. And they were the predecessor to
17 SAMHSA. S-A-M-H-S-A?

18 A. As far as the certification of laboratories,
19 yes.

20 Q. Okay. So that would be a certification
21 pursuant to the NLCP, the National Laboratories
22 Certification Program?

23 A. Correct.

24 Q. Okay. And USDTL is not certified by SAMHSA
25 under the NLCP program, correct?

1 A. Correct.

2 Q. Okay. And USDTL is not permitted therefore,
3 to conduct any testing under the DOT mandated drug and
4 alcohol testing programs, correct?

5 A. Correct.

6 Q. And it's not submitted to conduct any testing
7 under DHHS, Department of Health and Human Services,
8 mandated testing, correct?

9 A. Under the Federal Drug Free Workplace Act,
10 no, we are not.

11 Q. Okay. Now, would you agree with me that in
12 setting out its certification program, NLCP sets forth
13 a number of forensic standards designed for the
14 protection of the individual employee being tested?

15 A. With regard to urine testing, yes.

16 Q. Okay. And a number of those safeguards that
17 had been implemented through 49 -- part 40 and the
18 NLCP program are protections that your testing
19 methodology for DBS -- is not a DOT, correct?

20 A. I'm sorry, could you repeat the question?
21 And also, I'm having a little issue with your audio.
22 It's -- it's breaking in and out.

23 Q. Okay. Try that --

24 A. It's like somethings rubbing up against the
25 microphone.

1 Q. Let's see. So my question is would you agree
2 with me that there are a number of forensic safeguards
3 that are established under 49 CFR Part 40 and the NLCP
4 program that are not followed by USDTL in the context
5 of its DBS PEth testing?

6 A. That is correct.

7 Q. So for example, you referred to the fact that
8 ideally, you would have two different chemical
9 methodologies confirming a PEth result, correct?

10 A. Correct.

11 Q. And in fact the NLCP program reported there's
12 an immunoassay, followed by a distinct methodology, gas
13 chromatography, mass spectrometry, correct?

14 A. This is the exact reason why they're --
15 they're limited to a truck drug panel that makes sense
16 in 1986 and they've not been able to update that since
17 then. And -- and it's for one of those reasons. But
18 -- but there's a very different purpose in that testing
19 in that, that is for workplace testing, and so that's a
20 very different arena than for what we're talking about
21 here today. And so they -- they're not even concerned
22 with the kind of testing that we do.

23 Q. Is it not the case that it's a bedrock
24 concept of forensic toxicology in terms of substance
25 abuse testing, that there would be two cross checking

1 chemical methodologies?

2 A. That is not true.

3 Q. Okay. And isn't it as mandated that even
4 when there was an evolution from substance abuse
5 testing to adulterant testing, the National
6 Transportation Safety Board mandated that there should
7 be two different chemical methodologies, cross
8 checking?

9 A. Yes. And they adopted that over time.

10 Q. Well, they adopted --

11 A. But that still doesn't make that a true
12 statement.

13 Q. They adopted it as a mandated decision,
14 correct?

15 A. For the -- for the two different analytical
16 methodologies, that is an ideal, but it is not true
17 that that is across the board true for everything.

18 Q. And that's a --

19 A. A perfect example is a DUI. And so if
20 someone has a DUI, and they -- and they have a blood --

21 MR. SEHAM: Excuse me, when there's an objection, I
22 think we have to set some ground rules here, Arbitrator
23 Burdette. If there's an objection, the witness should
24 stop talking until the objection is addressed. Is that
25 not correct?

1 THE ARBITRATOR: Yes, it is. That's correct.

2 MR. SEHAM: I'm objecting that the witness here is
3 launching into a narrative that's non-responsive to my
4 question. And if on redirect, Delta wants to pick up
5 these issues, they can pick up these issues, but if
6 we're going to allow the witness to engage in
7 narratives that are non-responsive, this is going to be
8 a six-day hearing.

9 THE ARBITRATOR: Yeah. Dr. Jones, you need to
10 confine your response and answer to his questions,
11 please.

12 THE WITNESS: Okay.

13 BY MR. SEHAM:

14 Q. Now, in the context of NLCP audited at Part
15 40 testing, there's also selection of a split specimen?

16 A. Correct.

17 Q. Correct. Okay. And then under your program
18 for USDTL, there is no split specimen, correct?

19 A. Correct.

20 Q. And under the NLCP program, there's blind
21 testing that's initiated or overseen by a third-party
22 administrator that's independent of the lab, correct?

23 A. Correct.

24 Q. And by contrast, your blind testing is
25 handled internally, correct?

1 A. Correct.

2 Q. And it's my understanding that there can be a
3 deviancy as much as 20-30 percent in your internal
4 blind test and the expected result and the produced
5 result, and that would be considered acceptable?

6 A. Yes.

7 Q. Okay. And under the Part 40 program,
8 specimen collectors have to be certified as qualified;
9 is that correct?

10 A. Correct.

11 Q. And they have to have to -- form five
12 collections in the --

13 THE WITNESS: I'm sorry, I'm still having trouble
14 with your audio. Is anyone else having this trouble or
15 is it just my connection?

16 MR. KASSIN: No, I -- I am too. I'm having -- I'm
17 having the same problem. Like there's a reverb or
18 something going on, Mr. Seham.

19 MR. SEHAM: I sent -- actually, to avoid that, I
20 sent my -- I sent my grievant down three offices, so
21 I'm not sure. Does the administrator have any
22 suggestion on what could be done in that regard?

23 MR. KASSIN: It seems like it's cleared up a little
24 bit now.

25 MR. SEHAM: Okay. You know, I just moved my screen

1 towards me. Maybe that helped. So I'll try to speak
2 more slowly and articulate carefully.

3 MR. KASSIN: Okay.

4 BY MR. SEHAM:

5 Q. And Dr. Jones, please stop me if you want me
6 to reiterate the question. I'm happy to do that
7 because I do want a clear record. So I think where I
8 was was that there is a whole training program for
9 specimen collectors under the Part 40 program, correct?

10 A. Correct.

11 Q. And there's no federal parallel for specimen
12 collectors collecting DBS specimens, correct?

13 A. Correct.

14 Q. And in fact, USDTL doesn't have a training
15 program aside from sending out a card of listing the
16 instructions on how to perform the collection, correct?

17 A. Not true.

18 Q. You engage in face-to-face training of
19 specimen collectors?

20 A. It's a -- it's a video. It's not
21 face-to-face, but we do offer a training program, with
22 a certificate.

23 Q. Is an individual required to undergo that
24 video training in order to perform the collection?

25 A. No, it's voluntary.

1 Q. Okay. And you get a certificate if you have
2 watched the video; is that correct?

3 A. And pass a test.

4 Q. And pass a test. Do you know if the specimen
5 collector who collected Mr. Danford's specimen was
6 certified by USDTL?

7 A. No, they were not.

8 Q. Okay. Why do you have a certification
9 program if it's purely voluntary?

10 A. Well, the certification of collectors is for
11 very, very narrow range of testing in our field, with
12 NLCP testing, which is a very small subset of all the
13 testing out there. The rest of the testing out there
14 does not require that.

15 Q. That wasn't my question. My question was:
16 You offer a voluntary certification program for your
17 DBS collection process; is that right?

18 A. Right. Right.

19 Q. And then you certify the individual who goes
20 through that process?

21 A. Certainly, yes.

22 Q. Why do you not mandatory that a specimen
23 collector have your video training prior to allowing
24 that person to collect specimens?

25 A. Our collector sites are our clients, and we

1 have an arm's length relationship with them, and so we
2 have no control of who comes and goes from their
3 employer. It's their responsibility. They decide what
4 their local policies are, and the standard of our
5 business is that the collectors -- I have to say a good
6 portion of the collectors out there are not certified
7 by NLCP to do collections because only a portion of all
8 the samples are even urine anyway. You've got fluid,
9 you've got hair. Now, you've got blood spots, which is
10 relatively new thing. And so there -- there is no NLCP
11 equivalent for that -- for that so it would be
12 impractical.

13 Q. Okay. So being impractical is what you're
14 saying, but you do have a protocol for collecting the
15 DBS samples that you send out to --

16 A. Yes.

17 Q. Okay. And would you agree with me that it is
18 imperative that these protocols be --

19 THE WITNESS: Hold on one second.

20 MR. SEHAM: Yeah, sure.

21 THE WITNESS: It's the Amazon man.

22 MR. SEHAM: There's feedback. It's not my fault
23 this time. All right. So --

24 THE WITNESS: I'm sorry.

25 MR. SEHAM: No, that's --

1 THE WITNESS: Hang on. She's coming back again. I
2 don't know why. I apologize for this.

3 MR. SEHAM: No, that's fine.

4 THE WITNESS: The Amazon man is quite upsetting. I
5 apologize again, I'm sorry. Please -- please.

6 BY MR. SEHAM:

7 Q. Don't worry. If Fido doesn't object my next
8 question is, would you agree with me that it's
9 imperative that the specimen collectors adhere to the
10 protocols for collection set forth by USDTL, in order
11 to have confidence in the ultimate test result?

12 A. Correct.

13 Q. Okay. Now, I'd like to turn to Union Exhibit
14 1. Multiple people don't have these exhibits, so I
15 think we're going to have them on the screen.

16 (Union Exhibit 1 marked for identification)

17 THE REPORTER: Just a moment.

18 MR. SEHAM: Okay.

19 THE ARBITRATOR: I think we've got an issue with
20 Mr. Seham here. He's got a little yellow triangle up
21 by its --

22 REMOTE TECH: Yeah. It's indicating that his
23 bandwidth is low, so it seems to be a location issue.

24 THE ARBITRATOR: And we lost Mr. Danford, too, so
25 we need to wait for a minute and see if we can get that

1 resolved.

2 REMOTE TECH: I'll reach out to them via e-mail to
3 see if I can get this.

4 MR. SEHAM: Can you hear me now?

5 THE REPORTER: Well, we can't see you. You've got
6 a little bandwidth issue, Mr. Seham. Your video is not
7 coming through and Mr. Danford is also -- we've lost
8 his video as well. You're back. Okay. We've got both
9 of you back now. Okay. You're muted though, Mr.
10 Seham.

11 MR. SEHAM: Yeah. I was going to move to Union
12 Exhibit 1 and I was hoping that Emily could put that up
13 on the -- or whoever is our host to put that up on the
14 screen.

15 THE ARBITRATOR: Emily. Emily's our host. Emily,
16 can you put Union Exhibit 1 up? There we go.

17 MR. SEHAM: Okay. Just for the record -- oh, let's
18 make it a little bit bigger. Thank you so much.

19 BY MR. SEHAM:

20 Q. Just for the record, I'll state the title for
21 the record. Official International Association for
22 Therapeutic Drug Monitoring and Clinical Toxicology
23 Guideline Development and Validation of Dried Blood
24 Spot-Based Methods for Therapeutic Drug Monitoring,
25 with a lead author being Sara Capiou. That's

1 C-A-P-I-A-U. If we could maybe scroll down about an
2 inch, I just want to point out that below that first
3 line across that goes entirely across from left to
4 right, it says, "Received for publication November
5 29th, 2018. Accepted March 16th, 2019.".

6 What I'd like to do is move through page 416 of
7 this document, which I think is about seven pages down,
8 and in the bottom right it will say, analytical
9 validation. There we go. I think that's it. My
10 question is based on this first sentence contained in
11 this treatise, where it states that, None of the
12 currently existing bioanalytical validation guidelines
13 have been set up for dried blood sample-based methods."
14 Dr. Jones, would you agree with that statement or
15 disagree with that statement?

16 A. I would disagree with that statement.

17 Q. Okay. If you could move down to page 417.
18 Now, I'm going to ask a question based on table 1,
19 which is titled Overview of the Analytical Validation
20 Parameters That Require Additional Evaluation in Dried
21 Blood Spot-Based Methods and How to Assess Them. Would
22 you agree with me, Dr. Jones -- well, actually let me
23 pause and let you read that table and let me know when
24 you've completed reading that table.

25 A. I'm familiar with this document so you can go

1 ahead.

2 Q. Okay. How are you familiar with this
3 document?

4 A. Based on your subpoena, some of the
5 terminology that you were using that I replied back
6 saying was irrelevant, I figured you were getting it
7 from somewhere and so I started looking and I found
8 this and I read it. Now, I see where your questions
9 came from.

10 Q. Okay. And would you agree with me in terms
11 of the validation parameters listed on the left column
12 going down, that USDTL has not completed validation
13 studies in the areas listed here?

14 A. I do not agree with your statement.

15 Q. Okay. Very good. Now I'm going to ask you,
16 you mentioned laboratories -- there are other
17 laboratories in the United States conducting PEth
18 testing. Could you list them again for us?

19 A. The ones that I know about are MedTox in
20 Minneapolis, which is a LabCorp facility, and you have
21 DRUGSCAN outside of Philadelphia, and coming online
22 like right about now is Associated Regional University
23 of Pathologists, ARUP in Salt Lake City and Clinical
24 Reference Laboratories down in Lenexa, Kansas, I
25 believe they are, and then the University of Texas

1 Medical Branch.

2 Q. And how about Quest Diagnostics?

3 A. I'm not aware if they are doing PEth or not.

4 Q. Okay. And you actually answered what I was
5 looking for, so the MedTox operation in Minnesota is
6 effectively a subsidiary of LabCorp?

7 A. Yes.

8 Q. Okay. From the organizations or the
9 laboratories you identified which, if any, is doing DBS
10 PEth testing?

11 A. University of Texas.

12 Q. Any other?

13 A. CRL is working on it, but I can't confirm
14 that.

15 Q. Do you have any -- I'm sorry, I didn't mean
16 to cut you off. Were you still answering that
17 question?

18 A. I was just defining CRL, Clinical Reference
19 Laboratories.

20 Q. Okay. Do you have any reason to challenge
21 the testing practices or proficiency of any of those
22 laboratories?

23 A. No. Well, yeah. Yeah, I do. A couple of
24 them, yes.

25 Q. Which ones?

1 A. The MedTox laboratory accepts whole blood in
2 purple top tubes and that should not be. They should
3 be collected in the gray top tubes.

