STORYCLOUD

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

(866) 787-6774 | depos@storycloud.co | www.storycloud.co

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

APPEARANCES

ARBITRATOR:

Mark Burdette

FOR THE COMPANY, DELTA AIR LINES CO.:

THOMAS J. KASSIN, ESQ.
SARAH F. AUFDENKAMPE, ESQ.
FORD HARRISON
271 17th Street NW, Suite 1900
Atlanta, Georgia 30363
404-888-3800
tkassin@fordharrison.com

CHRIS PUCKETT, ESQ.
DELTA AIR LINES, INC.
1010 Delta Blvd.
Department 943
Atlanta, GA 30354
404-715-1152
Chris.B.Puckett@delta.com

Also Present for the Company:

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

FOR THE UNION,
DELTA MEC AIR LINE PILOTS ASSOCIATION,INT'L:

LEE SEHAM, ESQ.
SEHAM SEHAM MELTZ PETERSEN
199 Main Street
White Plains, New York 10601
914-997-1346
lseham@ssmplaw.com

RACHEL SAMUDA, ESQ.
AIR LINE PILOTS ASSOCIATION, INT'L
100 Hartsfield Centre Parkway
Suite 800
Atlanta, GA 30354
404-763-5198
Rachel.Samuda@alpa.org

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

INDEX

INDEX TO EXHIBITS

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.

THE ARBITRATOR: Okay. Thank you. Go ahead.

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

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

provision.

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

(Company Exhibit 1 marked for identification)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE REPORTER: About 10.

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

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

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

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

all the circumstances.

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

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

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

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

REMOTE TECH: Is he signed in as USDTL WebEx?

MR. KASSIN: Yes.

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

MR. KASSIN: Okay.

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

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

noted on the record, Mr. Seham.

MR. SEHAM: Thank you.

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

MR. KASSIN: Is Dr. Jones, here?

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

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

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

MR. KASSIN: Thank you, sir.

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

THE WITNESS: I do.

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

yourself?

THE WITNESS: I am.

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

THE WITNESS: I do.

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

JOE JONES,

having been first duly sworn, testifies as follows:

DIRECT EXAMINATION

BY MR. KASSIN:.

(Company Exhibit 9-10 marked for identification)

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

A. I do.

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

THE REPORTER: Can we hold on just a minute.

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

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

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

THE WITNESS: Okay.

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

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

BY MR. KASSIN:

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

A. Joseph Timothy Jones.

Q. Who are you employed by?

A. United States Drug Testing Laboratories.

Q. What is your position with US DTL?

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

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

position?

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

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

A. Three years.

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

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

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

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

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

Q. How do you describe your professional specialty?

A. Forensic Toxicologist.

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

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

(Company Exhibit 12 marked for identification)

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

A. Yeah. So the first would be 30 years

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

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

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

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

MR. SEHAM: No objection.

THE ARBITRATOR: Thank you. It's admitted.

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

A. USDTL is a forensic toxicology laboratory.

Q. Okay. Exactly what does that mean?

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

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

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

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

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

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

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

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

hearing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Company Exhibit 13 marked for identification)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PEth is present?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But there's some limitations that we have to be

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

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

Even in the freezer, those bacteria will still work.

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

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

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

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

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

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

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

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

Q. How long has USDTL been doing PEth testing?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

result you go, oops I need to watch my sugar or okay, great, I'm -- I'm staying in glycemic control. The hemoglobin A1c that your physician may order on you as a diabetic, the result from that hemoglobin A1c may direct that physician as to further intervention that he may need to conduct with regard to your glycemic control.

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

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

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

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

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

A. Absolutely.

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

A. Sure.

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

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

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

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

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

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

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

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

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

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

A. Yes.

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

A. Yes.

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

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

A. Yes.

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

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

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

A. Yes.

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

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

A. None.

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

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

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

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

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

A. Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. Yes.

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

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

Routinely and again, this depends on the

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

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

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

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

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

MR. KASSIN: I think the witness is describing

what's made available to them.

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

Q. Dr. Jones, can you clarify?

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

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

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

Q. You mentioned earlier that USDTL has the

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

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

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

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

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

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

service than the whole blood.

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

A. Between 120 and 150,000.

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

A. No.

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

A. Yes.

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

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

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

A. Yes and no. There was one poster

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

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

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

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

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

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

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

please?

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

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

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

A. No, quite the opposite.

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

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

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

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

A. That was not me.

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

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

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

A. Yeah, sir.

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

A. Yeah.

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

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

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

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

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

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

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

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

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

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

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

A. That is correct.

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

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

Q. Okay.

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

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

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

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

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

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

Q. Okay. Go ahead and continue, please.

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

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

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

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

Q. Okay.

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

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

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

Q. Okay.

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

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

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

number 23.

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

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

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

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

patients.

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

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

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

Q. All right. .

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

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

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

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

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

MR. KASSIN: Yeah.

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

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

MR. SEHAM: Okay. Thank you.

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

(OFF THE RECORD)

BY MR. KASSIN:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

review.

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

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

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

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

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

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

So the calculated concentration in the middle of the page was 7.7664, expected concentration was 8. So this is very close. And the calculated ion ratio was 30.86 percent, which is within ratio. We've got checkmark as being okay, it's within 20 percent. Return to the next page for the chromatograms. Next page, there we go. Inside the top row of this is the PEth 1 and 2. The lower chromatograms are internal standard, and they pass all peak appearance criteria.

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

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

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

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

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

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

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

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

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

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

reproducibility in the testing process?

A. Well, they have to match with regard to low, medium, or high on the screen compared to the confirm. Well, that's a very subjective thing. All right. Well, at the -- at the end of the day, one of the parameters that is calculated in a -- in a validation package is -- is -- is this figure called the uncertainty. And so the uncertainty is this procedure that the quality management team goes through where they evaluate all the different sources of uncertainty or precision, if you will, accuracy and precision, all the way from, you know, what's the uncertainty of the pipettes that are being used to put in the -- in the internal standard. What's the accuracy of the -- or what's the precision and accuracy of the quantitation of the controls over a period of time.

