

**FDA Webinar: Clinical Laboratory Improvement Amendments (CLIA) Waiver
Applications Final Guidances**

Moderator: Irene Aihie

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Operator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question-and-answer session of today's conference. At that time, you may press Star 1 on your phone to ask a question. I would like to inform all parties that today's conference is being recorded. If you have any objections you may disconnect at this time.

I will now turn the conference over to Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education.

On February 25, the FDA issued two Clinical Laboratory Improvement Amendment waiver applications related to final guidance documents. The recommendations for Clinical Laboratory Improvement Amendment of 1988, Waiver Applications for Manufacturers of In Vitro Diagnostic Devices, final guidance which provides recommendations for CLIA Waiver Applications for in vitro diagnostic tests. And the recommendations for Dual 510(k) and CLIA Waiver by application study final guidance describes study design for generating data that may support both 510(k) CLIA and CLIA waivers.

Today, Peter Tobin, Chemist in the Office of In Vitro Diagnostics here in CDRH, will present the overview of the two guidance documents. Following the presentation, we will open the lines for your questions related to the information provided during the presentation. Now I give you Peter.

Peter Tobin: Good afternoon everyone and thanks for joining us for today's webinar on Clinical Laboratory Improvement Amendments of 1988 or CLIA Waiver Applications Final Guidances. Next slide please.

This webinar covers two complementary final guidances for CLIA Waivers. Throughout the presentation, I'll refer to the recommendations for Clinical Laboratory Improvement Amendments of 1988 -- CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices Guidance -- as the CLIA Waiver Guidance. And the recommendations for Dual 510(k) and CLIA Waiver by Application Studies Guidance as the Dual Guidance. Next slide please.

Here's the agenda for today's webinar. I'll start off with some background and then cover the highlights for each final guidance including the updated Section 5 of the CLIA Waiver Guidance. After my presentation, there will also be plenty of time for questions. Next slide please.

The first objective for today's webinar is to understand the two CLIA Waiver pathway options covered in the final guidances. The stepwise CLIA Waiver pathway -- which is the CLIA Waiver Application following CLIA approval -- and the Dual Submission or Dual Pathway -- which is a combined 510(k) CLIA Waiver Application following a Pre-Submission. And the second objective is to understand the FDA's current thinking on study designs for both pathways. Next slide please.

Okay let's get started with the background. Next slide please.

As background for discussing the final guidances, I'm going to cover the

following four areas over the next few slides: the CLIA Waiver Statutory Criteria, 21st Century Cures requirements to update the 2008 CLIA Waiver Guidance, CLIA Waiver Pathways addressed by the two final guidances, and the draft CLIA Waiver guidances issued in 2017 and 2018. Next slide please.

Here is the CLIA Statutory Criteria for Waiver as modified by FDAMA. In today's presentation, I will concentrate on Clause A shown in bold, that a test employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, because this is the clause that is primarily used and is the focus of both final guidances. Next slide please.

Twenty-first Century Cures requires an update to Section V of the previous Final CLIA Waiver Guidance issued on January 30 2008 to include the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy. The Final CLIA Waiver Guidance issued in February 2020 addresses this requirement and I'll be going into more detail about this later in the presentation. Next slide please.

There are currently three pathways to a waived categorization. In the first pathway shown at the top of the slide, if a test is cleared or approved for one of the nine test sites listed in 42 CFR 493.15(c) such as uranalysis dipstick or non-automated fecal occult blood, or if the test is cleared or approved for home use, then the test will be categorized as waived following clearance or approval. Otherwise, following clearance or approval, tests may be categorized either as moderate or high complexity according to the CLIA Categorization Criteria listed in 42 CFR 493.17.

The two CLIA Waiver Pathways that are addressed by the final guidances are shown in the bottom half of the slide. The stepwise CLIA Waiver Pathway is covered in the CLIA Waiver Guidance. In this pathway, a manufacturer first obtains clearance or approval and a moderate categorization prior to submitting a CLIA Waiver Application. In the Dual Pathway, a manufacturer first submits a Pre-Submission to inform FDA that it plans to submit a Dual submission. This Pre-Submission provides a forum for the applicant and the FDA to discuss

proposed study designs for the Dual Submission.