4 Q. Okay. Any other objection to the LabCorp
5 processing?

6 A. Yeah. And them and DRUGSCAN do not calibrate
7 at the cutoff. They calibrate it -- at least the data
8 I've seen -- it's been time since I've seen this, but
9 they calibrate at like 100 and then report down to
10 their limit of detection or limit of quantitation, and
11 I disagree with that on doing that for a routine assay
12 offered out to the public. I think -- it's my opinion
13 that you should calibrate at the cutoff and you should
14 demonstrate a limited detection and the limit of
15 quantitations sufficiently lowered from that cutoff.

16 Q. Is what --

17 A. -- at the bottom of the barrel every day that
18 you've got a lot of comfort room between what you can
19 detect and what you report.

20 Q. Okay. I want to make sure that -- the court
21 reporter, did you get all that?

22 THE REPORTER: The last question. I'll need you to
23 repeat that.

24 MR. SEHAM: Okay.

25 THE REPORTER: Not the entire last question. Just

1 that part where you spoke during his answer.

2 MR. SEHAM: Oh, yeah and I didn't mean to. That
3 was an advert -- I'll come back to that question, but I
4 just want to make sure that you got the doctor's
5 answer.

6 THE REPORTER: Yes, the doctors answer is audible.

7 MR. SEHAM: Okay. Very good. Thank you.

8 BY MR. SEHAM:

9 Q. These -- the MedTox and other laboratory
10 processes that you find fault with, are these part of
11 an LDT or Laboratory Developed Test?

12 A. Yes.

13 Q. And they would have been reviewed by CLIA as
14 well?

15 A. The data would have been made available to
16 them. Whether or not that specific assay was reviewed,
17 I do not know.

18 Q. Okay. In your view, there are other
19 laboratories getting through the CLIA process that
20 perhaps should not be getting through the CLIA process?

21 A. Well, no, I disagree with that statement.
22 What they're doing is allowed. You asked me, did I
23 disagree with it, and that's not the way I run my
24 laboratory and so in my laboratory we choose to
25 calibrate at the cutoff. There are many laboratories

1 and it's completely allowable that do what I've
2 described. It's just that, I personally disagree with
3 them.

4 Q. Okay. Why do you disagree with them?

5 A. Because I feel like -- that you need to have
6 a little comfort between the cutoff that I'm telling my
7 client so that I can come in, day in and day out and
8 get that cutoff every day. That I believe that there
9 needs to be some room between there and my limit of
10 protection so that if I'm challenged 11 months later, I
11 still have room to give in case there was decomposition
12 of the sample. And then number two, on the purple top
13 tubes, well, that was a -- earlier on, that was an
14 acceptable tray. We found out that PEth can still form
15 in transit, and it also decomposes, the -- the gray top
16 totally shuts that down, so that's why we -- as soon as
17 that literature became available, we went to the gray
18 top tube exclusively, and we've done that ever since.

19 Q. When did that information become available
20 about the difference between the tops and the
21 decomposition?

22 A. That information became available sometime
23 between 2013 and 2016.

24 Q. Why are you giving that range? You don't
25 remember specifically?

1 A. I don't remember specifically, but it was at
2 some point during that time period.

3 (Union Exhibit 2 marked for identification)

4 Q. Emily, would you please put Union Exhibit 2
5 up on the screen? And yeah. Scroll down a little bit
6 if you would. Okay. Now, That's perfect, Emily.
7 Thank you. Dr. Jones, I'm going to draw your
8 attention to the, I guess, two paragraphs that start
9 with the words PEth levels. That PEth levels -- 'PEth
10 levels in excess of 20 nanograms per milliliter are
11 considered evidence of moderate to heavy ethanol
12 consumption. However, alternative explanations should
13 be explored following any positive finding. Please
14 note that while PEth is considered relatively
15 insensitive to incidental ethanol exposures, the
16 possibility remains that an individual elevated PEth
17 level may result from incidental or unintentional
18 ethanol exposure.' I'll stop the quote there. But Dr.
19 Jones, do you disagree with this statement?

20 A. I disagree with the statement in that I'm not
21 aware of any literature that says that incidental or
22 unintentional exposure to ethanol, can produce a
23 positive PEth in blood. Maybe they have access to a
24 journal article I've not read before, but I've never
25 seen that.

1 Q. Okay. Very good. LabCorp is certified under
2 the NLC program, correct?

3 A. Not this test.

4 Q. Not for this stuff. Very good. So --

5 A. -- this is -- test is performed in a whole
6 different building.

7 Q. Okay. If we could move to Union Exhibit 3.
8 Okay. I'm providing you with Union Exhibit 3 that
9 references a USDTL report based on a blood specimen
10 collected on February 13th, 2018, 2/13/218. Do you
11 recognize this document as reflecting the reporting
12 format used by USDTL?

13 A. Yes.

14 MR. KASSIN: Before you answer any further, we're
15 going to object to Union Exhibit 3. I mean, not only
16 is there a relevancy issue, but there's no
17 authentication or foundations to the accuracy or
18 reliability of whatever sample was discussed here. I
19 mean, the names are blacked out, the Social Security
20 information's blacked out. We have no idea under what
21 circumstances the testing was taken. I mean, this
22 lacks any foundation to give it any basis to even being
23 suggested for evidence and should not be considered by
24 the board.

25 MR. SEHAM: I'd like to respond to that, Arbitrator

1 Burdette.

2 THE ARBITRATOR: Please.

3 MR. SEHAM: At this point, we aren't not moving for
4 its admission. However, we will have the individual
5 for whom this test was reported and who received this
6 directly from USDTL. That individual will come and
7 testify. And we would prefer not to go through a
8 process of having that individual testify and then
9 recall this witness.

10 THE ARBITRATOR: Okay.

11 MR. KASSIN: Wait a minute. But you can't put in
12 front of a witness something that has not already been
13 established in evidence and start cross-examining them
14 about that. I mean, there's a due fairness issue
15 involved and Mr. Seham has just as much acknowledged
16 that with his last statement. I mean, this is just
17 totally inappropriate to be referring to this without
18 any appropriate foundation or validation as to the
19 credibility of what all is involved in this. And so
20 you can't cross-examine over something that's not
21 properly in evidence.

22 MR. SEHAM: Yes, you can and if I could respond to
23 that, this is an individual who's being submitted to
24 the board as a -- or offered to the board as an expert
25 witness. What these documents are doing, are just

1 illustrating a hypothetical situation. They're setting
2 forth specific quantitation numbers and then pursuing
3 questions about what conclusions should be reached
4 based on the data that's being provided.

5 MR. KASSIN: Mr. Seham now --

6 MR. SEHAM: They're questions.

7 MR. KASSIN: -- this is all speculative.

8 MR. SEHAM: No, it's not -- not speculative. And
9 in fact, even if it were, that would not be a problem.
10 This is in aid of hypothetical questions that are
11 appropriate to put to this witness. Document in terms
12 of its authenticity, will be confirmed by a witness.
13 But in the meantime, what the questions go to is
14 testing this individual as an expert witness and what
15 conclusions can be drawn by hypothetical facts. And as
16 a practical matter, unless we're engaging in
17 obfuscation here and try again, trying to drag this out
18 to a sixth-day hearing. Then delaying this and not
19 allowing us to proceed based on hypotheticals and
20 submitting this to the expert witness is that we'll
21 just merely have to recall him another day and there's
22 no point to that. We're submitting that yes, these
23 will be authenticated and we want the expert witness
24 here, the director of the laboratory, to comment on the
25 data, and that we will authenticate these documents.

1 But in the meantime, these are important hypothetical
2 issues that go to the reliability of his testimony, go
3 to his knowledge as an expert.

4 THE ARBITRATOR: Okay. Let me --

5 MR. KASSIN: -- he's not been -- wait a minute.

6 Mr. Burdette --

7 THE ARBITRATOR: -- yes.

8 MR. KASSIN: This is important. Dr. Jones is here
9 to support the result of the test that was submitted by
10 Mr. Danford on May 9, 2018. He has not been tendered
11 as an expert. A matter of fact, in an earlier
12 pre-hearing discussions with Mr. Seham and you, it was
13 clear that he has not been identified by the company as
14 an expert. Matter of fact, as the chief operating
15 officer laboratories sponsored this, he's not
16 testifying as an expert, nor do I believe that he can
17 testify as an expert. He's knowledgeable. He has
18 experience, but he's here just strictly on behalf -- to
19 put into evidence to make sure the board understands
20 what was in that litigation package on the May 9th
21 dried blood spot. If Mr. Seham wants to bring another
22 expert, I mean, he's only identified to us one expert
23 that he's calling a Dr. Padel or Fidel. Tordella.
24 Sorry. I mean, that's the only expert that we know of.
25 So Dr. Jones is not here as an expert and is not

1 subject to hypothetical questions. He can be
2 questioned all he wants over his litigation package,
3 but not on some hypothetical. He's not here as an
4 expert. I'm sorry.

5 MR. SEHAM: Now then I'm sorry too because then all
6 of his testimony should be thrown out. He testified at
7 great length based on a slideshow concerning his
8 laboratory developed test, a home brew, and why that it
9 should be relied upon as evidence of non abstinence.
10 There is a slideshow we went through with chemical
11 illustrations and testimony elicited specifically to
12 substantiate the point that this very rarefied home
13 brewed testing process should be relied upon as
14 indicating abstinence. That's not expert testimony, I
15 don't know what is. I think it's very interesting that
16 the Delta Airlines is denying his expert status, but I
17 think that's specious. And clearly, the submission of
18 the CV, the testimony elicited is all based on
19 establishing that this is a forensically reliable
20 toxicological test. And we would be denied the ability
21 to challenge the real liability of that testing and
22 provide evidence that there are in fact false positives
23 and unreliable test results if we're not allowed to
24 proceed.

25 MR. KASSIN: I can respond more, Mr. Burdette, if

1 you'll let me.

2 THE ARBITRATOR: Okay. Go ahead.

3 MR. KASSIN: Okay. Dr. Jones is here to show the
4 accuracy and the reliability of the testing that was
5 used and the results that came of it with Mr. Danford,
6 which were being challenged by Mr. Seham on behalf of
7 Mr. Danford. And his credentials and the process that
8 he used were important foundation questions in order to
9 properly submit into evidence the litigation package
10 that was done for the dried bloods by taken on May
11 9,2018.

12 THE ARBITRATOR: All right. Okay. Mr. Seham,
13 could you just clarify for me what -- I'm a little
14 confused as to what you're intending to elicit from
15 this witness with respect to this document?

16 MR. SEHAM: Well, it's very confusing unless I'm
17 allowed to ask the questions and present all the
18 evidence. But what the evidence ultimately will prove
19 is that individuals were sent test results that are
20 inconsistent with USDTL's representations concerning
21 accuracy and proficiency.

22 THE ARBITRATOR: Okay. But can you not get at that
23 through this witness when you put this witness on?

24 MR. SEHAM: I would have lost the opportunity to at
25 that point, to be able to cross-examine this individual

1 and impeach that his credibility and impeach the
2 credibility of the laboratory testing process.

3 THE ARBITRATOR: Okay. Well, ultimately that's the
4 purpose of the system board, is to determine the
5 credibility of the witnesses as they're presented. So
6 I mean, I think if you're going to introduce the person
7 who can testify to this document, I think that we
8 should be able to make a determination at that point as
9 to whether or not there are any credibility issues with
10 respect to it.

11 MR. SEHAM: But that's a credibility issue
12 concerning the tested individual. It doesn't go to the
13 credibility of this witness. I mean, that there are
14 going to be situations here where we have exhibits with
15 names on them, different results on the same day. And
16 I would like to ask this witness, how would you account
17 for these distinct results to see if this witness can
18 provide an answer to that.

19 THE ARBITRATOR: Okay. Can you -- can you not ask
20 him that without -- without introducing this document?
21 Can you not just pose that question to him of how you
22 would deal with inconsistent results on the same day?

23 MR. SEHAM: I think it would be extremely awkward.
24 I mean, if I am conceding that these documents are
25 submitted at this point to establish a hypothetical and

1 moving for their admission will be delayed until that
2 witness appears, to try to recreate the hypothetical in
3 my head without the use of these documents, it will be
4 paralyzed.

5 MR. KASSIN: I'm sorry. Go ahead, Mr. Seham. I'm
6 sorry.

7 MR. SEHAM: No. It sounds like Arbitrator Burdette
8 is asking you to look at the documents, not show them,
9 and recreate data in the way of a question, and I could
10 do that. It would just, I think, perhaps, I could do
11 that, would be paralyzing really slow. And I would not
12 illustrate the point in an effective way, the way we
13 mean to. And is an unnecessary circumvention or a
14 certain locution given the fact that we undertake to
15 provide confirmation of these documents' authenticity.

16 THE ARBITRATOR: Yeah. I mean --

17 MR. KASSIN: Mr. Burdette, you need to know that
18 this is the first of many documents that have not been
19 authenticated. May not be able to be authenticated,
20 are very questionable in terms of their legitimacy.
21 And there's just a whole series of these that are
22 coming along that have no foundation. And this is just
23 the first of them. So I think -- we are objecting to
24 every single one of these that have either no names
25 associated with them or questionable -- on their face

1 are questionable in terms of their credibility. So I
2 think if it's not in evidence appropriately, then this
3 is not fair for Dr. Jones to have to be questioned
4 about it.

5 THE ARBITRATOR: All right. I'm going to sustain
6 Mr. Kassin's objection because of the principle that
7 you can't unsee something that you're seeing or you
8 can't unthink about something that's been presented
9 even if you're instructed to ignore it later. So let's
10 move on from this point in time.

11 BY MR. SEHAM:

12 Q. I will limp ahead the best I can with this
13 objection because I believe this very much undercuts
14 our ability to cross examine the witness. Having said
15 that, USDTL's -- Dr. Jones, USDTL's FAQ defines the
16 half-life for PEth quantitative results as being
17 approximately 4.5 days, correct?

18 A. Correct.

19 Q. The meaning of the half-life concept is that
20 every approximately 4.5 days the PEth quantitative
21 level should be cut in half; is that correct?

22 A. On average, yes.

23 Q. An individual has a quantitative result of 59
24 nanograms per milliliter on a USDTL-DBS PEth test. How
25 many days on average would it take for that individual

1 to obtain a negative?

2 A. On average, about four to seven days.

3 Q. At USDTL do you have any system in place to
4 cross-check tests from the same individual that provide
5 quantitative results that are not consistent with
6 half-life expectations?