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

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

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

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

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

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

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

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

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

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

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

Q. Okay.

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

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

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

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

A. No.

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

THE ARBITRATOR: Sure.

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

THE ARBITRATOR: Okay.

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

could reconvene at your direction.

(OFF THE RECORD)

THE REPORTER: We're back on the record a t 2:01 p.m.

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

MR. SEHAM: Yes.

THE ARBITRATOR: Cross examination of Dr. Jones?

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

CROSS EXAMINATION

BY MR. SEHAM:

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

A. Yes.

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

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

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

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

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

A. With regard to urine testing, yes.

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

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

Q. Okay. Try that --

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

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

A. That is correct.

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

A. Correct.

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

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

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

chemical methodologies?

A. That is not true.

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

A. Yes. And they adopted that over time.

Q. Well, they adopted --

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

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

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

Q. And that's a --

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

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

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

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

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

THE WITNESS: Okay.

BY MR. SEHAM:

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

A. Yes.

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

A. Correct.

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

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

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

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

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

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

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

MR. KASSIN: Okay.

BY MR. SEHAM:

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

A. Correct.

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

A. Correct.

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

A. Not true.

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

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

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

A. No, it's voluntary.

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

A. And pass a test.

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

A. No, they were not.

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

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

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

A. Right. Right.

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

A. Certainly, yes.

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

A. Our collector sites are our clients, and we

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

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

A. Yes.

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

THE WITNESS: Hold on one second.

MR. SEHAM: Yeah, sure.

THE WITNESS: It's the Amazon man.

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

THE WITNESS: I'm sorry.

MR. SEHAM: No, that's --

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

MR. SEHAM: No, that's fine.

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

BY MR. SEHAM:

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

A. Correct.

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

(Union Exhibit 1 marked for identification)

THE REPORTER: Just a moment.

MR. SEHAM: Okay.

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

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

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

resolved.

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

MR. SEHAM: Can you hear me now?

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

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

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

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

BY MR. SEHAM:

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

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

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

A. I would disagree with that statement.

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

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

ahead.

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

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

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

A. I do not agree with your statement.

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

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

Medical Branch.

Q. And how about Quest Diagnostics?

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

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

A. Yes.

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

A. University of Texas.

Q. Any other?

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

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

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

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

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

Q. Which ones?

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

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

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

Q. Is what --

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

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

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

MR. SEHAM: Okay.

THE REPORTER: Not the entire last question. Just

that part where you spoke during his answer.

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

THE REPORTER: Yes, the doctors answer is audible.

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

BY MR. SEHAM:

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

A. Yes.

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

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

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

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

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

Q. Okay. Why do you disagree with them?

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

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

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

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

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

(Union Exhibit 2 marked for identification)

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

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

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

A. Not this test.

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

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

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

A. Yes.

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

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

Burdette.

THE ARBITRATOR: Please.

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

THE ARBITRATOR: Okay.

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

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

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

MR. KASSIN: Mr. Seham now --

MR. SEHAM: They're questions.

MR. KASSIN: -- this is all speculative.

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

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

THE ARBITRATOR: Okay. Let me --

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

THE ARBITRATOR: -- yes.

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

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

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

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

you'll let me.

THE ARBITRATOR: Okay. Go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

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

THE ARBITRATOR: Yeah. I mean --

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

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

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

BY MR. SEHAM:

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

A. Correct.

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

A. On average, yes.

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

to obtain a negative?

A. On average, about four to seven days.

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

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

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

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

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

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

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

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

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

A. Yes.

Q. Can you explain that?

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

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

quantitative value in the sample change over time?

A. Yes.

Q. It does?

A. Yes.

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

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

Q. Okay.

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

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

A. Exactly. Yes.

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

to 15 percent drop in quantitative level?

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

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

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

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

A. Say that again, please?

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

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

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

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

(Union Exhibit 19 marked for identification)

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

A. It looks familiar, yes.

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

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

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

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

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

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

A. Yes.

Q. Okay.

A. Yes.

(Union Exhibit 7 marked for identification)

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

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

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

THE ARBITRATOR: Okay. Well --

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

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

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

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

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

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

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

THE ARBITRATOR: Okay.

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

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

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

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

MR. KASSIN: No, sir.

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

THE WITNESS: Maybe 10 minutes.

THE ARBITRATOR: Okay.

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

THE ARBITRATOR: Sure, that's fine. Go ahead.
THE WITNESS: Okay.
THE ARBITRATOR: Okay. Emily, can you unmute? Are you there?
THE REPORTER: Yeah, it's all right. You'll be able to join easily using the same link. Well, we'll be able to right back in.
THE ARBITRATOR: Thank you. Okay. All right. In the meantime, could you put me and Mr. Seham and Mr. Kassin into a breakout room, please?
THE REPORTER: Yes. Hold on one moment.
THE WITNESS: So I'm -- I'm stepping out.
THE ARBITRATOR: Okay. Thank you. You can come back in. Okay.
THE REPORTER: If Emily is there, Arbitrator Burdette asked that -- that Arbitrator Burdette and the individual referred to as Howard Taylor and Lee Seham be placed in a breakout.
REMOTE TECH: Yes. I apologize I couldn't unmute myself. I'm doing so right now.
THE ARBITRATOR: Thank you.
MR. SEHAM: And if Rachel Samuda could also be included. Would that --
THE ARBITRATOR: That's fine.
MR. KASSIN: And Chris Puckett.

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

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

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

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

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

(OFF THE RECORD)

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

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

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

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

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

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

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

BY MR. SEHAM:

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

to validate those documents?

A. Yes.

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

A. Yes.

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

A. Yes.

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

A. Yes.

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

A. Yes.

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

A. No.

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

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

A. Could you repeat that question, please?

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

A. Yes.

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

A. Yes.

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

A. Was Whatman 903 paper.

Q. Okay. Who was the manufacturer?

A. GE is the current owner of that patent.

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

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

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

A. Guanidinium salts.

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

A. It's guanidinium salts

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

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

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

A. All kinds of testing including PEth.

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

A. Yes.

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

A. Roughly seven years or so.

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

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

communicate the instructions better.