Following the Pre-Submission, the manufacturer submits a complete 510(k) and CLIA Waiver Application in a single submission package. The Dual Guidance addresses recommendations for study designs for this CLIA Waiver Pathway. Next slide please.

Previous drafts of both CLIA Waiver Guidances were first issued in November 2017. The Draft CLIA Waiver Guidance was entitled "Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988, (CLIA) Waiver Application for Manufacturers of In Vitro Diagnostic Devices," and included draft revisions to Section V of the 2008 CLIA Waiver Guidance. I'll refer to this draft guidance as the Select Updates Guidance.

The Draft Dual Guidance had the same title as the current final guidance. Based on comments received and multiple meetings with stakeholders, significantly revised drafts were issued in November of 2018. Next slide please.

Now we'll go over highlights of the CLIA Waiver Guidance. In the next two slides I'll provide an overview of the final CLIA Waiver Guidance, and then I'll go into more detail about the updated Section V. Next slide please.

As I mentioned earlier, the CLIA Waiver Guidance provides study design recommendations for the stepwise CLIA Waiver Pathway where a CLIA Waiver Application follows a cleared or approved marketing submission. We only received minor comments on the 2018 Select Updates Draft Guidance so significant changes were not made between this draft and the final CLIA Waiver Guidance. Some limited edits were made to address the minor technical comments that were received and to incorporate Section V from the 2018 Select Update Draft Guidance into the 2008 CLIA Waiver Guidance. Next slide please.

CLIA Waiver focuses on two questions from the CLIA statutory criteria; one, is the test simple; and two, does the test system have an insignificant risk of

erroneous results in the hands of intended users? Over the next few slides, I'll briefly describe recommendations in the final CLIA Waiver Guidance for how a test manufacturer can address these two questions. Next slide please.

First, a test should be simple to use. CLIA does not have requirements for the education or training of test operators in a facility with a CLIA Certificate of Waiver, so CLIA-waived tests should not require laboratory experience or training in order to generate correct results. CLIA-waived tests should be automated or simple unitized test systems. Simple tests should use direct unprocessed samples and not require complex reagent manipulation. The test system instructions also need to be simple, so we recommend that CLIA-waived tests include a Quick Reference Guide for test operators that is written at a seventh-grade level.

Another important aspect of a simple test is that it should have simple to interpret and easily actionable error codes. The test should not require complex troubleshooting by the CLIA-waived user and should have easy to read test results. Next slide please.

In order to demonstrate that the likelihood of erroneous results by the user is negligible, we recommend that the candidate test manufacturer first conduct a comprehensive risk analysis. We recommend ISO 14971 as a resource for this analysis. Potential sources of error to consider include operator errors, specimen and reagent integrity, and environmental factors. Next slide please.

In order to mitigate risk, fail-safe and fail rate mechanisms should be included in the design of the test. Fail-safe mechanisms are features that prevent the return of erroneous results such as temperature lockout mechanisms that prevent the system from running a test or returning results when the temperature is out of range. Failure rate mechanisms alert the operator when a condition has occurred that may lead to erroneous results. For example, indicator desiccants that alert when the agent has been stored outside recommended storage conditions. Next slide please.

Flex and/or validation studies should be conducted based on the risk analysis, and the results of these studies should demonstrate that the test system is robust to environmental and usage variation, or that risk mitigations such as fail-safe mechanisms are effective.

For example, if the test procedure calls for the addition of three drops of reagent in one step, then flex or validation studies should evaluate whether correct or erroneous results are returned if two few or two many drops are added. Next slide please.

Test instructions that are intended for untrained operators are important components of simple CLIA-waived tests. As I mentioned previously, since there are not clear requirements for the education of operators in settings with a CLIA Certificate of Waiver, we recommend that the test instructions intended for these operators be written at no higher than a seventh-grade reading level. We recommend that CLIA-waived devices include a Quick Reference Instruction -- or QRG -- and an Operator's Instrument Manual if the test system includes an instrument.