7 A. Can you repeat that question? I don't quite
8 understand it.

9 Q. Do you have any system in place at USDTL, a
10 standard in your SOP that provides that if an
11 individual has successive quantitative results at USDTL
12 that don't conform to the expected half-life, that that
13 would trigger an internal review?

14 A. No. Each specimen that comes in is treated
15 independent of any other specimens, either from the
16 same person or any other persons.

17 Q. Do you have any system in place at USDTL
18 incorporated in the SOP or otherwise, to conduct an
19 internal review where samples received for the same
20 person collected on the same day produced both a
21 positive and a negative? Two separate samples.

22 A. No. They're both treated as independent
23 specimens.

24 Q. If we could get UX-21. Dr. Jones, can you
25 identify this document?

1 A. Yes. This is a marketing document that we
2 distribute from our -- our sales department.

3 Q. Okay. If you look at, there's a series of
4 plus signs and maybe we can, Emily, if we can make it
5 just a tad bigger. There's a reference here to
6 Specimen Stability Card Binds Blood Cells, Preventing
7 Changes to PEth levels.

8 A. Yes.

9 Q. Can you explain that?

10 A. Yeah. As I mentioned before with the Whatman
11 903 specimen paper, the guanidinium salts on that paper
12 are key to the effectiveness of using that for
13 collecting of dried blood spots. So once the cells are
14 captured on the paper, the guanidinium salts slices
15 opens to cells and all of the components are then fixed
16 to the paper, and so by fixing the components, there's
17 a couple of things that are like permanent to doing
18 blood testing and that the blood-borne pathogens like
19 HIV, HCV, and all of those are fixed to the salt and
20 it's not infectious anymore. So that's important. And
21 then number two, the enzyme that creates or destroys
22 PEth, is fixed to the paper as well. So it's unable to
23 do its formation or decomposition of PEth.

24 Q. Okay. But for the answer -- well, I guess
25 I'm not quite clear on is -- is -- does the

1 quantitative value in the sample change over time?

2 A. Yes.

3 Q. It does?

4 A. Yes.

5 Q. So specimen stability does not mean there
6 would not be a change in the quantitative result if you
7 tested it several times over a period of time?

8 A. Yes, specimen stability does not mean zero
9 percent.

10 Q. Okay.

11 A. It means that it has an acceptable level of
12 stability, and that's the subjective thing. The whole
13 blood, for some blood the stability, it drops 90
14 percent over a course of period of time. We don't see
15 that with blood spots, so we do see maybe a 10 or 15
16 percent drop, but not the big precipitous drops like
17 you see with the whole blood. In some of them -- in
18 some -- in some whole blood, you come back and you get
19 the same thing a year later so there's a lot of
20 inter-individual variables.

21 Q. Whole blood, you mean blood that's extracted
22 by a phlebotomist, correct?

23 A. Exactly. Yes.

24 Q. Okay. And so I want to focus just so I
25 understand on DBS. DBS, you're saying would be at 10

1 to 15 percent drop in quantitative level?

2 A. Some of the literature that you see that sort
3 of depending on the storage conditions, this is sort of
4 in the ballpark of what you see over various periods of
5 time.

6 Q. Well, I'm referring to the storage conditions
7 that would prevail at USDTL.

8 A. Yeah. So I would expect that on average,
9 there would be 10 to 15 percent drop in quantitation
10 over about a year's period of time.

11 Q. Okay. And is it a similar concept when
12 there's a reference by USDTL to a PEth specimen
13 maintaining its integrity?

14 A. Say that again, please?

15 Q. What does it mean when USDTL refers to a
16 specimen maintaining its integrity?

17 A. Where do you see that at so I can get the
18 context?

19 Q. Let's see if it's on this document. Was that
20 not an expression you're familiar with t, he specimen
21 integrity?

22 A. It can mean different things under different
23 contexts. So if I could see the context of what you're
24 referring to.

25 (Union Exhibit 19 marked for identification)

1 Q. Let me see if I can get that for you. Emily,
2 if you could bring up Union Exhibit 19. And if you
3 could make that a little bit bigger. I would want to
4 move down to the ninth page of this document. First of
5 all -- actually, I'm sorry. Let's go to the first
6 page. Would you recognize this, Dr. Jones, as the FAQ
7 from USDTL's website?

8 A. It looks familiar, yes.

9 Q. Okay. Now, Emily, I'm sorry, we can move
10 down to page 9. Is that page 9? I would like to focus
11 on the top of the page. So this may provide some
12 context for you and perhaps, confirms what you said
13 before. I'm referring to the first bullet point which
14 reads, "'What is the length of time PEth dried blood
15 spot specimens can be stored while still maintaining
16 their integrity? '" And it says, "Room temperature,
17 one-year. Refrigerated, one-year. Frozen, one-year at
18 20 -- actually, if you could explain the rest of that
19 bullet point because it's symbols I don't recognize.
20 But it indicates the --

21 A. You've got a -- a formatting printer problem
22 with, like, the negative 20 degrees. So the -- it just
23 -- it was a print issue when you printed this out. So
24 what we're saying there -- and -- and we say this in a
25 couple of different places and a couple of different

1 ways, and -- and -- and you have to keep in mind that
2 we are -- we are educating a non-technical clientele in
3 some very technical things so you have to say things
4 maybe a couple of different ways. So when I'm talking
5 to the medical director of a state physician health
6 program, I'm kind of going to use one language that he
7 uses and when I'm talking to the -- the shift manager
8 at a local franchise of a collection facility, we have
9 to kind of use another language and meet people where
10 they're at. And so this question here is, like, so
11 what's the length of time this -- the PEth still
12 maintains its integrity, which means, can we go back
13 and retest it and still find the compound?

14 And so this is a standard set of -- of elements,
15 experiments and the validation required by CLIA and CAP
16 in New York and ISO and all of them. And -- and one of
17 the things that we're looking for is, how long can it
18 be stored at room temperature? How long can it be
19 stored in a standard refrigerator? And how long can it
20 be stored in a freezer? And so those experiments have
21 been done and what we've demonstrated is that at room
22 temperature and in the refrigerator and frozen, we can
23 pull a sample that's a year old and it will reconfirm
24 and so this is what we mean by the integrity. There
25 are tests out there, outside of a drug test -- well,

1 maybe LSD and psilocybin, but I -- I don't have much
2 experience with them. But there are tests out there
3 that, like, three weeks later it's gone and so we've
4 got the opportunity and then it's done. The tests that
5 we do, by and large, do have some pretty good room as
6 far as -- as the maintaining the integrity for the
7 ability for retest. So that's kind of what that's
8 getting at. And that frozen at one year is negative
9 20, that's the standard by freezer.

10 Q. So here is integrity used in a manner that's
11 synonymous with our references to stability before?

12 A. Yes.

13 Q. Okay.

14 A. Yes.

15 (Union Exhibit 7 marked for identification)

16 Q. Now, if we could turn to Union Exhibit 7.
17 Emily, if you could maybe increase the size a little
18 bit. Okay, we may have to -- let me --

19 MR. KASSIN: This is another one of those
20 objections. We just went through this again earlier.
21 It's the same sort of documentation. There's no
22 authentication for it, there's no foundation for it.
23 And it's not appropriate for Dr. Jones to be questioned
24 about it. I mean, this just has no credibility, it has
25 no authentication. We don't know what it is.

1 MR. SEHAM: Well, this could be -- well, first of
2 all, this is a different situation because the
3 objection before was based on the redaction of the
4 name. Here we have the name, we have the lab sample
5 ID, we have the specimen ID, which matches between
6 these two. And here it's more glaring that Delta is
7 engaging in a game of obfuscation because there would
8 be nothing easier than for USDTL to produce these
9 documents from its own files. So I would like to
10 proceed given that we have specimen ID, we have the
11 name of the individual. And USDTL could easily
12 authenticate this themselves. But in any case, we will
13 have a witness who will authenticate. I would like to
14 proceed with these questions.

15 THE ARBITRATOR: Okay. Well --

16 MR. KASSIN: Let's have this authenticated, first
17 of all. And it's a due fairness issued -- a due
18 process issue to do this properly. I mean, this is
19 just not appropriate.

20 MR. SEHAM: Is the suggestion that the union and/or
21 the grievant have fabricated these documents? Is that
22 what's being suggested? We in good faith, bring these
23 documents of this laboratory using a home brew test and
24 ask them that, how would these results obtain and what
25 internal checks do they have under the circumstances?

1 THE ARBITRATOR: Okay. Can you just ask Dr. Jones
2 if he can authenticate these documents as having been
3 coming from USDTL.

4 Q. Well, let me ask a few questions and see if
5 it gets the arbitrator to where he needs to be. So
6 would you recognize this format that we're seeing in
7 these two documents as standard USDTL test result
8 reporting format?

9 A. There's a couple of items that look
10 questionable here to me. One of the things that we run
11 into is photo shopping of reports. And so I would -- I
12 would need to have some time to go to my computer
13 system and call this up and -- and make sure that this
14 has not been adulterated.

15 MR. SEHAM: Well, I would ask that the -- that the
16 witness take those steps.

17 THE WITNESS: I would need to log of this hearing
18 and log in and come back.

19 THE ARBITRATOR: Okay.

20 MR. KASSIN: And additionally, Mr. Arbitrator, he
21 said he has a witness to authenticate this. This is
22 something not in evidence and not properly before the
23 board. You just -- it's not appropriate to do it. And
24 while I'm objecting -- I object to some of these
25 inappropriate characterizations that are going on from

1 Mr. Seham, this is not a home brew. It's properly a
2 laboratory developed test. We talked about a
3 laboratory developed test. I don't think the
4 characterization -- I know it doesn't affect the
5 arbitrator, board members, but it's just not
6 appropriate. We don't need that approach or
7 collegiality in this hearing. That's not the way we do
8 things at Delta Airlines and LPA.

9 MR. SEHAM: There is in fact treatise material that
10 uses that term. That's not a term that I came up with.
11 That something that I'm borrowing from the treatises
12 that I have read. If it hurts the sensibilities of
13 Delta, then I'll try to use a different term.

14 THE ARBITRATOR: Okay. So Mr. Kassin, do you have
15 an objection to taking a break while Dr. Jones attempts
16 to authenticate these documents?

17 MR. KASSIN: No, sir.

18 THE ARBITRATOR: Okay. So Emily, that's not going
19 to cause a problem with him getting back in, is it?
20 Emily, you're muted. Dr. Jones, can you give us an
21 estimate as to how long it might take you to do this?

22 THE WITNESS: Maybe 10 minutes.

23 THE ARBITRATOR: Okay.

24 THE WITNESS: I'll need to write down a couple of
25 numbers first, please.

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1 THE ARBITRATOR: Sure, that's fine. Go ahead.

2 THE WITNESS: Okay.

3 THE ARBITRATOR: Okay. Emily, can you unmute? Are
4 you there?

5 THE REPORTER: Yeah, it's all right. You'll be
6 able to join easily using the same link. Well, we'll
7 be able to right back in.

8 THE ARBITRATOR: Thank you. Okay. All right. In
9 the meantime, could you put me and Mr. Seham and Mr.
10 Kassin into a breakout room, please?

11 THE REPORTER: Yes. Hold on one moment.

12 THE WITNESS: So I'm -- I'm stepping out.

13 THE ARBITRATOR: Okay. Thank you. You can come
14 back in. Okay.

15 THE REPORTER: If Emily is there, Arbitrator
16 Burdette asked that -- that Arbitrator Burdette and the
17 individual referred to as Howard Taylor and Lee Seham
18 be placed in a breakout.

19 REMOTE TECH: Yes. I apologize I couldn't unmute
20 myself. I'm doing so right now.

21 THE ARBITRATOR: Thank you.

22 MR. SEHAM: And if Rachel Samuda could also be
23 included. Would that --

24 THE ARBITRATOR: That's fine.

25 MR. KASSIN: And Chris Puckett.

1 THE ARBITRATOR: Yes, that's good too. He's listed
2 as Chris B. I don't see -- Rachel's not here yet. And
3 I still have Mr. Pickett who should not be come here
4 with us, Emily.

5 MR. KASSIN: I'm not sure who George Ellis is.

6 THE ARBITRATOR: That is ZM, but -- oh, wait. Here
7 we go. We're not -- all right. We're not in the
8 breakout room yet. No problem.

9 MR. SEHAM: I get -- I'm getting -- I joined now.
10 I can -- I guess I click on that.

11 THE REPORTER: Yes. If you could, then you'll head
12 to the breakout.

13 (OFF THE RECORD)

14 THE REPORTER: Back on the record at 3:13 p.m.

15 THE ARBITRATOR: Okay. Back on the record. We had
16 a sidebar discussion with the counsel, and I think Mr.
17 Kassin would like to make a statement on the record as
18 to the purpose of calling Dr. Jones.

19 MR. KASSIN: I'll start there. As we've said all
20 along in this case, and we said in the earlier two
21 phone calls with Mr. Seham, our whole purpose in
22 calling Dr. Jones was he's the chief operating officer
23 of US Drug Testing Laboratory, and for him to sponsor
24 and validate the company exhibit on the litigation
25 package of USDTL. We believed it was appropriate to

1 present the direct testimony that we did as
2 foundational information for that document, so that the
3 document would make sense to the arbitrator and board
4 members, as well as the other participants in this
5 phone call. And so his purpose in being here is to
6 sponsor that document and explain the USDTL laboratory
7 developed test on PEth testing, so that the board, in
8 reviewing it, will have confidence in finding that the
9 results were accurate -- true and accurate, and
10 appropriate.

11 THE ARBITRATOR: Thank you. Mr. Seham, you're
12 muted.

13 MR. SEHAM: Thank you. I -- I believe it was on
14 the record before, but it was -- it was stated during
15 our caucus between the counsel and both parties and the
16 arbitrator, that based on the representation of Delta,
17 that Dr. Jones is not being offered as an expert
18 witness in this proceeding, that we will curtail our
19 questioning with respect to the next several exhibits,
20 and defer that until we have our own witness.

21 THE ARBITRATOR: Okay. Okay. And then, you're
22 still in -- you're still cross-examining Dr. Jones, Mr.
23 Seham?

24 BY MR. SEHAM:

25 Q. Correct. Correct. Dr. Jones, were you able

1 to validate those documents?