Q. But the substantive content has not --

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

(Union Exhibit 11 marked for identification)

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

A. It seems familiar, yes.

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

A. Could you enlarge it just a little bit?

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

terms of the testing process?

A. It would be best practice, yes.

Q. Why is adherence to these collection protocols imperative?

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

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

A. Correct.

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

A. No.

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

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

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

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

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

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

Q. Did you publish that study?

A. Yes.

Q. Okay. Where would we find that study?

A. On the Internet.

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

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

(Union Exhibit 80 marked for identification)

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

A. No.

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

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

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

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

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

A. Yeah.

Q. Do you not recognize DBS System SA in this

context as the manufacturer of DBS Supplies?

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

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

A. Yes.

Q. Okay. And what does an SOP cover?

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

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

A. It covers everything.

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

A. Yes.

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

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

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

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

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

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

BY MR. SEHAM:

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

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

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

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

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

A. No.

Q. I didn't think so.

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

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

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

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

A. Yes.

(Union Exhibit 13 marked for identification)

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

A. There was a response that was sent back to

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

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

A. It looks familiar, yes.

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

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

(OFF THE RECORD).

(Union Exhibit 12 and 14 marked for identification)

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

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

A. Yes.

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

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

(Union Exhibit 15 marked for identification)

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

THE WITNESS: Yeah.

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

A. Yes.

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

A. No.

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

A. No.

Q. And the study involved 31 participants, correct?
A. I don't recall the numbers.
Q. All right. The collections were all performed by the same group of personnel, correct?
A. I don't recall the research project.
Q. Okay. The samples were all left to dry for three hours on a flat surface, correct?
A. I'd have to review that document again with that question in mind.
Q. But isn't that what the manufacturer recommends?
A. Yes.
Q. Yes, it is?
A. For -- for new -- for newborn, yes.
Q. Okay. Well, was this --
A. These were -- these were babies.
Q. So the USDTL does not require its collectors to dry the specimen for three hours, correct?
A. That is correct.
Q. Okay. And if you could move back to UX-12, Emily. And move down, I'm sorry, move down a little bit to item 8. So item 8, that we requested, "All documents setting forth required applicable standards for drying and storage of DBS samples at collection

site prior to shipment at USDTL"?

A. Yes.

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

A. Yes.

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

A. Correct.

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

A. Correct.

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

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

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

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

that had to get back to work.

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

A. Correct.

Q. Okay.

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

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

A. Repeat your question please.

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

A. Right.

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

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

Q. Okay.

A. If my memory serves me correct.

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

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

A. Yes.

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

A. Yeah. Yes.

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

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

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

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

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

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

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

(Union Exhibit 16 marked for identification)

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

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

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

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

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

THE ARBITRATOR: That's it. Okay.

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

A. Say that again, please.

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

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

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

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

A. That's correct.

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

A. No.

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

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

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

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

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

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

A. What was the question then?

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

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

Q. Thank you.

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

(Union Exhibit 17 marked for identification)

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

A. Yes.

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

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

Q. Okay --

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

Q. Would you --

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

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

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

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

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

A. Everything in the litigation package, absolutely.

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

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

Q. But --

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

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

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

Q. Thank you.

A. The answer is no.

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

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

Q. Was --

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

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

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

Q. Okay.
A. I don't recall that in the conversation.
Q. So it'd be an aero medical examiner by the name of Joseph Tordella, correct?
A. That is correct.
Q. All right. And did you discuss this issue with Mr. Kassin?
A. It was brought up briefly, and I was told like late last night that Tordella might be a witness on your behalf. Some of the documents that came over really late --
MR. KASSIN: He's getting into work product in terms of the company's case. I think the witness has answered his questions in terms of the initial question. So I mean, I object to him getting into any discussions we've had for preparation for this arbitration.
MR. SEHAM: I'll make it easy. The answer is sufficient. I just wanted to confirm the fact that there had been some pre-advisement of this issue. And I'm satisfied on the --
MR. KASSIN: Well, no, hold on a second.
MR. SEHAM: Okay.
MR. KASSIN: I don't think the board can conclude that. I think that's a misrepresentation of what I

just said.

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

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

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

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

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

THE ARBITRATOR: All right. Please proceed.

BY MR. SEHAM:

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

A. Say that again, please.

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

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

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

A. Yes.

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

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

A. Yes.

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

A. Could you repeat that question, please?

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

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

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

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

(Union Exhibit 18 marked for identification)

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

spoken to about this document?

A. I'm familiar with this document.

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

A. Correct.

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

A. Yeah.

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

A. Yes.

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

A. Those are the instructions, yes.

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

MR. SEHAM: The question you or the answer?

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

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

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

MR. SEHAM: Sure. All right.

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

(OFF THE RECORD)

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

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

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

THE ARBITRATOR: Okay.

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

filter paper or the collection card.

THE ARBITRATOR: Okay.

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

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

BY MR. SEHAM:

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

A. I would not say imperative.

Q. Why is it --

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

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

specimen transport bag?

A. No.

Q. No.

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

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

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

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

A. That's correct.

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

fingertip came into contact with the filter paper, correct?

A. There could be one explanation, yes.

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

A. I'll disagree with that.

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

A. No, I don't.

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

A. Right.

Q. All right.

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

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

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

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

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

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

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

BY MR. SEHAM:

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

A. I disagree with that statement.

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

A. I disagree with that statement.

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

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

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

A. No.

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

A. Irrelevant.

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

A. Of course, it affects the homogeneity, but for the purpose of the test it's irrelevant.

Q. What is the duration of drying time, that USDTL has determined is necessary to ensure the samples' reliability?

A. Could you rephrase that question please?

Q. I'll ask it again. What is the duration of drying time that USDTL has determined as necessary to ensure the samples reliability?

A. We request that the specimen be placed in the drying box and the box is not airtight. And so once it's in there, it's got all day and during the entire shipment time to dry. And so the primary concern that we have is the fixing of the blood-borne pathogens, not some production or decomposition of the PEth.