The Quick Referent Guide -- or QRG -- is a short -- usually one or two page -- version of the test instructions preferably laminated and attached to the test system. It is intended for the untrained operators and contains the step-by-step instructions needed to perform the test with a negligible likelihood of erroneous results.

An Operator's Instrument Manual is a short version of the instrument manual that is intended for untrained operators and includes instructions for start-up of the instrument, long-term maintenance including calibration, if applicable, error codes, etc. The calibration mentioned here, if applicable, should be simple and automated, such as simply inserting a calibration cartridge when prompted by the instrument at a certain time intervals.

There has been some confusion as to whether the package insert for waived devices needs to be written at a seventh-grade reading level, so we clarified in

the final CLIA Waive Guidance that the package insert is intended for the medical professional prescribing the test rather than the untrained operator performing the test. And so the package insert does not need to be written at a seventh-grade reading level. Next slide please.

In the next few slides, I will go into more detail about the updated Section V, “Demonstrating Insignificant Risk of an Erroneous Result – Accuracy. Next slide please.

The updated Section V focuses in on study design aspects directly related to meeting the statutory criteria for CLIA Waiver. Specifically, it emphasizes validating that the accuracy of the candidate test is not meaningfully impacted by differences between non-waived and waived use, including: user training and experience, testing environment, or patient populations. General information on test accuracy issues not specific to CLIA-waived tests has been replaced with references to FDA-recognized consensus standards.

Please note that the standards referenced in the guidance are simply examples of appropriate FDA-recognized consensus standards that may be used. Please see the FDA Recognized Consensus Standard Database for the current edition of the standards referenced in the guidance, and whether recognition of the current edition is partial or complete. A link to the FDA Recognized Consensus Standard Database is provided on Page 3 of the CLIA Waiver Guidance. For additional information about the use of consensus standards, please see the FDA Guidance “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.”

In addition to the general information on study designs available in FDA-recognized consensus standards, specific examples of successful CLIA waiver study designs can be found in publicly posted CLIA Waiver Decision Summaries. Next slide please.

Before getting into the details of the updated Section V, I want to mention two definitions that are used in both final guidances. An Untrained Operator or

Waived User -- is a test operator in waived settings who has limited or no training or hands-on experience in conducting laboratory testing. And a Trained Operator or Moderately Complex Laboratory User -- is a test operator who meets the qualifications to perform moderate complexity testing (42 CFR 493.1423) and with previous training in performing the test.

These definitions connect the “untrained operator” and “trained operator” terminology used in the final guidances with the “waived user” and “moderately complex laboratory user” terminology from Section 3057 of 21st Century Cures. Note: please also see Section V.C.2 Operators for additional recommendations. Next slide please.

Section V in the Final CLIA Waiver Guidance includes four study design options and provides additional flexibility regarding how manufacturers may leverage existing accuracy data from previous marketing submissions such as 510(k)s, PMAs, or De Novos. Option 1 through 3 are appropriate when sufficient valid scientific evidence to demonstrate that a candidate test meets the CLIA Statutory Criteria for Waiver can be derived from the combination of the previous performance studies included in marketing submissions and the new CLIA waiver studies to demonstrate that a candidate test meets the CLIA Statutory Criteria for Waiver.

Now I'll describe each of the four options. Option 1 -- commonly called Agreement Studies -- includes comparison study designs in which the results of the candidate test in the hands of untrained operators are compared to the results of the candidate tests in the hands of trained operators. Since premarket performance studies generally include data sets establishing the accuracy of the candidate test in the hands of trained operators, FDA believes Option 1 would be appropriate for the majority of candidate tests.

Option 2 is similar to Option 1, but specifically includes Agreement Studies modeled after approaches in the FDA Guidance on “Assay Migration Studies for In Vitro Diagnostic Devices.” Under this option, these studies compare the performance of the candidate test between untrained and trained operators

instead of comparing performance between “new” and “old” systems as described in the Assay Migration Guidance.

Option 3 includes flex and human factors engineering studies. As an alternative to comparison study designs for certain test systems, flex and human factors engineering studies may provide sufficient assurance that the change in user populations and environment of use between non-waived and waived settings will not adversely impact results provided by the candidate test. Possible study design approaches that may be suitable include flex study designs described in Section IV of the CLIA Waiver Guidance and human factor study designs described in FDA’s guidance “Applying Human Factors and Usability Engineering to Medical Devices.”