2 A. Yes.

3 Q. All right. Nevertheless, in the interest of
4 an expedited proceeding, I will move forward with -- I
5 will skip over the line of questions that I have. Few
6 questions about validation paper. The validation of
7 the paper that was used or the card that was used.
8 Would you agree with me that the paper used for the DBS
9 collection must be carefully chosen?

10 A. Yes.

11 Q. And the type of paper may affect the
12 occurrence of interferences?

13 A. Yes.

14 Q. And that type of paper might actually affect
15 the blood's spreading behavior?

16 A. Yes.

17 Q. And the type of paper might affect sample
18 homogeneity, correct?

19 A. Yes.

20 Q. Would you agree that it's essential to
21 evaluate DBS homogeneity in order to assess whether
22 results from central punches are equivalent to
23 peripheral punches?

24 A. No.

25 Q. No, you don't agree. And that the paper

1 should be analyzed in order to -- or validated on order
2 to confirm that it provides for analyte stability and
3 recovery?

4 A. Could you repeat that question, please?

5 Q. The use of that paper must be valid -- there
6 must be a validation study confirming that the paper
7 provides for analyte stability and recovery?

8 A. Yes.

9 Q. Okay. And you conducted a validation study
10 indicating that the -- in terms of stability, that
11 quantitative result within 10 or 15 percent could be
12 recovered after the passing of a year, correct?

13 A. Yes.

14 Q. Okay. And what was your filter paper source?

15 A. Was Whatman 903 paper.

16 Q. Okay. Who was the manufacturer?

17 A. GE is the current owner of that patent.

18 Q. It's considered -- when it comes in the
19 boxes, is the manufacturing referenced to GE or some
20 other --

21 A. When -- GE then goes out, the distributor
22 ships to other vendors. But the paper itself will be
23 stamped with the 903 logo. And it would be stamped
24 with the IVD logo saying that FDA it's been cleared for
25 blood spot collections.

1 Q. Okay. And what denaturing agents is it pre
2 treated with?

3 A. Guanidinium salts.

4 Q. Okay. And the enzyme inhibitors, do you know
5 what they are?

6 A. It's guanidinium salts

7 Q. Okay. That's the same. Okay. Any use of
8 Chitosan C-H-I-T-O-S-A-N or alginate A-L-G-I N-A-T-E
9 foams?

10 A. You would need to get like a expert on the
11 paper construction. What I know about the paper is
12 that it's a reputable paper that has been used for 50
13 years for the collection of dried blood spots. The FDA
14 has specifically cleared that -- that paper, there's a
15 couple of others now. They specifically cleared that
16 paper for the collection of dried blood spots for
17 analysis. And so when we were choosing what to use
18 there were other options, but we chose what we felt was
19 the best, and that was what we validated our assay
20 with. Other groups internationally have chosen the
21 same paper as well.

22 Q. And they've chosen the same paper. Has that
23 been for alcohol testing or some other testing? Do you
24 know?

25 A. All kinds of testing including PEth.

1 Q. Now I think we -- just to put this in
2 context, so USDTL set forth, its own specimen
3 collection protocols, correct?

4 A. Yes.

5 Q. And have they changed -- well, let me ask
6 this first. How long has USDTL had been conducting DBS
7 alcohol testing?

8 A. Roughly seven years or so.

9 Q. And have the specimen protocols been changed
10 within that period of seven years?

11 A. The content no, but like the format has been
12 updated, you know colors, some pictures and describing
13 things as I mentioned before. Well, this would be
14 something that you wouldn't know, but, you know when
15 you start with a new assay like this, one of your
16 earlier doctors will be university professors that are
17 funded by the National Institutes of Health. So when
18 you're writing collection instructions, you're going to
19 use kind of the language that they're expecting it to
20 get. But when you start moving that kind of a test
21 into the general public, you have to like be cognizant
22 of the language that you use and how you use pictures
23 and maybe do slides or maybe the video. And so with
24 that it has -- it has changed over time as we -- as we
25 try to make the language more effective and -- and

1 communicate the instructions better.

2 Q. But the substantive content has not --

3 A. The substantive part has not changed
4 substantively. No.

5 (Union Exhibit 11 marked for identification)

6 Q. If you could bring up Union Exhibit 11,
7 please, and then I'm going to stand up for 30 seconds
8 because I think I'm getting some reverb or something.
9 I'll be back in 30 seconds to check what's happening
10 here. Okay. We have in front of you, Union Exhibit
11 11. Do you recognize this document?

12 A. It seems familiar, yes.

13 Q. And if you look at the first sentence? It
14 concludes -- well, let me just read the first small
15 paragraph. Dried blood --

16 A. Could you enlarge it just a little bit?

17 Q. Yes, that would be great. It's for the idea.
18 It states here that, "Dried blood spot collection is a
19 donor performed collection. In some cases it may be
20 beneficial for the collector to assist the donor or
21 perform the collection completely. In either case, it
22 is imperative to follow the steps carefully in order to
23 ensure a proper specimen collection." I believe you
24 testified before, but just to confirm, you would agree
25 that compliance with the protocols is imperative in

1 terms of the testing process?

2 A. It would be best practice, yes.

3 Q. Why is adherence to these collection
4 protocols imperative?

5 A. Well, so that we get an adequate sample for
6 testing.

7 Q. Well, how about step 5? Step 5, if we can
8 move down to step 5. Okay. "Wipe the finger with an
9 isopropyl alcohol pad. Caution: do not use an
10 ethanol-based alcohol pad." Now what's in bold there,
11 "Caution: do not use an ethanol-based alcohol pad,"
12 that doesn't address the issue of adequacy of specimen,
13 correct?

14 A. Correct.

15 Q. That addresses the issue of the potential
16 interference with a quantitative result of the test,
17 correct?

18 A. No.

19 Q. Why would you not want someone to use an
20 ethanol-based alcohol pad?

21 A. Because we have -- in our validation, we have
22 evaluated the PEth's blood spot cards to see if you
23 place ethanol on the card itself after the blood has
24 been collected, if you add the ethanol to the blood
25 just before it's collected, or if you just expose the

1 blood spot that's been collected to, ethanol vapors
2 like in a closed bell jar. And so the results of those
3 experiments was that, when it's on the blood card, it
4 will not form PEth. However, in an abundance of
5 caution and to eliminate 1,500 phone calls a month, of,
6 hey, I used the ethanol wipe to collect the sample, is
7 that why it was positive and we go no, we just take
8 that red herring out at the very beginning and say,
9 don't use ethanol based anything on the collection.

10 Even though we have no data to show that it
11 produces PEth, we do it so the insincere disputers
12 don't use that to waste everyone's time claiming it
13 must have been the ethanol-based wipe pads. So just
14 take it out, use isopropanol and then it's not an
15 issue. So the question that you asked was -- the
16 answer is no. It's there for a logistics reason of
17 preventing thousands of phone calls.

18 Q. Okay. And when did you conduct the study?

19 A. Back when we first began in the 2011, 2013,
20 when we were executing the National Institutes of
21 Health grant that we received from the National
22 Institute of Alcoholism and Alcohol Abuse.

23 Q. Did you publish that study?

24 A. Yes.

25 Q. Okay. Where would we find that study?

1 A. On the Internet.

2 Q. On the Internet, can you be more specific?

3 A. It's in the American Journal of -- of
4 Chemistry. And if you google the word
5 phosphatidylethanol, and my last name, it will come up
6 like the second or third page or so.

7 (Union Exhibit 80 marked for identification)

8 Q. Okay. Thank you. Now, if we can move to
9 Union Exhibit 80. Before we ask questions about that.
10 Are you familiar with a company by the name of DBS
11 Systems SA?

12 A. No.

13 Q. No. If we could scroll down on this document
14 a little further, please. Okay. Are you familiar with
15 this study by M. Augsburger and E. Lauer and F.
16 Spokert?

17 A. This was the non-peer reviewed poster that I
18 was talking about earlier today. And that they wash
19 their hands with pure ethanol. And they were -- and
20 they produced measurable amounts of PEth. And that was
21 when I was talking about why would anybody being
22 monitored for alcohol markers, wash their hands with
23 liquor immediately before a test. That's what this
24 poster was about. This was presented to The Society of
25 Hair Testing a couple of years ago.

1 Q. Okay. You have any reason to doubt the
2 reliability of this report?

3 A. Well, the -- the question remains as to why
4 they didn't publish it. Of course, what will solve
5 this, I contacted one of the researchers who I know
6 through the through The Society of Hair Testing and I
7 was asking him about it and they said this was one of
8 their master students and it was part of their thesis
9 and they saw the observation. The individual in
10 question here in this poster, had questionable conflict
11 of interest with regard to this, and that's why they've
12 not moved forward, at least that was what he told me.
13 With publishing this, they were considering doing a
14 larger study to see if it could be reproduced. But
15 this was the project of a master -- what I was
16 explained to, this was the project of a master student
17 that presented this at a scientific conference. This
18 is not a peer reviewed journal article.

19 Q. Okay. Could you move up the -- Emily if you
20 can move up the document just an inch or so. There we
21 go, and I'm referring, I guess the middle of the second
22 column. It says disclosure of interest, J. Deglon and
23 A. Thomas are co-founders of DBS System SA.

24 A. Yeah.

25 Q. Do you not recognize DBS System SA in this

1 context as the manufacturer of DBS Supplies?

2 A. No. I'm familiar with those names as
3 university professors over in Europe, but I'm not
4 familiar with their affiliations with any commercial
5 entities, those things kind of come and go over time.

6 Q. Now, you referenced an SOP or a Standard
7 Operating Procedure?

8 A. Yes.

9 Q. Okay. And what does an SOP cover?

10 A. A Standard Operating Procedure is an official
11 document approved by the laboratory director. That is
12 the official instructions on how to conduct any assay
13 in the laboratory.

14 Q. Does it just apply to the application of the
15 SA or does it address other issues?

16 A. It covers everything.

17 Q. So it would address the receiving and
18 handling of the sample?

19 A. Yes.

20 Q. And you're aware of the fact that the USDTL
21 refused to provide us with a copy of this document, in
22 response to the board subpoena?

23 MR. KASSIN: Objection. Mr. Burdette, USDTL, my
24 understanding has offered to allow Mr. Seham to come to
25 their laboratory and examine the standard operating

1 procedure. It is a highly confidential document that
2 they do not let leave their premise. On the other
3 hand, they did let Mr. Burdette -- I'm sorry, Mr. Seham
4 come and offered him to come in and review it and he
5 never did.

6 MR. SEHAM: Arbitrator Burdette, that is not an
7 objection, what we just heard, that was testimony. I
8 asked a question to this witness and the witness should
9 have answered it. And I would ask that counsel for
10 Delta refrain from giving testimony going forward. I
11 had a question.

12 THE ARBITRATOR: You may answer the question, Dr.
13 Jones.

14 THE WITNESS: I'm sorry. Two people are speaking
15 at once. I didn't hear.

16 BY MR. SEHAM:

17 Q. Okay. Now the question is, is it not true
18 that USDTL refused to provide our law firm with a copy
19 of its SOP?

20 A. That is correct. Our SOP's do not leave our
21 premises.

22 Q. Emily, if you could put UX-12 up on the
23 screen.

24 A. You're still welcome to come look at it if
25 you want. It's there any time you want to see it.

1 Q. Would you allow me to make a photocopy of it
2 when I get there?

3 A. No.

4 Q. I didn't think so.

5 A. No photocopies and no pictures. You can take
6 notes.

7 Q. Do you recognize what's been put on the
8 screen? And we can scroll down. Would you agree with
9 me that this is a subpoena that you received from our
10 office and that you worked with your attorney, Todd
11 Duffield, D-U--F-F-I-E-L-D, in terms of responding to
12 it?

13 A. I received the subpoena from you earlier this
14 year and this appears to be a copy of that.

15 Q. And did you work with Todd Duffield in terms
16 of providing a response?

17 A. Yes.

18 (Union Exhibit 13 marked for identification)

19 Q. If UX-13 could be put up on the screen.
20 Would you recognize this document and it can be
21 scrolled through at your direction. Maybe scroll
22 through a little bit. Would you recognize this
23 September 2nd document as a preliminary response to our
24 firm's subpoena?

25 A. There was a response that was sent back to

1 you and this looks familiar. It looks similar to that,
2 like it's a copy of it.

3 Q. Okay. And then, Emily if you could put UX-14
4 up on the screen. And would this be a supplementary
5 response? It was provided to us on September 10th,
6 2020 by Todd Duffield on behalf of USDTL.

7 A. It looks familiar, yes.

8 MR. SEHAM: If there's no objection at this point,
9 I would I would ask for a five-minute break. Just a
10 call of nature.

11 THE ARBITRATOR: Okay. We'll take a five-minute
12 break, off the record.

13 (OFF THE RECORD).

14 (Union Exhibit 12 and 14 marked for identification)

15 Q. Emily, if you could scroll down to item
16 number 3. So Emily, just to give you a heads up, we're
17 going to be shifting between 12 and 14. So bringing to
18 the witness's attention that 3 reads, "All documents
19 related to validation studies conducted by USDTL with
20 respect to the DBS collection procedures prescribed by
21 the laboratory, including any documents related to
22 incurred sample reanalysis ISR." So that was the
23 request if we could move Emily to Union Exhibit 4,
24 excuse me, 14. Move down to item 3, the response. So
25 the response reads, "A peer reviewed study that

1 evaluated reanalysis over time may be found at
2 academic.oup.com/alcalc/articles/51/3" and a lot of
3 numbers. And then it goes on to say USDTL has no other
4 documents responsive to this request. Was that an
5 accurate response to the subpoena?

6 A. Yes.

7 Q. Okay. And does the article reference there,
8 is that a study conducted by USDTL?

9 A. Yes. I believe so. I'd have to double-check
10 that.

11 (Union Exhibit 15 marked for identification)

12 MR. SEHAM: Well, if we could bring up UX-15. I
13 guess we need to scroll down to get the -- okay. So
14 this is the -- oh, thank you. Perfect.

15 THE WITNESS: Yeah.

16 Q. Stability of, I'm just going to say PEth, in
17 Dry Blood Spot Cards. Now, this is the article that
18 you're referring to in the response number 3, correct?