Q. Well, isn't it true that USDTL has

recommended a one-hour drying process?

A. When we were beginning, yes. We were -- we did not have the drawing box to begin with. And for the newborn toxicology, those procedures are written for the workflow in a -- in a nursery. So you get the heel sticks from the babies and they have these little cardboard supports that you can hang your heel sticks and so a nurse can go through and get the heel sticks and -- and -- and put those on the little support. And then she can go and do whatever she needs to do. And so whenever they are talking about, you need three hours to dry, there's just -- they don't want the nurse to come back in an hour and 15 minutes and one of them still be damp. They just put out three hours and it's been dry by then. And then they can collect them up, stack them up, and send them down to be shipped up to the laboratory.

Q. I'm going to object and move to strike the question was isn't the -- hasn't USDTL mandated a one-hour drying time?

A. And that was -- I'm leading up to that and there's a -- that was the background to it.

Q. Sir, I've objected. Sir, I've objected and hopefully counsel will let you know when there's an objection, we have to wait for the arbitrator to

respond and you just can't bulldoze over an objection.

THE ARBITRATOR: Yeah, I'm going to -- I'll sustain the objection, Mr. Seham and again, direct Dr. Jones to respond directly to his question -- to your questions in a simple a way as possible.

A. Okay. So the answer is yes.

Q. If Emily, if you could pull up Union Exhibit 19. And within that document, if you could move to the 3. And then if we could move down -- assuming that's the top, if we can move down a little bit. Okay. Okay. So yes, that's where I am. If -- if you look in terms of bullet points here, if you look at the second to last one where it reads, "Can we put blood spot cards into a sealed plastic bag?" And the answer is, "Before placing blood spot cards into a sealed plastic bag, you must" -- now everything after you is underlined and must is capitalized. "You must allow the card to dry for one full hour. Once dry, you can place dried blood spot cards in a plastic bag. But you must include, " and again, I note that must is capitalized. "Must include desiccant packs to reduce the moisture in the bag. It is highly recommended that the cards are placed in a non-plasticized envelope for transport when possible to avoid any issues with moisture." And my question, Dr. Jones is, is there any

other part of USDTL's FAQ where the answer is underscored as it is here?

A. That was the decision made by the marketing department to communicate to the collection sites who are of a non-technical nature. And so emphasizing best practices that was a choice that was made by the marketing director.

Q. Okay. And so where there -- the fact that the word must is capitalized --

A. Yeah.

Q. -- that in block letters, is that also a marketing decision as opposed to scientific decision?

A. Yeah. It's similar to the ethanol hand sanitizer. And that out of an abundance of caution to avoid having these questions coming up later, these are best practices that they should follow.

Q. Okay. Did USDTL conduct any validation studies related to the use versus non-use of desiccant patches?

A. No. No, we did not.

MR. SEHAM: If you look at Union Exhibit 11 and if you could go to the top of that. Okay. Yeah, okay. I actually, I guess I need to move to the very top of Union Exhibit 11. All right. So that -- and if you could expand it Emily, yeah just expanded it. I guess

--

THE REPORTER: Can you specify how you'd like it adjusted?

MR. SEHAM: No, I think that's good enough. I was looking to make it a little -- to magnify it a little bit.

THE REPORTER: If you can just direct me to which portion.

MR. SEHAM: I care only about the -- the depiction of the contents at the top, which ends with the A, B, C, D and the language to the left of that. Maybe a little -- I'd like to get the C and D and then, you know, we might be able to struggle through with this. That's fine, Emily. Thank you very much.

BY MR. SEHAM:

Q. Now, looking at the top here, the material provided by USDTL, it lists a dried blood spot collection supplies and drying box, the custody and control form. And then it depicts A and B to the right. Is that the intent of this document in this respect to depict at A and B those supplies that are provided, by USDTL to the collector?

A. Yes.

(Union Exhibit 20 marked for identification)

Q. Okay. And those supplies, and I guess the

witness is at a disadvantage here, but we provided actual bags to the arbitrator, which is Union Exhibit 20. But it looks to consist of what's referred to as the drying box, the dried blood spot card, two lens sets, an alcohol prep pad, and a seal. Is that a fair description of the contents of the collection package?

A. Yes.

Q. Okay. So the collection materials sent to the collector do not include a desiccant pack, correct?

A. No.

(Union Exhibit 21 marked for identification)

Q. Okay. If you could look at document Union Exhibit 21. I think we've seen this before. This is provided by USDTL as recently included in the September 24th, 2020 webinar, correct?

A. It looks familiar, yes.

Q. And if you can scroll down a little bit. Thank you. And it says no dry time. What is meant by no dry time?

A. You can put it in the drying box and move along. And you can put the tamper evidence, security seals.

Q. And you agree that you have no knowledge of how the specimen was stored at the collection site?

A. No, I do not.

Q. Okay. And how are the specimens stored at USDTL?

A. They're stored in the box and they're stored in a locked file drawer in boxes by year or by month rather, by month and year.

Q. Now, you've testified, I believe that it's only your laboratory and one other that is currently using DBS as a matrix or --

A. In this country, yes.

Q. So that other laboratory is performing commercial dried blood PEth testing?

A. No. He's -- you're talking about University of Texas?

Q. Correct.

A. University of Texas?

Q. Yes, sir.

A. No. Yeah. No, he's not doing it as a commercial entity. He is one of the testing locations for National Institute of Alcoholism and Alcohol Abuse Researchers. He's a resour- resource for them. And -- and they can conduct these tests for the researchers. We know him through the Research Society of Alcoholism. And that's how we got the collaboration to be available to do re-testing.

Q. If Emily, if we can move to Union Exhibit 19,

which is again the USDTL FAQ. And I want to go to the first page. And if you could go down a little bit. There we go. That's it. Stop please. That's fine. I'm looking at the bullet pointing towards the middle that says, "Are you aware of any other labs splitting specimens for PEth or sending two specimen cards filled with dried blood for testing". The answer is, "There --

A. Yeah.

Q. "There are no other labs that do commercial dried blood spot PEth testing, so there are no labs for comparison. Is that an accurate answer?