FDA believes this approach is generally appropriate for test systems that meet the following three conditions; one, collection of a specimen is either always performed by a professional – (for example an endocervical swab collected by a doctor) -- or always by a patient (for example, a urine specimen collected by the patient); and two, other pre-analytical steps are very simple (for example, placing the entire specimen in the analyzer); and three, intended use patient populations are sufficiently similar between non-waived and waived use.

Additionally, another scenario where this option may be appropriate is a CLIA Waiver Application for a modification of a previously waived test system where the Quick References Guide was not modified or minimally modified.

FDA encourages manufacturers considering modification of a test system previously waived by application to contact FDA through a Pre-Submission to discuss planned modifications, as well as study designs and analyses to validate that the modified test system meets the statutory criteria for CLIA waiver.

Option 4 is the approach included in Section V of the 2008 CLIA Waiver Guidance. Option 4 includes comparison study designs in which the results of the candidate test in the hands of untrained operators are directly compared to the results of an appropriate comparative method in the hands of trained

operators. The FDA-recognized consensus standards referenced in this section include recommendations about selection of an appropriate comparative method. Option 4 is also the approach recommended for Dual Submissions.

For Options 1, 2 and 4, if sufficient valid scientific evidence on the imprecision of the test and the performance of the test at low levels -- such as limit of detection and limit of quantitation -- when performed by untrained operators is not available from the particular studies conducted under the option selected, additional studies should be performed to allow comparison of the imprecision and limit of detection or limit of quantitation of the test when performed by untrained and trained operators. Next slide please.

Another important piece of the updated Section V is Section V.B – “Considerations in Satisfying CLIA Waiver Requirements.” Section V.B describes how we are harmonizing our approach to benefit-risk consideration for CLIA Waivers with other FDA-benefit risk guidances. In thinking about benefit-risk considerations for CLIA Waivers, we need to go back to the statutory criteria for CLIA Waiver; that a test should be “so simple and accurate as to render the likelihood of erroneous results by the user negligible.”

All tests have some likelihood of erroneous results, but whether the likelihood of erroneous results in the hands of waived test users is negligible will vary from test to test depending on a number of factors, including: intended use, context of use -- for example patient population in the use environment -- and the probable benefits and probable risks or harms associated with waived use of the test.

Accordingly, the appropriate acceptance criteria for CLIA Waiver accuracy studies will vary from test to test. For details about the FDA's current thinking about benefit-risk considerations for medical devices, CDRH benefit-risk guidances are referenced rather than repeating similar material. Next slide please.

One aspect of Section V that has not changed are general CLIA Waiver study

design considerations. FDA recommends that applicants evaluate test performance in settings designed to replicate, as closely as possible, intended CLIA-waived settings, patients, samples, and test operators. Therefore, we recommend that studies include: testing sites that are representative of the intended use of the waived test, subject populations that are representative of the intended patient population(s), and intended sample type and matrix.

Untrained operators should be representative of those at intended waived settings, and we encourage you to enroll operators with the least amount of training that might be encountered at the type of sites for which the device is intended.

Testing should also be integrated into the daily workflow of the facility since operators at sites with a CLIA Certificate of Waiver are often multitasking between patient care, testing, and other duties.

Finally, Pre-Submissions are highly recommended for feedback from FDA on study design for any of the four options before conducting the studies. FDA also welcomes discussion of additional study design approaches besides the four options presented in this guidance. For additional information on Pre-Submissions, please refer to FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" which is linked here. Next slide please.

Now let's move on to the final Dual Guidance. Next slide please.

In contrast to the stepwise CLIA waiver pathway covered by the CLIA Waiver Guidance, the Dual Guidance is intended for new In Vitro Diagnostic tests that have not yet been cleared, and so there is not generally accuracy data available yet for these tests. The Dual Guidance describes an efficient single set of comparison and reproducibility study designs with untrained users for a Dual 510(k) and CLIA Waiver by Application, often called a "Dual Submission" or just a "Dual."

