# Life of a Test Method Part 2: Emergency Use Authorizations

My name is Chelsea Parsons, and I am a consultant with Guidehouse, supporting the CDC OneLab initiative. I have a couple of notes before we jump into the webinar today. If you’re having any technical issues at all, you can access support through the entire time of the webinar through our OneLab inbox. That’s OneLab@CDC.gov. Again, that’s OneLab@CDC.gov.

If you have questions throughout the session regarding the content of the session, we have a Q&A box. You’ll see it in the bottom banner of your web page right now, it says Q&A. You can submit questions in there throughout the entirety of the session. We’re going to have multiple speakers today, so if you could indicate as best you can who the question is for. You can either say the organization that they represent, or the name, if you remember their name. And if you could do that for us so that when we get into our Q&A session we know exactly who the question’s for, that would be great. We’ll have that Q&A session at the end of the session today.

Note that I posted the live link to the captions in the chat, so you’ll see that popping up in a moment. If you need live captions today throughout the session you’ll want to click that link in the chat and keep that box open while the Zoom webinar is also open. So just keeping both of those open. Let’s get into our agenda.

All right. So we’re going to start today by introducing some of the presenters that we have joining us. We’re going to show you some of our new and featured OneLab resources and then we’ll get into that main presentation with all of our various presenters. We’ll have that Q&A session that I mentioned, and then we will just highlight our next OneLab event for you all.

All right. So I want to introduce our amazing presenters today, starting with Michael J. Wagner. Michael is the Senior Corporate Counsel for Quest Diagnostics. His practice is focused in regulatory, advertising, and import-export. He was responsible for several FDA cleared tests, including West Nile test in 2003 and herpes select tests in 1999. Michael is admitted to the State Bar of California and is registered to practice before the US Patent and Trademark Office. He earned his JD from Loyola Law School in Los Angeles, and his Bachelor of Science in Microbiology from the University of California at Irvine.

Christine Sabol is the Senior Director for Medical Operations and Regulations. Her responsibilities are focused in advising Quest Diagnostics laboratories in meeting the federal and state agency laboratory requirements and interacting with the agencies to help address concerns and drive to resolution. Christine is an ASCP certified technologist in cytogenetics, a California laboratory scientist in cytogenetics, and is a certified professional coder. Christine serves as a Board Member of the California Clinical Laboratory Association, and she earned her Bachelor in Science and Biology from East Stroudsburg University.

So thank you so much, Michael and Christine, for joining us today from Quest Diagnostics. Next up, we have Toby Lowe. Toby Lowe is the Associate Director for Regulatory Programs in OHT 7, the Office of In Vitro Diagnostics and Radiological Health, and the Office of Product Evaluation and Quality at the US Food and Drug Administration’s Center for Devices and Radiological Health.

As Associate Director, she guides development, implementation, and communication of policies to address regulatory issues for a wide range of in vitro diagnostic devices, including issues related to COVID-19, laboratory developed tests, pharmacogenomics, companion diagnostics and others. Miss Lowe also advises office and center leadership and staff on a variety of regulatory policy issues and manages communication efforts for the office. Miss Lowe is a biomedical engineer and has been at the FDA since 2008. Thank you so much for joining us today, Miss Lowe.

And finally, I’d like to introduce you to Monique Spruill. Monique began her science career early on conducting epidemiological studies at the University of Pittsburgh School of Public Health and Tulane University School of Public Health and Tropical Medicine. She has served as a clinical trial coordinator, biostatistician, assistant professor, Senior Advisor for the US Department of Health and Human Services, and health scientist and Chief of Health for Enforcement at the Department of Labor. She published several RFIs, NPRMs, and final rules as a health scientist and led enforcement efforts nationally for over 14,000 and 367,000 minors.

Monique assumed her role as the Director of the D.C. LIQ in January. Her goal is to support our state partners and recognize the work they do every day in the laboratory community. Monique also finds serving as a math and science tutor to be extremely rewarding. She says, quote, “students make her smile as they move forward with discovering her own talent.”

So thank you again to all of our presenters today. I’m really excited for this event, and I’ll now pass it over to Dr. Triona Henderson-Samuel from CDC’s Division of Laboratory Systems.