19 A. Yes.

20 Q. Okay. Is Ludmila Bakhireva -- is she
21 employed by USDTL?

22 A. No.

23 Q. No. Are any of the authors employed by
24 USDTL?

25 A. No.

1 Q. And the study involved 31 participants,
2 correct?

3 A. I don't recall the numbers.

4 Q. All right. The collections were all
5 performed by the same group of personnel, correct?

6 A. I don't recall the research project.

7 Q. Okay. The samples were all left to dry for
8 three hours on a flat surface, correct?

9 A. I'd have to review that document again with
10 that question in mind.

11 Q. But isn't that what the manufacturer
12 recommends?

13 A. Yes.

14 Q. Yes, it is?

15 A. For -- for new -- for newborn, yes.

16 Q. Okay. Well, was this --

17 A. These were -- these were babies.

18 Q. So the USDTL does not require its collectors
19 to dry the specimen for three hours, correct?

20 A. That is correct.

21 Q. Okay. And if you could move back to UX-12,
22 Emily. And move down, I'm sorry, move down a little
23 bit to item 8. So item 8, that we requested, "All
24 documents setting forth required applicable standards
25 for drying and storage of DBS samples at collection

1 site prior to shipment at USDTL"?

2 A. Yes.

3 Q. Okay. And if we can move to UX-14 and move
4 to the same item. A little further down. I guess
5 we're going at item 8. Okay. "Responsive documents
6 are available on USDTL's website at the link provided
7 in item 4. USDTL has no other documents responsive to
8 this request." Was that an accurate response?

9 A. Yes.

10 Q. Okay. Okay. So the instructions that USDTL
11 provide the collectors is for the immediate enclosure
12 of the DBS sample within a cardboard box, correct?

13 A. Correct.

14 Q. There's no reference to a, and you refer to
15 this as, a drying box, correct?

16 A. Correct.

17 Q. And in the article that we just looked at
18 UX-15, there's no reference to a drying box, correct?

19 A. Could you repeat that again? You're kind of
20 going quick and going back-and-forth.

21 Q. Yes. In UX-15, the article that we were just
22 looking at, by Ludmila Bakhireva, there's no reference
23 to a drying box in that study; is that correct?

24 A. No, that was newborn collections. They
25 weren't collecting -- they weren't collecting adults

1 that had to get back to work.

2 Q. I see. Okay. So there's no published study
3 concerning the use of a drying box to dry a specimen
4 prior to shipment, correct?

5 A. Correct.

6 Q. Okay.

7 A. There is no -- I'm not aware of a specific
8 study, other than some of the various research projects
9 that we've been involved with, with NIH funded
10 researchers. Any of those that have been published in
11 the past, five to seven years would have used that same
12 -- that collection procedure.

13 Q. In the study UX-15, there was no
14 transportation of those samples, correct?

15 A. Repeat your question please.

16 Q. In the study that I've been referring to
17 UX-15 by Ludmila Bakhireva --

18 A. Right.

19 Q. -- that did not involve the transportation of
20 the samples in question, correct?

21 A. Correct. They collected them and then sent
22 them in one big shipment to the lab.

23 Q. Okay.

24 A. If my memory serves me correct.

25 Q. Okay. Well, I guess in that respect, the

1 article will speak for itself. If we can go back to
2 Union Exhibit 12 again. And move down to item or move
3 up to item 4. And we asked there for, "All documents
4 related to any DBS specimen collection certification
5 program or other training conducted by USDTL for
6 collectors authorized to collect DBS samples for
7 process at USDTL laboratory." You see that request,
8 correct?

9 A. Yes.

10 Q. Okay. And then if we move to Union Exhibit
11 14, item 4, the response is, "The collection training
12 video and documents are available on USDTL's website,
13 with the link provided. USDTL has no other documents
14 responding to this request." Is that an accurate
15 response?

16 A. Yeah. Yes.

17 Q. Okay. Upon receipt of the DBS sample at
18 USDTL, could you describe the process followed to
19 access whether the DBS sample was collected in a manner
20 that complied with the procedures that USDTL has
21 described as imperative?

22 A. We review it to make sure that the tamper
23 evidence seal is still intact, and that -- that it's
24 not been tampered with from the time that the donor
25 gives it to the collector. And then from the collector

1 to the USDTL. And then when we open the specimen for
2 aliquoting, we look to see if we have an adequate
3 amount of specimen on the card. Other than that
4 there's not a whole lot that you can look for other
5 than, did you get enough sample or did you not get
6 enough sample.

7 Q. Okay. So there's no contact with the
8 specimen collector to see if he or she adhered to the
9 protocol?

10 A. Of -- of course not. Of course not.

11 Q. Okay. If you could turn to -- Emily, if you
12 could bring up --

13 A. But the collector -- the -- the -- the
14 collector does certify that they followed the
15 applicable requirements for the collection. That's
16 part of the attestation statement on the requisition
17 form.

18 (Union Exhibit 16 marked for identification)

19 MR. SEHAM: Okay. If you could please turn the
20 Union Exhibit 16. If you could turn -- I'm going to
21 ask for you to move to page 8. Let's see, if you turn
22 to page 8. If you can scroll. I'm sorry, is that page
23 8?

24 THE ARBITRATOR: It's not numbered page 8, but it
25 is the eighth page in the document.

1 MR. SEHAM: Okay. I made a plea, it may be page 7.
2 It might be the page before that. I'm looking for a
3 chain of custody doc.

4 THE ARBITRATOR: Page 7 is the initial document,
5 what he called the requisition.

6 MR. SEHAM: Whatever page this is, this is the page
7 I'm looking for.

8 THE ARBITRATOR: That's it. Okay.

9 Q. Okay. Thank you. I guess, we could scroll
10 down. Thank you. It looks like at the very bottom, if
11 you could expand where it says the laboratory
12 certifications. It reads, if I can make it out.
13 Perfect, thank you. It reads, "I certify that this
14 specimen received with this form was sealed in the
15 appropriate container with the seal intact, and the
16 identification number and/or name on this form matches
17 that on the specimen, and was transferred to a
18 temporary laboratory storage." The chain of custody
19 makes no provision for the laboratory personnel to
20 certify that the specimen was not shipped in an
21 airtight plastic specimen transport bag, correct?

22 A. Say that again, please.

23 Q. That your chain of custody document for DBS
24 in USDTL, it does not make any provision for the
25 laboratory personnel to certify that the specimen was

1 not shipped in an airtight plastic specimen transport
2 bag, correct?

3 A. Not at the receiving step, no. They're
4 looking to see if the ID's match and there's enough
5 specimen in the test.

6 Q. Okay. Well, in the event that a specimen
7 arrived in an airtight plastic bag or envelope, that
8 laboratory certification would then still be executed,
9 correct?

10 A. That's correct.

11 Q. Did you receive any documentation confirming
12 that Mr. Danford's specimen did not arrive in an
13 airtight plastic bag or container?

14 A. No.

15 Q. Okay. Other laboratories include in their
16 litigation packages a picture of the sealed specimen
17 container in the condition in which it arrived at the
18 laboratory; is that correct?

19 A. Some labs do, some labs do not. We do not
20 unless it's specifically requested -- requested.

21 Q. So the litigation packages that USDTL
22 prepared for Mr. Danford's specimens contained no
23 photographic evidence that the drying box arrived with
24 the seal intact, correct?

25 A. Well, you know, one of the issues that you

1 have on something like this, is that specimen if it's
2 over a year old, has been destroyed. And so it depends
3 on when the request came through and was the specimen
4 still available. I'm not certain when this request
5 came through for this litigation package. But we're
6 talking about, a 2018 specimen. There's no photograph
7 to get at this point.

8 Q. Okay. That doesn't answer my question. My
9 question is --

10 A. What was the question then?

11 Q. What I'm hearing as an explanation -- and I
12 want an answer to my question. The question being,
13 isn't it true that Mr. Danford's litigation package or
14 the litigation package that corresponds to his May 9th
15 sample, does not contain any photographic evidence that
16 the drying box arrived with the seal intact, correct?

17 A. That's correct. There's no photograph of the
18 specimen.

19 Q. Thank you.

20 A. That I'm aware of or I recall.

21 (Union Exhibit 17 marked for identification)

22 Q. Okay. Well, let's turn to the Union Exhibit
23 17. If you look at the first page you recognize the
24 signatory there, Liaqat Ali Abbas, as the preparer of
25 litigation packages for USDTL?

1 A. Yes.

2 Q. Okay. Could you turn to page 11, Emily,
3 please? That would be a picture of the mailing
4 envelope in which Mr. Danford's sample for this test
5 had been sent to USDTL, correct?

6 A. Yes. Well, it looks like it. I'm not sure.
7 This is -- this is all ambush to me. It could be. It
8 could not be.

9 Q. Okay --

10 A. I haven't had time to evaluate it.

11 Q. Would you --

12 A. Does this have to do with the May 15
13 collection?

14 Q. I'm not answering your questions, sir, with
15 all due respect. There is no corresponding page for
16 the May 9th litigation package, correct? That would --
17 that would detect an envelope of this nat --

18 A. But you know it -- it -- it sort of depends.
19 Because there are issues and situations where we have
20 to reply back to the collector under certain
21 circumstances to get further instruction. And in
22 those, clients services will get images of the
23 paperwork or the package that it comes in, sometimes
24 even the specimen itself. So I'm not aware of this
25 being an image associated with the -- with the -- with

1 the May 2018 specimen for Mr. Danford. And so that was
2 why I asked the question, does this belong to the
3 sample of the lit pack that we're looking at today, or
4 was there something else that's different? I'm -- I'm
5 -- I'm not -- I don't understand.

6 Q. You went through page by page, right? You
7 went through every page of the May 9th collection
8 litigation --

9 A. Everything in the litigation package,
10 absolutely.

11 Q. And it did not contain any photograph of
12 either the specimen, drying box, or the envelope in
13 which the specimen was mailed, correct?

14 A. That is -- that is -- that is not a standard
15 element in our litigation package. If it is specific
16 or requested, we can add it to it, but it was not
17 specifically requested.

18 Q. But --

19 A. But some labs -- some labs include it and
20 some labs don't, and we do not.

21 Q. So the answer is no to my question, correct?
22 That there's no equivalent of this photograph?

23 A. There is no equiv -- that is correct.

24 Q. Thank you.

25 A. The answer is no.

1 Q. Have you ever had reason for concern that
2 certain collectors or collection facilities that sent
3 DBS samples to USDTL were not complying with the USDTL
4 protocols?

5 A. I had one third-party administrator who had
6 raised that question. And he asked me to go back and
7 look at samples that were collected by one collector
8 versus another collector that was in his employ. And
9 -- and he asked me to do that. And I volunteered --
10 voluntarily, went back and looked at it. And what I
11 saw was that there was no difference in the number of
12 positives or the number of rejected specimens coming
13 from either of those two collections. I think one of
14 those collectors was his wife, and he was kind of
15 worried about that and the appearance of that.

16 Q. Was --

17 A. But that's the only instance that I'm aware
18 of at this point.

19 Q. But he was specifically talking to you about
20 his concern that a pilot under his care had received a
21 false positive; isn't that correct?

22 A. He was concerned about that, was raising the
23 question. And he was concerned that maybe his wife was
24 doing something incorrect, and -- I think it was his
25 wife. I'm not sure if it was or not.

1 Q. Okay.

2 A. I don't recall that in the conversation.

3 Q. So it'd be an aero medical examiner by the
4 name of Joseph Tordella, correct?

5 A. That is correct.

6 Q. All right. And did you discuss this issue
7 with Mr. Kassin?

8 A. It was brought up briefly, and I was told
9 like late last night that Tordella might be a witness
10 on your behalf. Some of the documents that came over
11 really late --

12 MR. KASSIN: He's getting into work product in
13 terms of the company's case. I think the witness has
14 answered his questions in terms of the initial
15 question. So I mean, I object to him getting into any
16 discussions we've had for preparation for this
17 arbitration.

18 MR. SEHAM: I'll make it easy. The answer is
19 sufficient. I just wanted to confirm the fact that
20 there had been some pre-advisement of this issue. And
21 I'm satisfied on the --

22 MR. KASSIN: Well, no, hold on a second.

23 MR. SEHAM: Okay.

24 MR. KASSIN: I don't think the board can conclude
25 that. I think that's a misrepresentation of what I

1 just said.

2 MR. SEHAM: The board can conclude what it wants.
3 I'm prepared to go to my next question. So I'm not
4 going to pursue this.

5 MR. KASSIN: Well, again I think it's just
6 inappropriate for Mr. Seham to make these types of
7 suggestions, and innuendos, and direct accusations.
8 And I think that's just not the way that our system
9 board conducts themselves. You know, he's a
10 third-party attorney coming in here. He's the third
11 attorney to represent this particular individual and
12 there needs to be a certain decorum and collegiality
13 about how this hearing is conducted, and that's not it.

14 MR. SEHAM: Well, I think that the court -- this is
15 about the fourth time that Mr. Kassin has made this
16 reference to different counsel. It is a false
17 representation. It is not appropriate. It's
18 suggesting some kind of instability on the part of my
19 client when in fact he was abandoned by prior counsel.
20 So if you want to talk about cordiality, I would ask
21 you to stop that.

22 Now with respect to Dr. Jones, my concern, and it
23 has already been answered, so there's no objection to
24 address, but my concern was how did he know that -- how
25 was this so -- asked a question whether he's

1 pre-advised. I think that's a fairly neutral term and
2 the answer came back. So I don't think these
3 accusations of my lack of cordiality, especially given
4 how we've been treated in this process with denials of
5 this witness's expertise, the withholding of an expert
6 outline or report. I don't consider our side to have
7 been the non-cordial side. I think we're the party
8 that's been gulled and deceived. But in any case,
9 there was an objection. The objection is moot. I'm
10 ready to go forward with my next question.

11 THE ARBITRATOR: All right. Please proceed.

12 BY MR. SEHAM:

13 Q. Thank you. So do you know, Dr. Jones, you
14 know what a HIMS doctor is?

15 A. Say that again, please.

16 Q. Do you know what a HIMS doctor is? I'm using
17 an acronym. For the court reporter, H-I-M-S. Do you
18 know what a HIMS doctor is?

19 A. I've heard of that term, yes.

20 Q. Okay. And you also know that Dr. Tordella is
21 a physician with substantial experience monitoring
22 pilots who have had incidents related to substance
23 abuse issues, correct?