The Dual study design recommendations in this guidance may also be utilized in a sequential submission approach in which a CLIA Waiver Application follows marketing authorization (such as a PMA or De Novo). In this approach, the Dual study data would be included in the marketing submission and could be referenced in the subsequent CLIA waiver application, rather than re-submitted. We only received minor comments on the 2018 Dual Draft Guidance so significant changes were not made from this draft; only minor edits to harmonize with technical edits to the CLIA Waiver Guidance.

The FDA believes the Dual Pathway is in many instances the least burdensome and fastest approach for manufacturers to obtain a CLIA waiver in addition to 510(k) clearance for new tests. Next slide please.

Over the next few slides, I will compare the types of studies conducted for the Stepwise and Dual CLIA waiver pathways starting with a little more background on the Stepwise pathway. Historically under the Stepwise CLIA waiver pathway, manufacturers conducted separate accuracy studies, in different clinical settings, first to support 510(k) clearance, and later to support CLIA waiver. Specifically, manufacturers often conducted comparison and reproducibility studies with trained users at non-waived Point-of-Care sites as part of the support for 510(k) clearance, and then later conducted similar studies with untrained users at waived sites to support their CLIA waiver application. Next slide please.

Before continuing with the comparison of the types of studies conducted for the Stepwise and Dual CLIA waiver pathways, I wanted to clarify a few details about the process and content of a Dual submission. Please inform the FDA that you plan to submit a Dual submission in a Pre-Submission prior to submitting the Dual Submission. This Pre-Submission is also a good opportunity to receive feedback from FDA on Dual study designs for your device before you begin conducting the studies.

A Dual submission should contain the same information as a complete 510(k) that the CLIA waiver allows by application. A single set of comparison

reproducibility studies may be used to support both 510(k) clearance and CLIA waiver, but all other content that would otherwise be included in separate, sequential 510(k) and CLIA Waiver by Application submissions should be included in the Dual Submission. Next slide please.

This slide directly compares the types of studies conducted for the Stepwise and Dual CLIA waiver pathways and shows why the Dual approach provides time and study efficiencies. The left column, including the bullets under the red X includes the typical study types for Point-of-Care 510(k), and the right column shows additional study types typically included in a CLIA Waiver Application.

The basic idea behind the Dual approach is that it is reasonable to assume that test performance in the hands of trained users will be equal to or better than test performance in the hands of untrained users. Therefore, a single set of comparison and reproducibility studies conducted at sites representative of CLIA-waived sites and with intended untrained users can be used as part of the support for both 510(k) clearance and CLIA waiver approval.

The types of studies typically performed for a Dual Submission include both the left and right columns, but do not include the 510(k) comparison and reproducibility studies with trained users under the red X. Because fewer studies are conducted, the Dual Pathway can provide considerable study efficiencies compared to the traditional Stepwise approach to CLIA waiver. Additionally, the overall FDA review time is also generally shorter for Dual Submissions. Next slide please.

Over the next two slides, I'll summarize recommendations for Dual comparison and reproducibility studies. For comparison study design and analysis to establish the performance characteristics related to the accuracy of the candidate test, we recommend you follow appropriate FDA-recognized consensus standards such as those listed here. These standards include discussion of the importance of selecting an appropriate comparative method and describe quality hierarchies of preferred comparative method types for quantitative and binary qualitative tests.

Comparison to higher quality comparative methods -- for example, reference methods and methods traceable to higher-order references when available -- provided more absolute information about the accuracy of the candidate test while comparison to lower quality comparative methods may provide only relative performance information. Where there is no generally accepted comparative method for the an IVD device type, the use of a legally marketed predicate device or other well-documented method as the comparative method would generally be appropriate.

We recommend discussing the selection of an appropriate comparative method as part of a Pre-Submission prior to conducting the comparison study. For Dual comparison studies, in addition to the recommendations in Section V of the Dual Guidance, please also see Section V of the CLIA Waiver Guidance for general study design considerations. Next slide please.

For Dual reproducibility study design and analysis, we also recommend you follow appropriate FDA-recognized consensus standards. We recommend conducting the reproducibility study at a minimum of three of the same sites that were included in the comparison study and are representative of the intended use of the waived test.