A. Correct, yes.

Q. In San Antonio -- I apologize. The laboratory you recently identified that's -- was it at UT San Antonio?

A. Yes.

Q. And what assay do they use for their testing?

A. They use a laboratory developed test that they've published numbers -- numerous times. I'm not aware of the specifics of their test, but it's rather similar to ours.

Q. What is the criteria applied -- you say you used that laboratory for confirmation?

A. No, we use the laboratory for re-testing. So

if a person has -- is refuting a result, we give them an opportunity to request for it to be sent out and so if we get the request, we can send it to them. At this point in time, that's the only other outside source. We can conduct the re-test in- house too, but sometimes that's perceived as a conflict to venture so they like to send it out to another lab.

Q. And what is the criteria that's applied in terms of UT San Antonio confirming a USDTL test result?

A. Could you repeat the question, please?

Q. What is the criteria for the re-test?

A. What do you mean by criteria?

Q. In terms of -- in terms of confirming or not confirming, is there -- for example, is there a specific cutoff applied during the re-test?

A. For any re-test, including University of Texas, San Antonio, they use their limit of detection. And so that's the standard practice with re-testing in that it either re-confirms or fails to re-confirm. And -- and that's the re-test answer.

Q. And the limit of detection for UT -- that's applied by UT San Antonio is four nanograms per milliliter, correct?

A. I'm not sure what their re-test limit of detection is.

Q. Okay. Would you agree that DBS has a shorter history than traditional matrices such as liquid blood, plasma, serum?

A. Yes, by and large. It's been around a long time in other fields. But in this utilization, it's -- it's rather a cutting edge.

Q. All right. Are you familiar with the term Hematocrit, sometimes referred to as HT, Hematocrit effects as applies to DBS testing?

A. Yes.

Q. All right. Could you define the term as you understand it?

A. Yeah. The Hematocrit is the percentage of the liquid versus the solids in simple terms. And so there's a very narrow range for humans to not be deathly ill. And during that range, for some assays, the Hematocrit variance can influence the outcome of a result.

Q. And are you familiar with the term matrix effect or ME?

A. Yes.

Q. Can you define that term as you understand?

A. Yeah. Matrix effect describes the effect that happens at the time that your analyte is entering into the mass spectrometer. And if there are an over

abundance of compounds in these little micro drops, as that little micro drop is evaporating in the inlet source, there is a charge that is applied to that droplet. If there's an enormous amount of some other something in that little droplet, it will hog all of the electrons and your compound may not get the electrons to become ionized. And so it hits the side of the detector and you'll never get to see it. So that would be an example of ion suppression.

You can also get an opposite effect called ion enhancement. And ion enhancement means that maybe that compound that's an enormous quantity on that little droplet as it's evaporating and gaining the charge, that compound may be very effective at grabbing that charge and then relaying that charge to your compound venture. So you get like this big response because more of your molecules have been ionized and that's detectable. So as a group, they're called matrix effects. And one of the elements of a validation package which you'll see in our validation package is that there are some recommended ways. There's a couple of different ways to do it, to evaluate your matrix effect. And for LC-MSMS, if specifically we're looking for -- for the ion suppression and ion enhancement, that's the main thing we're looking for.

Q. Did USDTL conduct any validation study on the impact of creatinine levels on quantitative analysis?

A. No.

Q. Would you agree that it is an essential -- well, let me skip that. Putting aside Mr. Kassin and any contacts you had with Delta leading up to this arbitration, did you have any prior contacts with Delta concerning the Danford test results, say in 2018 or 2019?

A. I don't think so. I don't recall.

Q. Okay. Did you have any knowledge of Mr. Danford having had a previous negative ETS result based on a May 1 collection, May 1, 2018?

A. Yes.

Q. Would you agree that an ETG positive result can arise from the incidental use of hand sanitizer or mouthwash?

A. Yes.

Q. Would you ever advise that the USDTL PEth test was for the purpose of resolving which of the two prior tests, an ETS or ETG, provided the correct result, originally?

A. Could -- could you repeat that question, please?

Q. Yes. I will definitely repeat that because I

fumbled that horribly. Were you ever advised that USDTL's PEth test was for the purpose of resolving which of two prior tests originating from a May 1 urine collection in 2018, the ETS or ETG provided the correct result?

A. For this specific case or as a general policy?

Q. No, for this specific case.

A. No. I was not aware of that, I don't think.

Q. Would you agree that PEth cannot determine the time, dose, or frequency of use?

A. I agree.

Q. Would you agree that there's no correlation between the quantitative result of a test and the level of consumption?

A. That is correct.

Q. Okay. So for example, if someone had a 100 nanogram per milliliter test result, that does not reflect a consumption level five times higher than 20 nanograms per milliliter, correct?

A. Correct.

Q. On what do you base the cut off level of 20 nanograms per milliliter?

A. It was the result of selecting criteria that would result in a service that was useful for the

substance use treatment field. So it was -- it was selected based on the previous research that existed at the time. And extrapolate -- extrapolating that to -- we need to achieve certain criteria, then it would be a useful product. As I mentioned earlier in my testimony about the evaporative light scattering detector, that technique was in the thousands of nanograms per meal. And so basically you're talking about people at that level, what they were doing their studies originally, you're talking about people in a alcohol rehab situation, going through DTs. You don't need a test, you know, to tell you that they've been drinking. They're going through DTs.

Under these circumstances like with the HIMS program or the state physician health programs, they -- they need more information so a one thousand cutoff is not useful to them at all. So based on the data at the time, we -- we hypothesized that 20 was an appropriate cutoff target. We worked on that. The NIH, they approved to fund us for that. And -- and since then, a couple other laboratories have also adopted that as a cutoff just because it works well in this environment.