24 A. Yes.

25 Q. And in fact, it's true that Dr. Tordella

1 communicated to you that he believed that the pilot in
2 his care had received a false positive test result from
3 your laboratory, correct?

4 A. Yes.

5 Q. And isn't it true that part of your response
6 to him was to advise him that you merely reported
7 laboratory results and did not make dispositive
8 determinations with respect to whether an individual
9 had experienced a relapse?

10 A. Could you repeat that question, please?

11 Q. The question is, isn't it true that you
12 advised Dr. Tordella that you merely reported
13 laboratory results and did not make any clinical
14 determinations with respect to whether an individual
15 had experienced a relapse?

16 A. Yeah. I mean, that sounds like something
17 that I would have said, yes. Yeah.

18 Q. Who is Liaqat Ali Abbas? We've seen him a
19 couple of times. What position does he hold?

20 A. Yeah, Liaqat Ali Abbas is the manager of our
21 Data Certification Department.

22 (Union Exhibit 18 marked for identification)

23 Q. So Emily, bring up Union Exhibit 18, please.
24 Is -- I have a new question here. So have you
25 previously been shown this document or have you been

1 spoken to about this document?

2 A. I'm familiar with this document.

3 Q. Okay, so this is correspondence between you
4 and Dr. Tordella, correct?

5 A. Correct.

6 Q. All right. And if you could, the second
7 page, let's see what I'm looking for is something --
8 yes, there would be perfect. Thank you. So the email
9 that I'm focusing on concerns Matthew Dacier,
10 D-A-C-I-E-R. The email reads, "Can you have one of
11 your guys pull all the tests that you have been sent on
12 this donor, specifically looking to see if there has
13 been any PEth or ETG posted below the cutoff. If so
14 could you send me a list of the samples in the amount
15 found? Can you query by collector name? It would be
16 interesting to see if the collector Lynn Collins, has
17 an unusual proportion of PEth positives."

18 A. Yeah.

19 Q. That email that you wrote to Liaqat A. Abbas,
20 correct?

21 A. Yes.

22 Q. In terms of collection protocols, would you
23 agree that it's imperative that only the blood drop and
24 not the fingertip catches the filter paper?

25 A. Those are the instructions, yes.

1 THE REPORTER: I'm sorry. Can you repeat that?
2 You're breaking up a little bit, sir.

3 MR. SEHAM: The question you or the answer?

4 THE REPORTER: Yes, your question. I heard the
5 answer. I need your question.

6 MR. SEHAM: Would you agree that it's imperative
7 that only the blood drop and not the fingertip touched
8 the filter?

9 MR. PICKETT: Everybody, this is Brian, it looks
10 like Mr. Burdette fell off the meeting, so if we can
11 hold on just a second.

12 MR. SEHAM: Sure. All right.

13 THE REPORTER: Off the record at 4:09 p.m.

14 (OFF THE RECORD)

15 THE REPORTER: Back on the record at 4:12 p.m.

16 THE ARBITRATOR: Okay. And I think Mr. Seham, the
17 point that I dropped off was where you were asking them
18 to pull Union Exhibit 18?

19 MR. SEHAM: Yes. Did you, that, we just confirmed
20 the authenticity of that correspondence and I was
21 moving forward with the questioning after that.

22 THE ARBITRATOR: Okay.

23 MR. SEHAM: Yeah. There was also a question and
24 answer concerning whether it was imperative that only
25 the blood drop, and not the fingertip touched the

1 filter paper or the collection card.

2 THE ARBITRATOR: Okay.

3 MR. SEHAM: The answer to that was yes. I mean,
4 the record would reflect that. I'm just trying to
5 catch you up.

6 THE ARBITRATOR: Right. Thank you. I appreciate
7 it.

8 BY MR. SEHAM:

9 Q. Okay. And then if we can move to back to
10 Union Exhibit 11. Move down to step 19. It says the
11 -- the last sentence in bold, it says, "Caution: do not
12 place inside an airtight plastic specimen transport
13 bag." And that's an imperative protocol on this
14 process, correct?

15 A. I would not say imperative.

16 Q. Why is it --

17 A. It is similar to the ethanol issue about the
18 appearances and so there's no -- there's no evidence at
19 this time that sealing a dried blood spot sample in a
20 airtight bag would interfere with the test or produce
21 PEth. This was a cautionary statement to use the
22 supplies that we send and then remove that question
23 from the table.

24 Q. Have you conducted any published validation
25 studies addressing the enclosure in an airtight plastic

1 specimen transport bag?

2 A. No.

3 Q. No.

4 A. I have some unpublished data, but I do not
5 have published data.

6 Q. Okay. If you can move to Union Exhibit 12,
7 focus on item 5. Hope I haven't addressed this
8 already. So item 5 reads, "All documents related to
9 any specimen collection training provided by USDTL or
10 any other training contractor with respect to the
11 specimen collectors who collected DBS samples from Mr.
12 Danford." And Emily, we can move to Union Exhibit 14.
13 Okay. And the answer is, "USDTL is in possession of no
14 documents responsive to this request." Is that an
15 accurate response?

16 A. Correct. Yes. We do not have any that I'm
17 aware of.

18 Q. Yes. Would you agree that in terms of the
19 blood that goes into the the card -- and we'll have
20 that up soon. On the card there are a series of
21 circles and the directive is to fill the circle fully
22 with a blood spot; is that correct?

23 A. That's correct.

24 Q. And if the DBS sample is smaller than what is
25 typically expected, that may be an indication that the

1 fingertip came into contact with the filter paper,
2 correct?

3 A. There could be one explanation, yes.

4 Q. And would you agree with me that if the DBS
5 is larger than expected, multiple drops were likely
6 collected?

7 A. I'll disagree with that.

8 Q. Yeah. Okay. So you don't know the name of
9 the collector in this case off the top of your head?

10 A. No, I don't.

11 Q. And she was never trained in USDTL, correct?

12 A. Right.

13 Q. All right.

14 A. At least I'm not aware of it.

15 Q. And you're aware under the 49 CFR Part 40
16 program specimen collectors have to be trained by
17 experienced trainers and perform at least five mock
18 collections in front of them, correct?

19 MR. KASSIN: Objection. That doesn't apply to
20 monitoring testing, that's part of the DOT testing
21 program.

22 THE ARBITRATOR: I understand. I'll sustain the
23 objection. Proceed.

24 MR. SEHAM: I'll just make a representation and we
25 can just put in our post hearing brief, but it's

1 certainly our position that 49 CFR Part 40 sets forth a
2 forensic standard that was vetted by the federal
3 government. We consider the extent to which USDTL
4 testing falls short of those forensic standards, that
5 that is relevant information for this board to have.

6 THE ARBITRATOR: You can make that argument in your
7 brief.

8 BY MR. SEHAM:

9 Q. Yes, I will. Thank you. Would you agree the
10 sample is not completely dry before putting it in a zip
11 lock bag for storage, microbi -- microbiological growth
12 may occur compromising sample quality?

13 A. I disagree with that statement.

14 Q. And if the DBS sample is not properly dried,
15 it may also affect analyte stability and recovery?

16 A. I disagree with that statement.

17 Q. Would you agree that the industry standard is
18 that DBS samples should be dried for at least three
19 hours under ambient conditions, and stored with a
20 desiccant to ensure the removal of all moisture?

21 A. Irrelevant for the test that we're offering.
22 So I disagree with that statement.

23 Q. Well, let me break that down. Isn't it
24 important that the sample that's collected under your
25 protocols be accompanied by a desiccant pouch?

1 A. No.

2 Q. Would you agree that ambient temperature and
3 humidity during drying have been suggested to affect --
4 or let me withdraw that. Would you agree that ambient
5 temperature and humidity during drying may affect DBS
6 homogeneity?

7 A. Irrelevant.

8 Q. In other words, no, you don't think it
9 affects DBS homogeneity for the purposes of --

10 A. Of course, it affects the homogeneity, but
11 for the purpose of the test it's irrelevant.

12 Q. What is the duration of drying time, that
13 USDTL has determined is necessary to ensure the
14 samples' reliability?

15 A. Could you rephrase that question please?

16 Q. I'll ask it again. What is the duration of
17 drying time that USDTL has determined as necessary to
18 ensure the samples reliability?

19 A. We request that the specimen be placed in the
20 drying box and the box is not airtight. And so once
21 it's in there, it's got all day and during the entire
22 shipment time to dry. And so the primary concern that
23 we have is the fixing of the blood-borne pathogens, not
24 some production or decomposition of the PEth.

25 Q. Well, isn't it true that USDTL has

1 recommended a one-hour drying process?

2 A. When we were beginning, yes. We were -- we
3 did not have the drawing box to begin with. And for
4 the newborn toxicology, those procedures are written
5 for the workflow in a -- in a nursery. So you get the
6 heel sticks from the babies and they have these little
7 cardboard supports that you can hang your heel sticks
8 and so a nurse can go through and get the heel sticks
9 and -- and -- and put those on the little support. And
10 then she can go and do whatever she needs to do. And
11 so whenever they are talking about, you need three
12 hours to dry, there's just -- they don't want the nurse
13 to come back in an hour and 15 minutes and one of them
14 still be damp. They just put out three hours and it's
15 been dry by then. And then they can collect them up,
16 stack them up, and send them down to be shipped up to
17 the laboratory.

18 Q. I'm going to object and move to strike the
19 question was isn't the -- hasn't USDTL mandated a
20 one-hour drying time?

21 A. And that was -- I'm leading up to that and
22 there's a -- that was the background to it.

23 Q. Sir, I've objected. Sir, I've objected and
24 hopefully counsel will let you know when there's an
25 objection, we have to wait for the arbitrator to

1 respond and you just can't bulldoze over an objection.

2 THE ARBITRATOR: Yeah, I'm going to -- I'll sustain
3 the objection, Mr. Seham and again, direct Dr. Jones to
4 respond directly to his question -- to your questions
5 in a simple a way as possible.

6 A. Okay. So the answer is yes.

7 Q. If Emily, if you could pull up Union Exhibit
8 19. And within that document, if you could move to the
9 3. And then if we could move down -- assuming that's
10 the top, if we can move down a little bit. Okay.
11 Okay. So yes, that's where I am. If -- if you look in
12 terms of bullet points here, if you look at the second
13 to last one where it reads, "Can we put blood spot
14 cards into a sealed plastic bag?" And the answer is,
15 "Before placing blood spot cards into a sealed plastic
16 bag, you must" -- now everything after you is
17 underlined and must is capitalized. "You must allow
18 the card to dry for one full hour. Once dry, you can
19 place dried blood spot cards in a plastic bag. But you
20 must include, " and again, I note that must is
21 capitalized. "Must include desiccant packs to reduce
22 the moisture in the bag. It is highly recommended that
23 the cards are placed in a non-plasticized envelope for
24 transport when possible to avoid any issues with
25 moisture." And my question, Dr. Jones is, is there any

1 other part of USDTL's FAQ where the answer is
2 underscored as it is here?

3 A. That was the decision made by the marketing
4 department to communicate to the collection sites who
5 are of a non-technical nature. And so emphasizing best
6 practices that was a choice that was made by the
7 marketing director.

8 Q. Okay. And so where there -- the fact that
9 the word must is capitalized --

10 A. Yeah.

11 Q. -- that in block letters, is that also a
12 marketing decision as opposed to scientific decision?

13 A. Yeah. It's similar to the ethanol hand
14 sanitizer. And that out of an abundance of caution to
15 avoid having these questions coming up later, these are
16 best practices that they should follow.

17 Q. Okay. Did USDTL conduct any validation
18 studies related to the use versus non-use of desiccant
19 patches?

20 A. No. No, we did not.

21 MR. SEHAM: If you look at Union Exhibit 11 and if
22 you could go to the top of that. Okay. Yeah, okay. I
23 actually, I guess I need to move to the very top of
24 Union Exhibit 11. All right. So that -- and if you
25 could expand it Emily, yeah just expanded it. I guess

1 --

2 THE REPORTER: Can you specify how you'd like it
3 adjusted?

4 MR. SEHAM: No, I think that's good enough. I was
5 looking to make it a little -- to magnify it a little
6 bit.

7 THE REPORTER: If you can just direct me to which
8 portion.

9 MR. SEHAM: I care only about the -- the depiction
10 of the contents at the top, which ends with the A, B,
11 C, D and the language to the left of that. Maybe a
12 little -- I'd like to get the C and D and then, you
13 know, we might be able to struggle through with this.
14 That's fine, Emily. Thank you very much.

15 BY MR. SEHAM:

16 Q. Now, looking at the top here, the material
17 provided by USDTL, it lists a dried blood spot
18 collection supplies and drying box, the custody and
19 control form. And then it depicts A and B to the
20 right. Is that the intent of this document in this
21 respect to depict at A and B those supplies that are
22 provided, by USDTL to the collector?

23 A. Yes.

24 (Union Exhibit 20 marked for identification)

25 Q. Okay. And those supplies, and I guess the

1 witness is at a disadvantage here, but we provided
2 actual bags to the arbitrator, which is Union Exhibit
3 20. But it looks to consist of what's referred to as
4 the drying box, the dried blood spot card, two lens
5 sets, an alcohol prep pad, and a seal. Is that a fair
6 description of the contents of the collection package?

7 A. Yes.

8 Q. Okay. So the collection materials sent to
9 the collector do not include a desiccant pack, correct?

10 A. No.

11 (Union Exhibit 21 marked for identification)

12 Q. Okay. If you could look at document Union
13 Exhibit 21. I think we've seen this before. This is
14 provided by USDTL as recently included in the September
15 24th, 2020 webinar, correct?

16 A. It looks familiar, yes.

17 Q. And if you can scroll down a little bit.
18 Thank you. And it says no dry time. What is meant by
19 no dry time?

20 A. You can put it in the drying box and move
21 along. And you can put the tamper evidence, security
22 seals.

23 Q. And you agree that you have no knowledge of
24 how the specimen was stored at the collection site?

25 A. No, I do not.

1 Q. Okay. And how are the specimens stored at
2 USDTL?

3 A. They're stored in the box and they're stored
4 in a locked file drawer in boxes by year or by month
5 rather, by month and year.