To facilitate statistical analysis, the same number of untrained operators -- likely two or three -- should be included at each site of the reproducibility study. We recommend that you include the following sources of variability: different sites, different untrained operators, different days, different run, different lots, if applicable, and a few replicates.

Finally, we recommend discussing reproducibility study design as part of a Pre-Submission prior to conducting the reproducibility study. Next slide please.

I've now finished the highlights of the two final CLIA Waiver guidances. This page includes links to the guidances covered today and also links to two other related final guidances: the "Administrative Procedures for CLIA

Categorization” guidance -- which describes administrative procedures for CLIA Record and CLIA Waiver by Application submissions, and the “Requests for Feedback and Meetings for Medical Device Submissions: the Q-Submission Program” guidance which includes Pre-Submission process information.

I've also included a link to the CDRH Transparency Page where CLIA Waiver Decision Summaries are posted. Next slide please.

Thank you again for your interest in these final CLIA Waiver guidances. In a few moments, an operator will be opening up the lines for questions. If you have other CLIA waiver or CLIA categorization questions that are not related to the final CLIA waiver guidances or if you think of questions later on after the webinar, please feel free to email us at CLIA@fda.hhs.gov and we'll be happy to help you.

Irene Aihie: The Operator will now take questions.

Operator: Thank you. At this time if you would like to ask a question, please press star 1 on your telephone keypad. Please ensure that the line is unmuted and record your name when prompted. Again, that is star 1 if you would like to ask a question. One moment for our first question to come in.

Peter Tobin: While the Q&A portion of the webinar is being set up, I would like to take a few minutes now to recommend FDA resources about the development of the diagnostic tests for SARS-CoV-2., since I understand many test developers and laboratories may have questions about the development of diagnostic tests for SARS-CoV-2, but many of these questions may be outside the scope of this webinar on the CLIA waiver final guidances.

A good place to start for information on the development of diagnostic tests for SARS-CoV-2 is the FDA's web page titled “FAQs on Diagnostic Testing for SARS-CoV-2.” We also have an industry hotline for COVID-19 diagnostic tests and COVID-19 device shortages including personal protective equipment.

You can contact our toll-free line 24 hours a day at 1-888-INFO-FDA and choose Option *. Or you can also send your questions by email. For shortages, please email deviceshortages@fda.hhs.gov. And for diagnostic test questions, please email COVID19DX@fda.hhs.gov. Again that email is C-O-V-I-D-1-9-D-X at FDA dot H-H-S dot G-O-V.

FDA is also hosting a weekly Virtual Town Hall series on the “Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests” to help answer questions from clinical laboratories and commercial manufacturers. The next virtual townhall will be tomorrow, Wednesday April 15, from 12:15 to 1:15 Eastern Time, and transcripts from previous sessions of this series are also posted on the series web page.

Irene Aihie: Thank you Peter. Operator, we'll now take our first question.

Operator: Our first question comes from (Scott). Your line is open.

(Scott): Yes, Hello, I just wanted to say thank you to the FDA for all of the hard work you guys have putting through. I'm a clinical pharmacist and I represent an organization that represents a network of 12,000 independent pharmacies.

I had read through the FAQs section regarding tests that have been issued an EUA, whether they are CLIA-waived or whether they are not CLIA-waived under Pathway D of the 3/16 Guidance. I know the HHS OASH office released more guidance regarding pharmacies and pharmacists being able to order and perform the test. I was hoping to see if you guys were able to shed more light regarding that process and the pharmacies are able to do this?

Peter Tobin: I don't have additional information on that question at this time. You know, I can go over a little bit about what the FAQ that you mentioned is on the web site. Essentially the question is when tests are offered prior to or without an EUA under FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019, whether the tests have received categorization. So the answer is basically tests offered prior to or without an EUA have not been reviewed by FDA and are not

authorized and have not received a CLIA categorization.

While FDA has indicated that these tests may be appropriate for use in clinical laboratories and by healthcare workers at the point of care, the policies in this guidance do not provide a CLIA categorization and do not override any CLIA requirements.