Thank you so much, Chelsea. And before we get into the main presentation I’d like to take a moment to orient you to some of our new resources. So DLS has released the Provider Perform Microscopy Procedures e-learning course. This course is intended for physicians, mid-level practitioners including nurse midwives, nurse practitioners, physician assistants, dentists, and laboratory directors that perform PPM procedures, have a general knowledge of CLIA, and have experience performing microscopic procedures.

This basic level e-learning course provides information on topics including the background of PPM procedures and overview on criteria, examination, and regulations, how to apply for a CLIA certificate for PPM procedures, requirements for PPM personnel, and additional CLIA requirements and quality practices. This course was designed to prepare physicians, mid-level providers and dentists to meet requirements or procedures under a CLIA certificate. All network members will receive an email with the information for this course tomorrow, September 23. Next slide, please.

DLS will soon be releasing the Introduction to Laboratory Risk Management e-learning course, which is the first in a series of courses focused on developing risk management strategies for laboratory settings. This course is intended for new or existing public health and clinical laboratory professionals who handle potentially hazardous materials. This basic level e-learning course provides information on risk management principles and briefly describes related practices to emphasize the importance of risk management in laboratory settings.

Topics covered include risk management goals, terminology, processes, and associated activities. Subsequent courses in the series will provide additional details on each overarching laboratory risk management principle to help learners gain an in-depth understanding of the risk management process and operation specific considerations.

We are currently developing a laboratory plain language toolkit to help laboratories develop clean language content. Look out for the release of this toolkit within the next few weeks. OneLab is developing a sensitivity and specificity job aid to help public and clinical laboratory professionals understand how specificity and sensitivity performance characteristics affect test result interpretation. This job aid is scheduled for release in October.

All resources mentioned plus any resources mentioned in the main presentation will be linked in these slides once they are shared with you all, and we will also compile a linked list on the event page. All network members will receive an email notifying you that this page is available as soon as it is published. Next slide. Thank you.

If you were unable to join the first part of the series, the Life of a Test Method– Validation, Verification, and Managing Quality, the audio recording, slides, and additional resources from that session can be found on the OneLab network page in the OneLab network meeting section, and the link has just been posted in the chat box. Next slide, please. In that session, Doctor Rex Astles described the test method model, differentiated test method validation verification, and listed instructional resources that explain the life of a test method.

Today, we are joined by a group of experts who will discuss the differences experienced in the test method model when emergency use authorization are in place. Here to present today from Quest Diagnostics is Michael J. Wagner and Christine Sabol. They will be explaining Quest’s personal experience with Zika and COVID, especially bringing on a test that wasn’t theirs for Zika, versus creating their own for COVID.

As a reminder, today’s audio transcript and slides will be posted online afterwards so you’ll have access to everything that’s been hyperlinked and existing resources. Additionally, my team and I will be monitoring the Q&A section in case you have any questions throughout the presentation. I will now hand this presentation over to Mr. Wagner and Miss Sabol.

Thank you so much. Can you hear us OK?

I can hear you, Michael. Can you hear me?

I sure can.

Then I think we’re good. Let’s get started.

Loud and clear.

May we have the next slide, please?

So this pandemic is much different from Zika virus. So Zika was really a front loaded sprint, while this has been not only a grueling marathon, but I think it’s hit much too close to home for almost all of us. Next slide, please.

So we looked at the differences between test development versus purchase, and there are many driving factors for that. Obviously, there’s the availability of the alternatives, testing capacity needs, resources, costs, and then there’s also several business drivers. There are many advantages as well as disadvantages to purchasing, but ultimately we found that there was really a need for the combination between development and in addition, purchasing.

Michael, would you walk us through the differences that we experienced for both Zika and COVID?

You bet. For Zika virus, we started developing our own molecular assay, the first commercial lab to get an emergency use authorization. And we did that primarily because there weren’t a whole lot of alternatives available to us. Over a period of time, a number of alternatives developed, became available, and they became available at a reasonable price.

In contrast with COVID, starting last year, again, we developed an assay very early on because there weren’t kits available off the shelf. We quickly added a couple of automated options very early in order to bring up our capacity. Next slide, please.