6 Q. Now, you've testified, I believe that it's
7 only your laboratory and one other that is currently
8 using DBS as a matrix or --

9 A. In this country, yes.

10 Q. So that other laboratory is performing
11 commercial dried blood PEth testing?

12 A. No. He's -- you're talking about University
13 of Texas?

14 Q. Correct.

15 A. University of Texas?

16 Q. Yes, sir.

17 A. No. Yeah. No, he's not doing it as a
18 commercial entity. He is one of the testing locations
19 for National Institute of Alcoholism and Alcohol Abuse
20 Researchers. He's a resour- resource for them. And --
21 and they can conduct these tests for the researchers.
22 We know him through the Research Society of Alcoholism.
23 And that's how we got the collaboration to be available
24 to do re-testing.

25 Q. If Emily, if we can move to Union Exhibit 19,

1 which is again the USDTL FAQ. And I want to go to the
2 first page. And if you could go down a little bit.
3 There we go. That's it. Stop please. That's fine.
4 I'm looking at the bullet pointing towards the middle
5 that says, "Are you aware of any other labs splitting
6 specimens for PEth or sending two specimen cards filled
7 with dried blood for testing". The answer is, "There
8 --

9 A. Yeah.

10 Q. "There are no other labs that do commercial
11 dried blood spot PEth testing, so there are no labs for
12 comparison. Is that an accurate answer?

13 A. Correct, yes.

14 Q. In San Antonio -- I apologize. The
15 laboratory you recently identified that's -- was it at
16 UT San Antonio?

17 A. Yes.

18 Q. And what assay do they use for their testing?

19 A. They use a laboratory developed test that
20 they've published numbers -- numerous times. I'm not
21 aware of the specifics of their test, but it's rather
22 similar to ours.

23 Q. What is the criteria applied -- you say you
24 used that laboratory for confirmation?

25 A. No, we use the laboratory for re-testing. So

1 if a person has -- is refuting a result, we give them
2 an opportunity to request for it to be sent out and so
3 if we get the request, we can send it to them. At this
4 point in time, that's the only other outside source.
5 We can conduct the re-test in-house too, but sometimes
6 that's perceived as a conflict to venture so they like
7 to send it out to another lab.

8 Q. And what is the criteria that's applied in
9 terms of UT San Antonio confirming a USDTL test result?

10 A. Could you repeat the question, please?

11 Q. What is the criteria for the re-test?

12 A. What do you mean by criteria?

13 Q. In terms of -- in terms of confirming or not
14 confirming, is there -- for example, is there a
15 specific cutoff applied during the re-test?

16 A. For any re-test, including University of
17 Texas, San Antonio, they use their limit of detection.
18 And so that's the standard practice with re-testing in
19 that it either re-confirms or fails to re-confirm. And
20 -- and that's the re-test answer.

21 Q. And the limit of detection for UT -- that's
22 applied by UT San Antonio is four nanograms per
23 milliliter, correct?

24 A. I'm not sure what their re-test limit of
25 detection is.

1 Q. Okay. Would you agree that DBS has a shorter
2 history than traditional matrices such as liquid blood,
3 plasma, serum?

4 A. Yes, by and large. It's been around a long
5 time in other fields. But in this utilization, it's --
6 it's rather a cutting edge.

7 Q. All right. Are you familiar with the term
8 Hematocrit, sometimes referred to as HT, Hematocrit
9 effects as applies to DBS testing?

10 A. Yes.

11 Q. All right. Could you define the term as you
12 understand it?

13 A. Yeah. The Hematocrit is the percentage of
14 the liquid versus the solids in simple terms. And so
15 there's a very narrow range for humans to not be
16 deathly ill. And during that range, for some assays,
17 the Hematocrit variance can influence the outcome of a
18 result.

19 Q. And are you familiar with the term matrix
20 effect or ME?

21 A. Yes.

22 Q. Can you define that term as you understand?

23 A. Yeah. Matrix effect describes the effect
24 that happens at the time that your analyte is entering
25 into the mass spectrometer. And if there are an over

1 abundance of compounds in these little micro drops, as
2 that little micro drop is evaporating in the inlet
3 source, there is a charge that is applied to that
4 droplet. If there's an enormous amount of some other
5 something in that little droplet, it will hog all of
6 the electrons and your compound may not get the
7 electrons to become ionized. And so it hits the side
8 of the detector and you'll never get to see it. So
9 that would be an example of ion suppression.

10 You can also get an opposite effect called ion
11 enhancement. And ion enhancement means that maybe that
12 compound that's an enormous quantity on that little
13 droplet as it's evaporating and gaining the charge,
14 that compound may be very effective at grabbing that
15 charge and then relaying that charge to your compound
16 venture. So you get like this big response because
17 more of your molecules have been ionized and that's
18 detectable. So as a group, they're called matrix
19 effects. And one of the elements of a validation
20 package which you'll see in our validation package is
21 that there are some recommended ways. There's a couple
22 of different ways to do it, to evaluate your matrix
23 effect. And for LC-MSMS, if specifically we're looking
24 for -- for the ion suppression and ion enhancement,
25 that's the main thing we're looking for.

1 Q. Did USDTL conduct any validation study on the
2 impact of creatinine levels on quantitative analysis?

3 A. No.

4 Q. Would you agree that it is an essential --
5 well, let me skip that. Putting aside Mr. Kassin and
6 any contacts you had with Delta leading up to this
7 arbitration, did you have any prior contacts with Delta
8 concerning the Danford test results, say in 2018 or
9 2019?

10 A. I don't think so. I don't recall.

11 Q. Okay. Did you have any knowledge of Mr.
12 Danford having had a previous negative ETS result based
13 on a May 1 collection, May 1, 2018?

14 A. Yes.

15 Q. Would you agree that an ETG positive result
16 can arise from the incidental use of hand sanitizer or
17 mouthwash?

18 A. Yes.

19 Q. Would you ever advise that the USDTL PEth
20 test was for the purpose of resolving which of the two
21 prior tests, an ETS or ETG, provided the correct
22 result, originally?

23 A. Could -- could you repeat that question,
24 please?

25 Q. Yes. I will definitely repeat that because I

1 fumbled that horribly. Were you ever advised that
2 USDTL's PEth test was for the purpose of resolving
3 which of two prior tests originating from a May 1 urine
4 collection in 2018, the ETS or ETG provided the correct
5 result?

6 A. For this specific case or as a general
7 policy?

8 Q. No, for this specific case.

9 A. No. I was not aware of that, I don't think.

10 Q. Would you agree that PEth cannot determine
11 the time, dose, or frequency of use?

12 A. I agree.

13 Q. Would you agree that there's no correlation
14 between the quantitative result of a test and the level
15 of consumption?

16 A. That is correct.

17 Q. Okay. So for example, if someone had a 100
18 nanogram per milliliter test result, that does not
19 reflect a consumption level five times higher than 20
20 nanograms per milliliter, correct?

21 A. Correct.

22 Q. On what do you base the cut off level of 20
23 nanograms per milliliter?

24 A. It was the result of selecting criteria that
25 would result in a service that was useful for the

1 substance use treatment field. So it was -- it was
2 selected based on the previous research that existed at
3 the time. And extrapolate -- extrapolating that to --
4 we need to achieve certain criteria, then it would be a
5 useful product. As I mentioned earlier in my testimony
6 about the evaporative light scattering detector, that
7 technique was in the thousands of nanograms per meal.
8 And so basically you're talking about people at that
9 level, what they were doing their studies originally,
10 you're talking about people in a alcohol rehab
11 situation, going through DTs. You don't need a test,
12 you know, to tell you that they've been drinking.
13 They're going through DTs.

14 Under these circumstances like with the HIMS
15 program or the state physician health programs, they --
16 they need more information so a one thousand cutoff is
17 not useful to them at all. So based on the data at the
18 time, we -- we hypothesized that 20 was an appropriate
19 cutoff target. We worked on that. The NIH, they
20 approved to fund us for that. And -- and since then, a
21 couple other laboratories have also adopted that as a
22 cutoff just because it works well in this environment.

23 Q. What does the term LOD refer to?

24 A. Limit of detection.

25 Q. And what -- could you explain that?

1 A. The limit of detection is a concentration
2 that has been determined one of two ways. It can be
3 determined statistically or empirically by examining
4 concentrations lower, lower, lower. The -- the -- the
5 easy way to envision this in your mind's eye is that if
6 you -- if you start with a certain concentration and
7 keep dropping it and you do this result in triplicate,
8 at some point you will end up to where all three of
9 those, because it's getting so low, you're not able to
10 properly identify your compound of interest. And so
11 the point, the highest point to where you have two out
12 of three of those replicates identifying your compound
13 of interest, that is your empirical limit of detection.

14 Now, in a routine production laboratory running
15 many, many samples, you know, we don't have time to do
16 that academic exercise. And, you know, you test 10 and
17 then 5 and then 1 and then 0.5, and 0.25 and ad
18 nauseum. So when we target our limit of detection, we
19 have a good idea of where we need that to be and then
20 we verify that our LOD is at least that low. And so
21 then we re-verify that every year with a process that
22 we call annual verification. But in a nutshell, that's
23 the limit of detection. It's the lowest value that you
24 can accurately identify the compound.

25 Q. Would you treat an eight nanogram per

1 milliliter result -- or would you represent that
2 result, rather, as indicative of non-abstinence?

3 A. At this point, I would have no opinion on
4 that. Eight is our -- do you want me to explain or you
5 got other questions?

6 Q. No, no. I just want you to answer the
7 question. Yes or no?

8 A. Repeat the question, please.

9 Q. Would you have any concern about representing
10 an eight nanogram per milliliter PEth re -- PEth test
11 result as establishing non-abstinence?

12 A. Yeah. I would not use eight to establish non
13 abstinence.

14 Q. Would you use 9 or 10?

15 A. No. I'd use 20.

16 Q. And why would you not use 9 or 10?

17 A. We don't have the data to -- to demonstrate
18 that we're not picking up other things other than
19 beverage alcohol consumption.

20 Q. Has USDTL ever altered its cutoff level in
21 terms of what it designates as a positive?

22 A. Yes.

23 Q. Okay. Could you tell us about -- did you
24 have a lower cutoff before or a higher cutoff?

25 A. We -- we -- we offer a lower cutoff for our

1 researchers. Because the researchers really don't
2 care. They want the number and then they're going to
3 do their statistics with the numbers as they fall. So
4 if we have a number, they want the number. So the
5 number 8 that you're referring to as a value, called
6 our limit of quantitation. So where the limit of
7 detection is the -- is the lowest amount that we can
8 day in and day out identify that analog of -- analyte
9 of interest. The limit of quantitation which is
10 typically something a little higher, that number is the
11 lowest number that we can accurately identify and
12 quantitate. So that's why it's called the limit of
13 quantitation.

14 Now we have a -- a regulatory requirements
15 specifically by the State of New York. And I don't
16 know why they have this, but at the end of the day, I
17 -- I agree with it because it -- it -- it's just a good
18 idea and a best practice. But whatever cutoff a
19 laboratory chooses to operate in, we need to
20 demonstrate that our limit of quantitation is no higher
21 than 40 percent of that. So that means that if my
22 cutoff is at 20, I need to demonstrate my limit of
23 quantitation is no higher than 8. And so that's the
24 target that we're going for. Now the case of
25 researchers, we give them the 8 because that's where we

1 can reliably quantitate and identify.

2 There will be certain instances where the client
3 calls and demands that we look at it at a lower number.
4 And we try to talk them out of it and say we shouldn't
5 look at below 20. But as, you know, they're the
6 client. And so sometimes we -- we -- we oblige them
7 with their question. It's occasionally, it's not
8 often, but occasionally we will go back and re -- not
9 actually re-analyze because the analysis has already
10 been done. But we will re-evaluate that specimen using
11 the limit of quantitation to demonstrate whether was
12 something there or whether something was not there. To
13 help them because at the end of the day, they're
14 probably looking at multiple pieces of evidence or
15 maybe this one piece of -- of information is not clear,
16 they're trying to get clarity. And sometimes that
17 little nugget, even though it's maybe non standard, can
18 be helpful -- helpful to them in working with their
19 subjects.

20 Q. Would you ever -- I hear you talking about
21 researchers and so I want to distinguish -- the coming
22 question is to distinguish --

23 A. Yeah.

24 Q. -- the researchers. Would you ever treat an
25 8, 9, or 10 as a positive for forensic purposes?

1 MR. SEHAM: Okay. Emily, if you could bring up or
2 whoever is assisting at this point. If you could bring
3 up the Union Exhibit 23. And within that, just for
4 reference to the arbitrator this is a -- we can scroll
5 down to the bottom of the first page.

6 BY MR. SEHAM:

7 Q. Okay. So this is a document that we received
8 in res -- so that we don't get into the objection
9 exchange that we've previously, indicated by the Bates
10 stamp at the bottom, this is a document that we
11 received in response to our subpoena as referred with
12 Bates USDTL 001106, and I would ask if the
13 administrator could turn to page 14 of this document
14 which would be Bates stamped 1119. Yeah. Okay. And
15 if you could just scroll down a little and probably
16 come right back up. But I just want to confirm that I
17 have the right page number. Yeah. Okay. Thank you.
18 And if you can move back where you were, which was
19 actually fine. Would you agree with me that this
20 document reflects a urine specimen collected from a
21 Michael Perez on December 7th, 2015 and tested by
22 USDTL?

23 A. Yes.

24 Q. Okay. And the test indicates ETS positive of
25 36 nanograms per milliliter?

1 A. Yes.

2 Q. Okay. Assuming that Michael Perez was a
3 Delta pilot in a HIMS program who was required to
4 maintain abstinence from alcohol, should this test
5 result had been the basis either for his termination or
6 mandatory re-entry into rehabilitation?

7 A. That's kind of outside of my call. It
8 depends on the policy of the -- of the employer.

9 Q. Let me rephrase it then. Is there any room
10 for doubt in your mind as to whether this test result
11 dispositively establishes non-abstinence?

12 A. This result interferes with being able to
13 confirm abstinence which is kind of a little slightly
14 different way of looking at that.

15 Q. I think it's a very different way of looking
16 at it, but so, is your answer that -- I prefer answers
17 to my question. My question was, does this test result
18 dispositively establish non-abstinence?