Q. What does the term LOD refer to?

A. Limit of detection.

Q. And what -- could you explain that?

A. The limit of detection is a concentration that has been determined one of two ways. It can be determined statistically or empirically by examining concentrations lower, lower, lower. The -- the -- the easy way to envision this in your mind's eye is that if you -- if you start with a certain concentration and keep dropping it and you do this result in triplicate, at some point you will end up to where all three of those, because it's getting so low, you're not able to properly identify your compound of interest. And so the point, the highest point to where you have two out of three of those replicates identifying your compound of interest, that is your empirical limit of detection.

Now, in a routine production laboratory running many, many samples, you know, we don't have time to do that academic exercise. And, you know, you test 10 and then 5 and then 1 and then 0.5, and 0.25 and ad nauseum. So when we target our limit of detection, we have a good idea of where we need that to be and then we verify that our LOD is at least that low. And so then we re-verify that every year with a process that we call annual verification. But in a nutshell, that's the limit of detection. It's the lowest value that you can accurately identify the compound.

Q. Would you treat an eight nanogram per

milliliter result -- or would you represent that result, rather, as indicative of non-abstinence?

A. At this point, I would have no opinion on that. Eight is our -- do you want me to explain or you got other questions?

Q. No, no. I just want you to answer the question. Yes or no?

A. Repeat the question, please.

Q. Would you have any concern about representing an eight nanogram per milliliter PEth re -- PEth test result as establishing non-abstinence?

A. Yeah. I would not use eight to establish non abstinence.

Q. Would you use 9 or 10?

A. No. I'd use 20.

Q. And why would you not use 9 or 10?

A. We don't have the data to -- to demonstrate that we're not picking up other things other than beverage alcohol consumption.

Q. Has USDTL ever altered its cutoff level in terms of what it designates as a positive?

A. Yes.

Q. Okay. Could you tell us about -- did you have a lower cutoff before or a higher cutoff?

A. We -- we -- we offer a lower cutoff for our

researchers. Because the researchers really don't care. They want the number and then they're going to do their statistics with the numbers as they fall. So if we have a number, they want the number. So the number 8 that you're referring to as a value, called our limit of quantitation. So where the limit of detection is the -- is the lowest amount that we can day in and day out identify that analog of -- analyte of interest. The limit of quantitation which is typically something a little higher, that number is the lowest number that we can accurately identify and quantitate. So that's why it's called the limit of quantitation.

Now we have a -- a regulatory requirements specifically by the State of New York. And I don't know why they have this, but at the end of the day, I -- I agree with it because it -- it -- it's just a good idea and a best practice. But whatever cutoff a laboratory chooses to operate in, we need to demonstrate that our limit of quantitation is no higher than 40 percent of that. So that means that if my cutoff is at 20, I need to demonstrate my limit of quantitation is no higher than 8. And so that's the target that we're going for. Now the case of researchers, we give them the 8 because that's where we

can reliably quantitate and identify.

There will be certain instances where the client calls and demands that we look at it at a lower number. And we try to talk them out of it and say we shouldn't look at below 20. But as, you know, they're the client. And so sometimes we -- we -- we oblige them with their question. It's occasionally, it's not often, but occasionally we will go back and re -- not actually re-analyze because the analysis has already been done. But we will re-evaluate that specimen using the limit of quantitation to demonstrate whether was something there or whether something was not there. To help them because at the end of the day, they're probably looking at multiple pieces of evidence or maybe this one piece of -- of information is not clear, they're trying to get clarity. And sometimes that little nugget, even though it's maybe non standard, can be helpful -- helpful to them in working with their subjects.

Q. Would you ever -- I hear you talking about researchers and so I want to distinguish -- the coming question is to distinguish --

A. Yeah.

Q. -- the researchers. Would you ever treat an 8, 9, or 10 as a positive for forensic purposes?

A. With extreme caution. I would -- I would urge -- I mean, the client is an adult and they can do what they want. But I would urge them to be very careful with low level results like that.

Q. I guess my question to clarify is, would you ever characterize in your communications to your client that 8, 9 or 10, was a positive result for forensic purposes?

A. I would say no. I would say that, that level would not be consistent with the binge drink in the last two to four weeks. Depending on other information, maybe we're looking at a much longer timeline and that would make sense that the illumination would fit into a pattern that would fall between 8 and 20. So it might be used to answer some of those questions, but just out of the blue, hey, Joe, run the sample of 8, I would call him back and say, you know what, we don't do that out of the gate. And so we need to refer to the standard cutoff of 20.

MR. SEHAM: Thank you. I do need a five-minute break. Is that acceptable, Arbitrator Burdette?

(OFF THE RECORD)

THE REPORTER: Okay. Back on the record at 5:03 p.m.

(Union Exhibit 23 marked for identification)

MR. SEHAM: Okay. Emily, if you could bring up or whoever is assisting at this point. If you could bring up the Union Exhibit 23. And within that, just for reference to the arbitrator this is a -- we can scroll down to the bottom of the first page.

BY MR. SEHAM:

Q. Okay. So this is a document that we received in res -- so that we don't get into the objection exchange that we've previously, indicated by the Bates stamp at the bottom, this is a document that we received in response to our subpoena as referred with Bates USDTL 001106, and I would ask if the administrator could turn to page 14 of this document which would be Bates stamped 1119. Yeah. Okay. And if you could just scroll down a little and probably come right back up. But I just want to confirm that I have the right page number. Yeah. Okay. Thank you. And if you can move back where you were, which was actually fine. Would you agree with me that this document reflects a urine specimen collected from a Michael Perez on December 7th, 2015 and tested by USDTL?

A. Yes.

Q. Okay. And the test indicates ETS positive of 36 nanograms per milliliter?

A. Yes.

Q. Okay. Assuming that Michael Perez was a Delta pilot in a HIMS program who was required to maintain abstinence from alcohol, should this test result had been the basis either for his termination or mandatory re-entry into rehabilitation?

A. That's kind of outside of my call. It depends on the policy of the -- of the employer.

Q. Let me rephrase it then. Is there any room for doubt in your mind as to whether this test result dispositively establishes non-abstinence?

A. This result interferes with being able to confirm abstinence which is kind of a little slightly different way of looking at that.

Q. I think it's a very different way of looking at it, but so, is your answer that -- I prefer answers to my question. My question was, does this test result dispositively establish non-abstinence?