So the big hurdle if you’re going to develop your own is really obtaining either specimens or the virus itself, and there’s a couple considerations to work through. One is having a biosafety program in place. In some cases, one will need permits from CDC, or USDA, or perhaps both. And then there’s a number of intellectual property considerations that come up as one’s looking for specimens or virus. And traditionally, Quest has relied on relationships with other laboratories and researchers globally. Next slide, please.

So keys to success. We just labeled out some of the keys to the Quest Diagnostics success for building our own test for the COVID response. We do want to call out that the FDA was extremely flexible and collaborative during this process, and it was their preparation and our ability to work as a laboratory with the FDA to discuss pre-submissions, and really get information ready as early as January and February, even prior to the emergency being declared, that really drove the success.

One of the other key factors that Quest Diagnostics significantly welcomed was the utilization of the emergency use notification program, and we’ll talk about that in a later slide. But ultimately, it allowed us to get our test available for testing eight days prior to receiving our authorization. Some of the other things, ultimately, is that the FDA, the CDC, CMS, all came together and really opened up the lines of communication between the laboratories and the agencies through the town halls, which really also led to the success of our laboratory, as well as the industry, for the response to the pandemic.

Some of the resources– oh, sorry. Michael, go ahead.

Sorry. Yeah. So as you’re trying to get specimens, the other plate you kind of get spinning is doing study design. And some of the resources that are available are obviously the templates available from Food and Drug Administration, but also consider looking at the labeling of tests that have already been authorized. And if there’s maybe a gap there between what you have and what’s being suggested, maybe you arrange for a pre-submission discussion with Food and Drug Administration. They’re very open to discussing some of the challenges. And one recommendation is, if you do have a discussion, you want to bring some solutions to the discussion and not just questions. And I think that covers it for this slide. Next slide, please.

Christine mentioned the emergency use notification process. This was new for this pandemic. It was very helpful in getting us out to launch the test, well, almost 10 days earlier than we would have if we’d been waiting for an EUA. There is five or six requirements first, that the LDT has to be valid under CLIA, in a CLIA high complexity laboratory. The lab has to give simple notice, written notice to the Food and Drug Administration. The lab has to provide proper disclosure in their printed materials and their test reports. The lab has to promptly confirm performance with the Public Health Lab for the first 10-ish specimens, and the lab has to submit an EUA request promptly. And there’s some other details available in the guidance, but it was very, very beneficial for us.

In addition to the benefits, we also found that there were some considerations as far as what to do with the EUN. Until the test ultimately, though, does receive authorization, any affiliate laboratories need to fully validate the EUN test, which is more labor intensive, especially when timing is crucial and specimens are in shortage. Payers may also have concerns about a notified test versus an authorized test. Notified tests may have some liability shield, or may not have some liability shield as much as an authorized test does have.

And then ultimately, there is some potential confusion related to updating the regulatory notices on the test reports and any marketing material. And then finally, one other consideration is disclosure for multiple tests that have different regulatory statuses. It can just be confusing to the authorized providers as they’re trying to select what tests to order. And you know, there is not as good of an understanding about what the differences are between emergency use notification versus an authorized test. Next slide, please.

So ultimately, we find ourselves in a conundrum, which is that our work is still ongoing, very much so. Laboratories, as well as the FDA, partner together to continue to respond to the current crisis. There is a need for increased capacity, and we’ve seen that frequently throughout the year. And each time we look at improving our tests, there’s a series of actions that need to come into play. Research and development needs to happen, additional studies. Further collaboration with the FDA. We have to do additional paperwork and submit an amendment to our authorization to the FDA for their consideration. And then ultimately, receiving an authorization for that amendment.

On the right side, we have our Quest Diagnostics submissions from March through December. And this is just a sampling, for just Quest Diagnostics, of what we’ve gone through. And this is not at all accounting what we’ve done for 2021. Michael has become very, very good at paperwork when it comes to our submissions. So not only are we grateful from a Quest Diagnostics perspective for his attention to detail, but also with the FDA and their partnership throughout this pandemic, and our amendments, and our authorizations.