Therefore, in accordance with CLIA, tests offered under these policies are considered high complexity by default until or unless they are authorized and deemed to be an appropriate through an EUA authorization or a general FDA review process to be performed as moderate or waived complexity tests. So on our list of IVD EUAs, we do have a column for that table that indicates the authorized locations and lists whether they could be potentially be used in high, moderate or waived labs.

But basically, the question about clinical pharmacists in HHS, I don't have additional information about that at this time. Please feel free to send in your question to COVID19DX@fda.hhs.gov or also there'll be a webinar tomorrow, as I mentioned, where the FDA staff that are directly involved in this effort could assist you with your questions.

(Scott): Okay thank you.

Operator: At this time, I'm showing there is no further questions. Again, if you would like to ask a question, please press star 1 to be queued up for a question. One moment please.

One moment for our next question. I believe our next question comes from (Lisa Lowe). Your line is open.

(Lisa Lowe): Yes, I have a question about the section where you said that you encourage the most untrained personnel in order to run these CLIA Waiver Tests. At most sites, a lot of these personnel already have experience with other point-of-care devices, they might be doing glucose testing or chemistry testing. They also can be educated. We've been told at one point that if they are highly educated, they

would not qualify as an operator. But in many cases, these people are the intended user of the device, or they may already be using similar devices.

Can you expand more on what you mean by untrained personnel and exactly what that means, and why they have to be? I understand that you really want to put it in the hands of the most unexperienced user, but this is not always the case in an intended environment so it makes it very difficult to locate sites for studies under these conditions.

Peter Tobin: Yes I definitely understand your question. So one of the issues is that there are not very many operators that are included in these studies. You know, the minimum that we recommend in the guidance is nine untrained operators. You know, we certainly encourage you if you are able to include more operators and many CLIA Waiver Applications do.

But because there is only nine operators potentially as the minimum included, it is pretty important that some of those operators are representative of the lower levels of training and experience that might be seen when the test actually is used and practiced in CLIA-waived settings across the whole country. So certainly there is a range of experience and training perhaps even at different CLIA-waived sites.

But because there is isn't a requirement for particular training or experience, we understand that, you know, at some sites, you know, some of the staff may have more experience. But other sites, you know, there may be new staff that are using the test for the first time and haven't necessarily performed testing perform. So we do want to ensure that the test is going to be able to be used by all operators at waived settings once it gets out in actual practical use.

So, you know, the first level is to really ensure that the operator are really representative. And we think that if you really are getting operators that are representative, that is going to include some operators that have very little experience. So that's why we recommend and encourage you to include some operators with the least training an experience likely to be encountered at

CLIA-waived sites for your intended use.

(Lisa Lowe): Okay so when you say "untrained personnel," are we talking untrained on all point-of-care devices, or are we talking about, say, you are doing a glucose study? Are we talking about untrained on doing glucose testing? So that's two different things.

Peter Tobin: Well we...

(Lisa Lowe): So do you want them to be completely ignorant of all types of point-of-care testing, or is it just what you're testing that's important that they haven't tested on a competitor's device, let's say, for glucose?

Peter Tobin: So they definitely shouldn't have experience with your candidate test. And we'd prefer that they have pretty limited experienced in conducting other waived or home-use testing. It is possible for some operators...we talked about it in the section on untrained operators that it is possible that some may have limited experience with other waived or home-use tests. But we really do encourage you to include at least some operators with very little to no experience or training because there are going to be some waived sites where, you know, they may have hired new staff and some of those staff may not have had any experience of laboratory testing including other waived tests. So we do want to ensure that users that are really new to testing can also perform the device correctly and get correct results.

(Lisa Lowe): Okay thank you.

Operator: There are no further questions at this time. Again if you would like...

Irene Aihie: Thank you Operator. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Page at www.FDA.Gov/training/CDRHLearn by Wednesday, April 22. If you have additional questions about today's presentation, please use the current links information provided at the end of the

slide presentation.

As always, we appreciate your feedback. Following the conclusion of today's live webinar, complete a short 13 question survey about your FDA CDRH Webinar experience. The survey can be found at www.FDA.gov/CDRHwebinar immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

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