A. Does this test result indicate non-abstinence?

Q. What I'm saying -- again, you keep changing my question, but maybe I'll make it an easier question.

A. But I'm trying to understand it. So if you can rephrase it somehow?

Q. Right. Right. So I'll rephrase it. I'll do

that. Could there be an explanation -- I'm sorry, the cleaning people are coming through, so I'm just going to close my door here. Could there be an explanation for this test result other than non-abstinence?

A. Yes.

Q. Okay. Did anyone from Delta or Ms. Gable -- Michele Gable consult with you about this test result?

A. I do not recall.

Q. Do you recall whether a PEth test was administered in response to this test?

A. There was a lot of testing that was done on Michael Perez that I was made aware of preparing these documents to send over to you. But at the time, I don't recall being involved in deciding what tests need to be ordered and what test not to be ordered.

MR. SEHAM: You could please turn to page 10 of the same PDF document, Emily -- or is it still Emily or we have -- is it Damien now whose --

REMOTE TECH: It's still me.

MR. SEHAM: Okay. Great. So I'm looking for page 10.

REMOTE TECH: You're on page 10.

MR. SEHAM: Thank you. And if you can move -- I want to look a little further down. Thank you. Perfect.

BY MR. SEHAM:

Q. Okay. So page 10 of the same PDF document, do you see this document concerns a urine specimen collected from Michael Perez on 12/17/2015, correct?

A. Yes.

Q. And this reflects an ETS positive at 20 nanograms per milliliter, correct?

A. 28.

Q. 28.

A. Yes.

Q. I'm sorry. If I've said something else, I misspoke. 28 nanograms per milliliter. And could there be an explanation for this ETS positive result other than non-abstinence?

A. Yes.

Q. Okay. Do you recall if anyone from Delta or Ms. Michele Gable consulted you with respect to this test result?

A. I -- I do not recall.

Q. Do you recall whether a PEth test was administered in response to this test?

A. I do not know.

(Union Exhibit 34 marked for identification)

Q. Now, if you could bring up the Union Exhibit 34, Emily? And I'd like to go to page 2. And this is

a Quest Diagnostics report indicating an ETG result of 138 nanograms per milliliter at the very bottom of the page, and a creatinine of 264.2 milligrams per deciliter. Based on the test result here just in terms of measurement, is a possible explanation for this result other than non abstinence?

A. Could you scroll it down so I can see the result?

Q. Yeah, I'm sorry. It's 138 at the bottom. I was looking at my hard copy.

A. So this was 138 ETG?

Q. Correct.

A. So yes, there could be alternative explanations other than beverage alcohol consumption.

Q. Okay. And creatinine measurement, is that a relevant consideration in your view?

A. Yeah. That plays into it as well, yes.

Q. How does creatinine play into it?

A. One way that you can evaluate these from a higher level is to normalize the result to a creatinine of 100, which is like an average creatinine value. People's creatinines in their urine can vary widely in the run of the day. You can see this personally in that your first void in the morning is typically darker than your last void at night and that tends to be a

typical trend with much big -- there will be differences. But your state of hydration can exist in -- in a wide acceptable range. So what does this mean? The more hydrated your urine is, the lower the concentration, the more concentrated your urine, obviously, the higher the concentration. So by normalizing this back to a 100 creatinine is one way to take a look at this. Some people just do the straight up ETG divided by creatinine, but that kind of gives numbers that I'm not accustomed to looking at. So I prefer to do the -- to do the 100.

Q. Okay. And what impact would that --

A. But I don't think there's any standard on that either, so --

Q. Okay. Well, applying the approach you described, the normalization using the 100 standard creatinine, what would that do to the actual value of the test?

A. It would drive it low. So in this case, if I were interpreting this, I would say it's positive. It's supposed to be negative, but it's positive. But it's 138, which is a low value to start with. And the creatinine being elevated like it is, kind of just mental math, I'm cutting that in half, so now we're at 60, 70, 80, somewhere in there. And so this is -- a

reasonable explanation would be the use of other products containing ethanol as a reasonable explanation.

Q. So I'm sorry, when you say 60, 70, 80, that would be --

A. Grams per mil per 100 creatinine.

Q. Okay. So once you apply the creatinine -- .

A. Yes.

Q. -- normalization formula that you accept, that would effectively reduce the real value of the ETG that's the 60, 80 --

A. I would call it the normalized value, yes.

Q. Okay. Now, if we could turn to -- go back, please, Emily, to Union Exhibit 23. And I'm looking for page 5. I guess if that's page 5, that should probably -- if you could scroll down a little bit. Okay. So this would be Perez -- Michael Perez test result for a blood specimen collected on March 16th, 2016, correct?

A. Yes.

Q. And it's reported as a positive, correct?

A. Yes.

Q. And the cutoff applied was 8?

A. Yes.

Q. Okay. And the positive was based on a

quantitation of 10 nanograms per milliliter?

A. Yes.

Q. Do you recall why the lower cutoff was applied in this instance?

A. We were requested by the client to do so.

Q. For this positive result, is there a possible explanation other than non-abstinence for this result?

A. With PEth, it's kind of hard to tell at this point. The data's limited on this subject. And so I would lean towards there may be other explanations. It's not as clear as it is with the ETG, ETS. But what is clear is that regardless, we are unable to confirm the abstinence of the donor, which again is asking that question in a slightly different way. That -- that -- this is kind of what we had -- this is the abstinence testing, is that we need to confirm their abstinence and if they were using Purell when they're not supposed to use Purell, then they're interfering with our ability to confirm their abstinence.

Q. Did anyone from Delta consult with you about this test result?

A. I don't recall.

Q. Okay. And if you could turn to -- Emily, if you could turn to page 7 of UX23. Okay. Here there's a reflected a reconfirmed and it's based on an LOD of

two.