We’ve been blessed to be part of a great team, and appreciate FDA’s and Public Health’s cooperation. Thank you so much.

Thank you so very much, Mr. Wagner and Miss Sabol. For our members, if you have any questions for either or both of these presenters, please input them in the Q&A function indicating who the question is directed to, and we will address these questions during the Q&A section.

Now we are joined by Toby Lowe from the US Food and Drug Administration to discuss their role in the EUA process and how the emergency response [INAUDIBLE] differs from typical IVD lifecycle, including LDTs. She will also discuss flexibility, challenges, and allowances during the COVID 19 response. Miss Lowe, I’ll hand it over to you.

Thank you, Triona. Thanks for the introduction. We can go right into the next slide and get started. So just to provide some background on FDA’s oversight of medical devices, in vitro diagnostics are medical devices that are regulated by FDA. And for traditional review pathways outside of an emergency, the review pathway, and the timeline, and the process is all determined by the risk classification of the device.

I have them listed here. I won’t go through all of the details, but 510(k) reviews are typically the fastest. They’re generally allotted 90 FDA review days. De novo classification requests are for novel devices and can be quite complex. We go through a process to develop special controls that are necessary to adequately mitigate the risks for the new device type during that review, and those are allotted 150 FDA review days. And then PMA reviews are for the highest risk devices, and are allotted 180 FDA review days.

And then during emergencies, we use the emergency use authorities, and our EUA reviews do not have a firm timeline, but we are able generally to complete them very quickly, depending on the provided data. Towards the beginning of the pandemic, especially, we were able to authorize many of the EUAs within a matter of hours or days. My next slide.

We have used EUA authorities during prior public health emergencies, but none of them have impacted the US and FDA in the way that COVID-19 has, as my Quest colleagues also discussed. We’ve been able to leverage our knowledge and expertise from prior emergencies, but we’ve also had to adjust and develop new approaches to our response for COVID-19. Next slide.

So our role in COVID-19 has been much more expansive than in previous public health emergencies. The use of our emergency use authority to issue EUAs has been only one aspect of our work to facilitate the availability and access to medical devices. We’ve also used additional regulatory strategies and leveraged our expertise in other ways, including stakeholder engagement and standing up an IVD shortages team to address supply chain shortages. Next slide.

Testing has been and remains a cornerstone of the fight against COVID-19, and we’ve been able to focus our review on the types of tests that will provide the most benefit for public health and adjust our approach as needed, as the needs of the pandemic have progressed throughout the past 18-plus months. Our performance recommendations do vary for different types of tests, and we take into consideration the technology, accessibility, and the speed of results.

For example, we’ve found that trading off some accuracy for greater availability and faster results may make sense for point of care and at home tests, and this is reflected in the recommendations that we’ve included in our EUA templates. And we do also always welcome developers who have alternative proposals to come talk with us.

So with all requests for emergency use authorization, we evaluate the totality of evidence available to determine whether the known and potential benefits of the device outweigh the known and potential risks, among other considerations. And as I mentioned before, we have the available we have the ability to authorize a test very quickly when a high priority submission comes in with a complete package and good data.

And we also have a responsibility to protect the public and decline to authorize a test if the submission does not look good. This includes submissions that include faulty data or demonstrate poor performance. And we also are able to work interactively, a lot of times, with sponsors when we see issues in a submission but we think that they’re able to be resolved. Next slide.

From the beginning of the COVID public health emergency, we’ve considered how best to balance the need for rapid access to testing with the assurance of FDA review. And throughout the pandemic, we’ve adjusted to respond to the needs at different times. I’m sure most people on this call, if not all, are familiar with our COVID-19 test guidance. That’s where the notification pathway that my Quest colleagues mentioned is included, and there have been a handful of iterations of that guidance that we’ve put out that provided different flexibilities for delayed review of COVID-19 tests after introduction for clinical use.

And in addition to that guidance, we’ve also issued policies to offer regulatory flexibility for viral transport media, and molecular influenza and RSV tests since they often use the same materials as SARS-coV-2 molecular tests. We also recognized the impact of COVID-19 in other areas. We issued an enforcement policy for remote digital pathology devices as well as FAQs on using home use blood glucose meters in hospitals during the pandemic. And we’ve also taken actions to mitigate testing supply chain shortages, including airlifting supplies, posting lists of appropriate testing policy alternatives on our FAQ page, and expanding the use of alternative specimen types, swab types, and transport media. Next slide.