19 A. Does this test result indicate
20 non-abstinence?

21 Q. What I'm saying -- again, you keep changing
22 my question, but maybe I'll make it an easier question.

23 A. But I'm trying to understand it. So if you
24 can rephrase it somehow?

25 Q. Right. Right. So I'll rephrase it. I'll do

1 that. Could there be an explanation -- I'm sorry, the
2 cleaning people are coming through, so I'm just going
3 to close my door here. Could there be an explanation
4 for this test result other than non-abstinence?

5 A. Yes.

6 Q. Okay. Did anyone from Delta or Ms. Gable --
7 Michele Gable consult with you about this test result?

8 A. I do not recall.

9 Q. Do you recall whether a PETH test was
10 administered in response to this test?

11 A. There was a lot of testing that was done on
12 Michael Perez that I was made aware of preparing these
13 documents to send over to you. But at the time, I
14 don't recall being involved in deciding what tests need
15 to be ordered and what test not to be ordered.

16 MR. SEHAM: You could please turn to page 10 of the
17 same PDF document, Emily -- or is it still Emily or we
18 have -- is it Damien now whose --

19 REMOTE TECH: It's still me.

20 MR. SEHAM: Okay. Great. So I'm looking for page
21 10.

22 REMOTE TECH: You're on page 10.

23 MR. SEHAM: Thank you. And if you can move -- I
24 want to look a little further down. Thank you.
25 Perfect.

1 BY MR. SEHAM:

2 Q. Okay. So page 10 of the same PDF document,
3 do you see this document concerns a urine specimen
4 collected from Michael Perez on 12/17/2015, correct?

5 A. Yes.

6 Q. And this reflects an ETS positive at 20
7 nanograms per milliliter, correct?

8 A. 28.

9 Q. 28.

10 A. Yes.

11 Q. I'm sorry. If I've said something else, I
12 misspoke. 28 nanograms per milliliter. And could
13 there be an explanation for this ETS positive result
14 other than non-abstinence?

15 A. Yes.

16 Q. Okay. Do you recall if anyone from Delta or
17 Ms. Michele Gable consulted you with respect to this
18 test result?

19 A. I -- I do not recall.

20 Q. Do you recall whether a PEth test was
21 administered in response to this test?

22 A. I do not know.

23 (Union Exhibit 34 marked for identification)

24 Q. Now, if you could bring up the Union Exhibit
25 34, Emily? And I'd like to go to page 2. And this is

1 a Quest Diagnostics report indicating an ETG result of
2 138 nanograms per milliliter at the very bottom of the
3 page, and a creatinine of 264.2 milligrams per
4 deciliter. Based on the test result here just in terms
5 of measurement, is a possible explanation for this
6 result other than non abstinence?

7 A. Could you scroll it down so I can see the
8 result?

9 Q. Yeah, I'm sorry. It's 138 at the bottom. I
10 was looking at my hard copy.

11 A. So this was 138 ETG?

12 Q. Correct.

13 A. So yes, there could be alternative
14 explanations other than beverage alcohol consumption.

15 Q. Okay. And creatinine measurement, is that a
16 relevant consideration in your view?

17 A. Yeah. That plays into it as well, yes.

18 Q. How does creatinine play into it?

19 A. One way that you can evaluate these from a
20 higher level is to normalize the result to a creatinine
21 of 100, which is like an average creatinine value.
22 People's creatinines in their urine can vary widely in
23 the run of the day. You can see this personally in
24 that your first void in the morning is typically darker
25 than your last void at night and that tends to be a

1 typical trend with much big -- there will be
2 differences. But your state of hydration can exist in
3 -- in a wide acceptable range. So what does this mean?
4 The more hydrated your urine is, the lower the
5 concentration, the more concentrated your urine,
6 obviously, the higher the concentration. So by
7 normalizing this back to a 100 creatinine is one way to
8 take a look at this. Some people just do the straight
9 up ETG divided by creatinine, but that kind of gives
10 numbers that I'm not accustomed to looking at. So I
11 prefer to do the -- to do the 100.

12 Q. Okay. And what impact would that --

13 A. But I don't think there's any standard on
14 that either, so --

15 Q. Okay. Well, applying the approach you
16 described, the normalization using the 100 standard
17 creatinine, what would that do to the actual value of
18 the test?

19 A. It would drive it low. So in this case, if I
20 were interpreting this, I would say it's positive.
21 It's supposed to be negative, but it's positive. But
22 it's 138, which is a low value to start with. And the
23 creatinine being elevated like it is, kind of just
24 mental math, I'm cutting that in half, so now we're at
25 60, 70, 80, somewhere in there. And so this is -- a

1 reasonable explanation would be the use of other
2 products containing ethanol as a reasonable
3 explanation.

4 Q. So I'm sorry, when you say 60, 70, 80, that
5 would be --

6 A. Grams per mil per 100 creatinine.

7 Q. Okay. So once you apply the creatinine -- .

8 A. Yes.

9 Q. -- normalization formula that you accept,
10 that would effectively reduce the real value of the ETG
11 that's the 60, 80 --

12 A. I would call it the normalized value, yes.

13 Q. Okay. Now, if we could turn to -- go back,
14 please, Emily, to Union Exhibit 23. And I'm looking
15 for page 5. I guess if that's page 5, that should
16 probably -- if you could scroll down a little bit.
17 Okay. So this would be Perez -- Michael Perez test
18 result for a blood specimen collected on March 16th,
19 2016, correct?

20 A. Yes.

21 Q. And it's reported as a positive, correct?

22 A. Yes.

23 Q. And the cutoff applied was 8?

24 A. Yes.

25 Q. Okay. And the positive was based on a

1 quantitation of 10 nanograms per milliliter?

2 A. Yes.

3 Q. Do you recall why the lower cutoff was
4 applied in this instance?

5 A. We were requested by the client to do so.

6 Q. For this positive result, is there a possible
7 explanation other than non-abstinence for this result?

8 A. With PEth, it's kind of hard to tell at this
9 point. The data's limited on this subject. And so I
10 would lean towards there may be other explanations.
11 It's not as clear as it is with the ETG, ETS. But what
12 is clear is that regardless, we are unable to confirm
13 the abstinence of the donor, which again is asking that
14 question in a slightly different way. That -- that --
15 this is kind of what we had -- this is the abstinence
16 testing, is that we need to confirm their abstinence
17 and if they were using Purell when they're not supposed
18 to use Purell, then they're interfering with our
19 ability to confirm their abstinence.

20 Q. Did anyone from Delta consult with you about
21 this test result?

22 A. I don't recall.

23 Q. Okay. And if you could turn to -- Emily, if
24 you could turn to page 7 of UX23. Okay. Here there's
25 a reflected a reconfirmed and it's based on an LOD of

1 two.

2 A. Yes.

3 Q. And I guess if we could scroll, kind of go to
4 the top of the page. All right. So this was an
5 internal re-testing?

6 A. Yes. We were requested by First Lab to
7 re-test the specimen.

8 Q. And so you reported this back as a confirmed
9 positive?

10 A. We reported this back as a reconfirmed.

11 Q. Emily, if you could scroll down so we can see
12 the bottom of the page. Okay. Let's stop there.

13 A. Reconfirmed.

14 Q. Reconfirmed.

15 A. The rules for re-test are different than
16 first-time through.

17 Q. Okay.

18 A. And so this is following the rules of
19 re-test.

20 Q. But what you were reconfirming in this case
21 was a positive test result, correct?

22 A. That is correct.

23 Q. And if you can go to page 3 of this PDF
24 document, UX23.

25 A. This is fingernails.

1 Q. Correct, right. So this is a collection of
2 fingernails that was conducted on May 4th, 2016,
3 correct?

4 A. Yeah.

5 Q. I'm sorry, I didn't hear your answer.

6 A. I -- I was waiting for it to scroll up so I
7 could see more.

8 Q. Oh, yeah. There you go.

9 A. Okay. So fingernails. So this appears to be
10 a fingernail test collected in May of 2016.

11 Q. And then ETG methodology was applied,
12 correct?

13 A. Correct.

14 Q. What can you tell us about the use of -- here
15 -- here we're doing a ETG with nails as opposed to
16 urine. Why would the laboratory be using nails --
17 fingernails, as opposed to urine as the testing matrix?

18 A. Well, because, number one, the client asked
19 us to. Number two, ETG and hair and fingernail are --
20 are good alternative specimen types to help try to fill
21 in gaps on the alcohol use behavior of -- of their
22 subjects, yes. So this is yet one more tool, that's at
23 their disposal to request. Has different level of
24 thresholds to positivity, has different disadvantages
25 as far as quantity of specimen, but it's one more tool.

1 Q. And what's the -- I think you said that the
2 look-back for PEth is about -- did you say two to four
3 weeks?

4 A. Yes. Up to two to four weeks following
5 chronic excessive drinking.

6 Q. And the look-back for urine ETG is what?

7 A. You'll see it reported at up to two to five
8 days following chronic excessive drinking. But the
9 five days, there was like this one guy in a withdrawal
10 program and the literature is now taking five. My
11 experience with ETG and urine is more like all the
12 other drugs that were typically testing for, which some
13 of them are Glucuronides as well, and two to three days
14 is kind of what you can depend on day in and day out.

15 Q. The -- and what's the look-back for an ETG
16 for nails?

17 A. Up to approximately three months.

18 Q. I forgot that -- I did not hear the first
19 part of that range, from what?

20 A. I said up to approximately three months.

21 Q. Is there a lower level expectation, is it one
22 to three months or two to three months?

23 A. One day to three months.

24 Q. Okay. And Mr. Perez's negative nail test,
25 based on this May 2016 collection was deemed to

1 overrule the prior positive tests for ETS, ETG and
2 PEth, isn't that correct?

3 A. No, that is not correct.

4 Q. Mr. Perez was not fired, correct?

5 A. I'm sorry, could you repeat that question,
6 maybe I misunderstood your question.

7 MR. KASSIN: So that's nothing within the realm of
8 Dr. Jones's knowledge of this. That's not an
9 appropriate question whether he was retained or fired.

10 MR. SEHAM: If he doesn't know, then he can answer
11 he doesn't know.

12 MR. KASSIN: But he's not a decision-maker on
13 something like that.

14 MR. SEHAM: I don't know that one way or the other.
15 I'm not -- again, we're having counsel testify. The
16 reason for these questions is for the witness to answer
17 it. And if he doesn't know or was not involved, that's
18 for him to answer.

19 MR. KASSIN: But he is qualified to discuss the
20 testing issues. He's not qualified to talk about
21 employment issues.

22 THE ARBITRATOR: Okay --

23 MR. SEHAM: It really depends on the facts whether
24 Delta talked to this man or not. I mean, again, I
25 think counsels testifying and I'd asked him not to. In

1 any case, let me ask the question again because asked
2 me to ask the question again. I'll ask it in perhaps
3 more accommodating way.

4 BY MR. SEHAM:

5 Q. Do you have any knowledge as to whether Mr.
6 Perez's negative nail test for this May 2016 collection
7 was deemed to overrule the prior positive tests for
8 ETS, ETG, urine and PEth?

9 A. Okay. So I've misunderstood your question
10 when I spoke too quickly earlier. The answer to your
11 specific question is I have no knowledge of the outcome
12 of Mr. Perez.

13 Q. That's --

14 A. I don't know what was used one way or the
15 other.

16 Q. Okay. So no -- no one from Delta or -- or
17 Michele Gable, no one consulted you in terms of the
18 testing strategy to be applied to Michael Perez in
19 terms of abstinence determination?

20 A. I -- I do not have any specific recollection
21 of that, no.

22 Q. Okay. Before you were talking about an
23 article that you had published, do you recall during
24 your earlier testimony referencing a website or an
25 Internet article that you had published?

1 A. Yes.

2 Q. Okay. Could you -- we're having problems
3 finding it and I wanted to know whether you could
4 identify it for us any better.

5 A. Let me -- I hope I don't lose you. If I lose
6 you I'll jump right back in. I'll minimize the screen.
7 Okay. Did I lose you?

8 MR. SEHAM: No, you did not.

9 THE WITNESS: I have pulled the paper up. If you
10 let me share my screen, I can show it to you.

11 MR. SEHAM: I'd rather just --

12 THE WITNESS: Would you want me to email it to you?

13 MR. SEHAM: I'm sorry?

14 THE WITNESS: Would you like for me to email it to
15 you?

16 MR. SEHAM: That would be lovely if you would, yes.
17 Thank you.

18 THE WITNESS: I'd be glad to, give me one second.
19 Let me get the link here. Tom, you want me to CC you
20 on that?

21 MR. KASSIN: Yes, please.

22 MR. SEHAM: Okay. You're -- you're ready for my
23 address?

24 THE WITNESS: No, I've got it, I believe.

25 MR. SEHAM: Okay. Very good. Well, thank you.

1 Thank you. I think we're at 5:26. With the permission
2 of the arbitrator, we're going to stop at 5:30. I'm
3 about to go into a series of questions that are
4 related. So it'd be my preference to stop now.

5 THE ARBITRATOR: Okay. And then we will pick back
6 up. What time do you want to start in the morning?

7 MR. KASSIN: Arbitrator Burdette, our witness, that
8 we're trying to accommodate is available at 9:30 East
9 Coast time, 8:30 your time.

10 THE ARBITRATOR: Okay.

11 MR. KASSIN: If we can start up at 9:30. That
12 would be awesome.

13 THE ARBITRATOR: Okay. Then that's what we'll do.
14 We'll start at 9:30 Eastern, 8:30 Central Time tomorrow
15 morning and we'll pick back up with the company's
16 witness out of order, and then we'll get back to Dr.
17 Jones when we can do that after the company's next
18 witness. Subject to his availability as well.

19 THE REPORTER: Off the record at 5:27 p.m.

20 (Whereupon the proceeding concluded at 5:27 p.m.)

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REPORTER CERTIFICATE

I, DAMIEN STONEBERGER, hereby certify that the foregoing proceedings were recorded by audio by me, a disinterested person, and that the proceedings were thereafter transcribed to typewriting, by computer;

That I am neither attorney for nor a relative or employee of any of the parties to the action; further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially interested in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand this October 28, 2020.



DAMIEN STONEBERGER
STORYCLOUD

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SCOPIST CERTIFICATE

I, the undersigned, do hereby affirm:

That the foregoing electronically-recorded proceedings were scoped by me to the best of my ability.

I further affirm I am neither certified or financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: November 16, 2020

Stephanie Morano

STEPHANIE MORANO

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