A. Yes.

Q. And I guess if we could scroll, kind of go to the top of the page. All right. So this was an internal re-testing?

A. Yes. We were requested by First Lab to re-test the specimen.

Q. And so you reported this back as a confirmed positive?

A. We reported this back as a reconfirmed.

Q. Emily, if you could scroll down so we can see the bottom of the page. Okay. Let's stop there.

A. Reconfirmed.

Q. Reconfirmed.

A. The rules for re-test are different than first-time through.

Q. Okay.

A. And so this is following the rules of re-test.

Q. But what you were reconfirming in this case was a positive test result, correct?

A. That is correct.

Q. And if you can go to page 3 of this PDF document, UX23.

A. This is fingernails.

Q. Correct, right. So this is a collection of fingernails that was conducted on May 4th, 2016, correct?

A. Yeah.

Q. I'm sorry, I didn't hear your answer.

A. I -- I was waiting for it to scroll up so I could see more.

Q. Oh, yeah. There you go.

A. Okay. So fingernails. So this appears to be a fingernail test collected in May of 2016.

Q. And then ETG methodology was applied, correct?

A. Correct.

Q. What can you tell us about the use of -- here -- here we're doing a ETG with nails as opposed to urine. Why would the laboratory be using nails -- fingernails, as opposed to urine as the testing matrix?

A. Well, because, number one, the client asked us to. Number two, ETG and hair and fingernail are -- are good alternative specimen types to help try to fill in gaps on the alcohol use behavior of -- of their subjects, yes. So this is yet one more tool, that's at their disposal to request. Has different level of thresholds to positivity, has different disadvantages as far as quantity of specimen, but it's one more tool.

Q. And what's the -- I think you said that the look-back for PEth is about -- did you say two to four weeks?

A. Yes. Up to two to four weeks following chronic excessive drinking.

Q. And the look-back for urine ETG is what?

A. You'll see it reported at up to two to five days following chronic excessive drinking. But the five days, there was like this one guy in a withdrawal program and the literature is now taking five. My experience with ETG and urine is more like all the other drugs that were typically testing for, which some of them are Glucuronides as well, and two to three days is kind of what you can depend on day in and day out.

Q. The -- and what's the look-back for an ETG for nails?

A. Up to approximately three months.

Q. I forgot that -- I did not hear the first part of that range, from what?

A. I said up to approximately three months.

Q. Is there a lower level expectation, is it one to three months or two to three months?

A. One day to three months.

Q. Okay. And Mr. Perez's negative nail test, based on this May 2016 collection was deemed to

overrule the prior positive tests for ETS, ETG and PEth, isn't that correct?

A. No, that is not correct.

Q. Mr. Perez was not fired, correct?

A. I'm sorry, could you repeat that question, maybe I misunderstood your question.

MR. KASSIN: So that's nothing within the realm of Dr. Jones's knowledge of this. That's not an appropriate question whether he was retained or fired.

MR. SEHAM: If he doesn't know, then he can answer he doesn't know.

MR. KASSIN: But he's not a decision-maker on something like that.

MR. SEHAM: I don't know that one way or the other. I'm not -- again, we're having counsel testify. The reason for these questions is for the witness to answer it. And if he doesn't know or was not involved, that's for him to answer.

MR. KASSIN: But he is qualified to discuss the testing issues. He's not qualified to talk about employment issues.

THE ARBITRATOR: Okay --

MR. SEHAM: It really depends on the facts whether Delta talked to this man or not. I mean, again, I think counsels testifying and I'd asked him not to. In

any case, let me ask the question again because asked me to ask the question again. I'll ask it in perhaps more accommodating way.

BY MR. SEHAM:

Q. Do you have any knowledge as to whether Mr. Perez's negative nail test for this May 2016 collection was deemed to overrule the prior positive tests for ETS, ETG, urine and PEth?

A. Okay. So I've misunderstood your question when I spoke too quickly earlier. The answer to your specific question is I have no knowledge of the outcome of Mr. Perez.

Q. That's --

A. I don't know what was used one way or the other.

Q. Okay. So no -- no one from Delta or -- or Michele Gable, no one consulted you in terms of the testing strategy to be applied to Michael Perez in terms of abstinence determination?

A. I -- I do not have any specific recollection of that, no.

Q. Okay. Before you were talking about an article that you had published, do you recall during your earlier testimony referencing a website or an Internet article that you had published?

A. Yes.

Q. Okay. Could you -- we're having problems finding it and I wanted to know whether you could identify it for us any better.

A. Let me -- I hope I don't lose you. If I lose you I'll jump right back in. I'll minimize the screen. Okay. Did I lose you?

MR. SEHAM: No, you did not.

THE WITNESS: I have pulled the paper up. If you let me share my screen, I can show it to you.

MR. SEHAM: I'd rather just --

THE WITNESS: Would you want me to email it to you?

MR. SEHAM: I'm sorry?

THE WITNESS: Would you like for me to email it to you?

MR. SEHAM: That would be lovely if you would, yes. Thank you.

THE WITNESS: I'd be glad to, give me one second. Let me get the link here. Tom, you want me to CC you on that?

MR. KASSIN: Yes, please.

MR. SEHAM: Okay. You're -- you're ready for my address?

THE WITNESS: No, I've got it, I believe.

MR. SEHAM: Okay. Very good. Well, thank you.

Thank you. I think we're at 5:26. With the permission of the arbitrator, we're going to stop at 5:30. I'm about to go into a series of questions that are related. So it'd be my preference to stop now.

THE ARBITRATOR: Okay. And then we will pick back up. What time do you want to start in the morning?

MR. KASSIN: Arbitrator Burdette, our witness, that we're trying to accommodate is available at 9:30 East Coast time, 8:30 your time.

THE ARBITRATOR: Okay.

MR. KASSIN: If we can start up at 9:30. That would be awesome.

THE ARBITRATOR: Okay. Then that's what we'll do. We'll start at 9:30 Eastern, 8:30 Central Time tomorrow morning and we'll pick back up with the company's witness out of order, and then we'll get back to Dr. Jones when we can do that after the company's next witness. Subject to his availability as well.

THE REPORTER: Off the record at 5:27 p.m.

(Whereupon the proceeding concluded at 5:27 p.m.)

* * *

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

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