We’ve considered transparency and outreach to be critical throughout the pandemic, and we’ve used a variety of forms of outreach to keep our stakeholders and the public informed. In the interest of time, I won’t go through all of what’s on this slide, but we have the EUA templates, the town halls, FAQs, and various forms of outreach that we’ve used throughout the pandemic. Next slide.

All of this has led to record numbers of authorized tests to meet a variety of needs throughout the pandemic. A large number of tests that span different test types, test settings, specimen types, and populations, and we’ve also granted full marketing authorization for the first test for use beyond the public health emergency. Next slide.

So as laboratories implement tests that are authorized under an EUA, there are important details that are included in the letter of authorization to be aware of. The letter of authorization spells out the indications for which the test is authorized, the authorized settings, and the conditions of authorization. And there are conditions of authorization that apply to an implementing laboratory.

The instructions for use also include these conditions that are important for laboratories. And the patient and health care provider fact sheets are part of the authorized labeling and a laboratory is responsible for providing those to the patient and health care provider. Next slide.

So as I mentioned, the indications for use is included in the letter of authorization, and this identifies how the test is authorized to be used. It goes through what the test does, what the specimen types are, who the target population is, as well as additional options that may be authorized such as testing of pooled samples. And these are a couple of examples from authorized tests. Next slide.

Included in the indication for use is the purpose of the test, such as whether it’s intended for diagnosing individuals suspected of COVID-19 or for broad screening of asymptomatic individuals who do not have a known or suspected exposure. Diagnostic and screening tests for COVID-19 both diagnose an active SARS-coV-2 infection and are distinguished by whether an individual is suspected of having COVID-19, generally referred to as diagnostic, or is being tested as part of an effort to identify asymptomatic infections, referred to as screening. The letter of authorization will indicate which individuals the test is authorized to be used.

We’ve emphasized the need for screening tests, and we’ve provided streamlined options for test developers to seek authorization for screening indications. The FDA does not generally regulate the use of tests for surveillance, which is a limited use typically performed for public health purposes and is not intended to provide information for individual decision making. Next slide.

EUA tests are not CLIA categorized, so the authorized laboratory section of the EUA provides similar information, and so it’ll list whether they can be used in high or moderate labs, or at the point of care. When a test is authorized under EUA for use at the point of care, the test is deemed waive for purposes of use at a certificate of waiver site. And it’s also important to note that any test being offered prior to authorization under a regulatory flexibility enforcement policy, such as the notification policy, are considered high complexity by default unless and until they’re authorized and deemed to be appropriate through an EUA authorization or another FDA review process to be performed as moderate or waive complexity tests. Next slide.

So the conditions of authorization may vary between different EUAs depending on the type of test. And there are some similarities between the different tests as well, including references to the fact sheets, using the test as authorized, notifying public health authorities, reporting test results, collecting information about the performance of the test, and having appropriately trained operators. And as always, laboratories should follow their CLIA requirements, as I’m sure my DMS colleagues will also talk about. Next slide.

So as I mentioned about the conditions of authorization, one of the conditions is that in order to comply with an EUA, laboratories must use the product as outlined in the authorized labeling without deviation. However, in the COVID-19 test policy guidance, we have provided some additional flexibilities for high complexity pre-certified labs to make certain modifications to an authorized SARS-coV-2 assay.

We’ve indicated that we do not intend to object to the use of a modified test without notification to FDA or a new or amended EUA for certain modifications when the laboratory has appropriately validated the modified test. As with other tests offered prior to or without authorization, modifications offered without authorization are considered high complexity by default. And these policies do not apply to home collection or at-home tests, and we do expect all tests for use with home collected specimens and at-home tests to be authorized prior to use. Next slide.

Throughout the pandemic we’ve learned a lot about interacting with our stakeholders about interacting with laboratories and different test developers. The value of regulatory flexibility has come up quite a bit, as you’ve seen with some of the actions that we’ve taken, as well as engagement. We’ve found very valuable to have a variety of different approaches for engaging with our stakeholders. And transparency– we have a lot of information that we provide on our website, and that has made it much easier for us to interact with our stakeholders and for our stakeholders to easily access the information that they need. Next slide.

Here are some resources, links to the EUAs that we have posted on our website, our FAQs, the test policy that I mentioned, and our email address. So happy to answer any questions when we get to that portion of the presentation.

Thank you so much, Miss Lowe, for that presentation. And again, if you have a question specifically on the FDA presentation, please input them in the Q&A function indicating that the question is for Miss Lowe, and we will address the question during the Q&A section. Finally, we are joined by Miss Monique Spruill from the Centers for Medicare and Medicaid Services to discuss CMSs experience during the COVID-19 response, such as all of the new testing sites and many waived tests, and the enforcement discretion allowed here versus typical emergency response. Monique, I will hand it over to you.

Thanks It’s great to join you today. I’m going to go to the next slide. This presentation was prepared for information purposes and is not intended to grant rights or impose obligations. So everyone else can finish reading the disclaimer at a later date. I’m going to go provide a brief overview, and I’d like to thank the CDC for inviting CMS CLIA to speak about our experience during the COVID-19 response.

What we really need to do is go back right now and look at our current CLIA statistics. We’ve had an increase in the number of certificates since March of 2020. That is, since the beginning of the public health emergency. As of August, we have had close to 310,000 CLIA certified laboratories now, and over 233 laboratories hold a certificate of waiver. And almost 30,000 laboratories hold a PPM certificate, and with 18,000 laboratories holding a certificate of compliance. And then also, close to 16,000 laboratories holding a certificate of accreditation.

And we also want to take note that we also have two exempt states, that would be New York and the state of Washington, and there are about 12,533 laboratory enrollments. And so the top line that you have on this slide, being that 309,914, thousand laboratories that we actually have CLIA statistics for, that would be all your labs, including the exempt and your non-exempt states. I’ll go on to the next slide.

Now, this slide is a representation of CLIA certificates as a whole. And if you notice here, the majority of the laboratories, they were actually with CLIA certificates, holding a certificate of waiver, that’s actually at 79%, where our PPM laboratories are at 10%, certificate of compliance at 6%, and a certificate of accreditation at 5%. And this slide actually does exclude the 12,533 exempt states, with New York and Washington are actually not included here. So this is actually the percent total of the 297,361 laboratories.

But really, I’m going to go onto the next slide now, and this is a slide we want to really concentrate on when it comes down to statistics. We thought it would be important to note the laboratories that have enrolled since the March of 2020, or since the public health emergency, we have enrolled close to 46,000 laboratories. And of those new laboratories, we have received CLIA certificates. Most of them are physician office labs, pharmacies, and assisted living facilities. The facilities and laboratories were part of the national testing strategy and they were really called upon by HHS during this pandemic, and theirs was a major effort to get these laboratories up and running, these facilities.

And our division worked extremely hard with getting them certified, and the facilities are now able to perform testing. And astonishingly enough, we keep having additional facilities come back and they’re enrolled now. So I just want to note, close to 11,500 physician office laboratories were enrolled, and nearly 8,500 new pharmacies were added, and close to 5,000 assisted living facilities were actually added. And they received certification during his time, since the public health emergency. So let’s just take note of those 46,000 laboratories that were actually added after the March of 2020. I’m going to go on to the next slide.

And I think everyone else has really spoken about this, but CMS, the FDA, and the CDC, we really joined together forces and really wanted to know, how do we respond to this public health emergency? And the tri-agency task force for emergency diagnostics was one of those ways in which CMS was able to come together with the FDA and with the CDC.

As the FDA announced that their emergency use authorization of many point of care tests would become one of their focus, we knew that our efforts would also, during a public health emergency, that would also be a response. So we wanted to ensure that point of care tests were actually being performed in CLIA certified laboratories. We wanted to address enforcement questions. And particularly, we knew that there were pop-up laboratories. Laboratories that were not CLIA certified, and they were actually using authorized tests that were actually in wavied settings. And so with this, we knew that we had to take enforcement actions and we have our three locations– and they readily are still doing this– where they’re writing cease and desist letters to these facilities that should not be conducting these point of care tests, and they do not actually hold a CLIA certificate.

The other thing that we noticed is that manufacturers were actually marketing tests as being CLIA waive tests, and so that was actually being misinterpreted, saying that you would actually not need a CLIA certificate. And so we’re still corresponding with facilities and ensuring that any of these point of care tests are actually being performed in CLIA certified laboratories, and that’s because we want patients to actually receive accurate and reliable test results. I’m going to go into the next slide now.

And we really wanted to highlight some administrative processes and process changes that we needed to conduct early on in this pandemic. One of them would be that for our certificate of waiver laboratories that actually wanted to be certified, and actually come aboard and perform SARS-coV-2 testing. During our normal process, what you would do was, you would identify a laboratory director that was qualified, then you could actually fill out your CMS 116 application and send that to a state. And then you would actually have a CLIA certificate number and also a physical server certificate issued out.

So part of that, CLIA didn’t want to stand in the way, so we didn’t want to actually have any facility or laboratory actually be slowed down because of this administrative process. And so instead, during this application period we were actually treating these facilities as if they were certificate of waiver laboratories, and therefore, they didn’t actually have to have a CLIA number to be issued out in order to start testing right away. So the whole intent behind us was one, was to start testing right away.

And then we still need it to look at all of our other types of laboratories and say, we still needed to expedite our application process. And so what we did was actually, after you then still identified your laboratory director and actually applied for your CMS 116 application, and that was provided to your state agency, and then after that, that would be processed. You obtained a CLIA number. You could begin testing and you did not actually have to wait until you receive that physical certificate right away, but however, these laboratories, they were assigned a CLIA number.

And I’m going to go now on to another enforcement discretion and process change that we actually put in place. Another process that we put in place early on was actually allowing pathologists to use temporary testing sites to review remote pathology slides. And this actually received a extremely positive response from the stakeholder community, and this is actually still taking place.

And this actually ensured that individuals would not actually be exposed to SARS-coV-2, especially during the height of this pandemic, and especially also, with the variant strains coming out. And so we just really wanted to make sure that pathologists were safe, and that we could actually not have CLIA stand in the way, and that medical procedures were still taking place and moving forward. I’m going to go onto the next slide now.

And for these temporary testing sites where we actually– one of these enforcement discretions that was extremely successful– and we have all seen these quite a bit during the height of the pandemic– was actually having these designated overflow locations where a CLIA certificate holder could actually extend their certificate over to another CLIA certified lab, but you actually had to have two considerations. The laboratory director actually had to be in agreement and the testing site, that alternative site, had to actually be equal to the type of testing that was actually approved for the primary certificate holder.

Basically, overall, you could not test above your certificate type. So if the primary certificate holder held a certificate of waiver, then that alternative site would obviously also have to be performing waived testing, and also be actually hold a certificate of waiver also. And this was extremely useful. We knew that with actually having, what? 33,000 new applications as of now, this would be quite cumbersome for us to actually process. And so pharmacies and schools actually use this enforcement discretion, and it was very successful, and still is successful.

For example, if a school district actually was holding a certificate of waiver, then actually, that school district could actually then have all of your other schools underneath the district were enabled to actually be under their certificate of waiver. So that primary certificate holder would actually be the school district, and those alternate sites would actually be your schools. I’m going to go on to the next slide now.

And particularly for EUA tests. Initially, for this enforcement discretion, it was specific only for point of care antigen tests that would be performed in certificate of waiver laboratories. But then we actually were hearing from our stakeholders to actually allow testing to be performed on asymptomatic individuals, even though the emergency use authorization from the FDA did not allow this use.

And really, our efforts were centered around nursing homes. This is a response to setting up testing within nursing homes. And HHS distributed these point-of-care tests to nursing homes. So what we receive feedback was that we knew that they had to actually follow the manufacturer’s instructions, and that these tests should only be performed on systematic individuals.

However, facilities were actually worried that they would be cited for off-label testing, and so we needed to provide enforcement discretion to actually just move forward with this. So we expanded and provide enforcement instructions that stated that laboratories performing COVID-19 testing on asymptomatic individuals would not be cited. But that was for our certificate of waiver laboratories. We also needed to make sure we had parity overall, for all certificate types, so we expanded this enforcement discretion to include other certificate types and also not just point of care antigen tests, but also point of care molecular tests.

And we didn’t want to cite an ER that was having a certificate of waiver and then go on to cite a hospital with a certificate of accreditation. So that parity really had to be a part of this process that we needed to look at. And so overall now, if you were actually performing a point of care antigen test or molecular test for an asymptomatic individual, you would not be cited during this public health emergency. I’m going to go on to the next slide.

Now I want to discuss the individualized quality control plans. So underneath normal circumstances– and I’ll say IQCP they’re not allowed to use when you actually have emergency use authorization. However, with emergency use authorization we ask that the manufacturer’s instructions be followed during testing, or that would be considered off-label or even a LTD, or a laboratory developed test.

CLIA received feedback from stakeholders on this matter from when the original FAQ was actually issued out. Stakeholders may CLIA aware that there was supply chain shortages and overall, because of these shortages, that would actually be affecting them, specifically for quality control usage. So therefore, CLIA issued out another frequently asked question in which IQCP was now an option for EUA tests classified as non-waive, but in certain conditions when the manufacturer’s quality control was actually less stringent than the CLIA quality control requirements. And so overall, now, IQCP is an option for EUA tests. I’m going to go on to my next slide, and that would be for– I’m going to go back a slide, I believe, for supply of reagents. Yes. That’s the slide I’m on now.

We understand that reagents were in short supply for COVID-19 testing and other testing. We wanted to be sure that CLIA was not a burden and did not stand in the way to responding to the public health emergency. This frequently asked question was actually just not for only SARS-coV-2 testing, but also for all reagents, overall. So we also received questions concerning test kits, and states received with their specific expiration dates. So if the manufacturer’s instructions stated not to use a test past their expiration date, then the enforcement discretion would not supersede the manufacturer’s expiration date, and this was also the case with the BinaxNOW test. I’m going to go on to the next slide.

Great. OK. Now we want to consider an enforcement discretion concerning surveillance testing. We need to provide clarification, particularly for this particular enforcement discretion, where a lot of questions are asked about it. And so this is for a non-CLIA certified facility should not report any presumptive positive or inconclusive test results in any manner. And that’s actually reporting back any patient specific test results. And that if you were a non-CLIA certified facility, you should actually go forth and refer individuals to a CLIA certified facility. We understand that this monitoring of SARS-coV-2 is a great epidemiological tool, but you cannot provide– or a non-CLIA certified laboratory– provide any presumptive positive or inconclusive test results. And I’m going to go on to the next slide.

And this would actually be now for non-CLIA certified facilities, we’re going to look at particularly with the SARS-coV-2 testing. First, if we consider non-CLIA certified laboratories conducting surveillance testing, a non-CLIA certified laboratory can report SARS-coV-2 test results to a public health laboratory for surveillance purposes. However, if the results would go on to be used for diagnosis, prevention, or any type of health assessment, they must be performed in a CLIA certified laboratory. So we really had to provide some clarification with our enforcement discretions. And finally, go on to the next slide.

Now let’s consider the CLIA laboratory conducting surveillance testing. A CLIA certified laboratory does not have to establish performance specifications if they are conducting surveillance testing and reporting the results to the public health department. But at any time, if the test results would be used for the diagnosis, prevention, or treatment of a health assessment, the test must be performed in a CLIA certified laboratory and in compliance with the CLIA regulations. And I’m going to go on to my last slide.

We just wanted to provide contact information. So we actually have our Lab Excellence mailbox, and also our main central phone number. So if you’d like to contact us at a later date, and if you have any questions, please do so. And thank you.

Thank you very much, Miss Spruill, for your presentation. Now we will be moving into the Q&A session led by Johanzynn Gatewood of the Division of Laboratory Systems.

Thank you, Dr. Henderson. My name is Johanzynn, and I’m from the Division of Laboratory Systems, and I’m going to be facilitating our Q&A session today. Thank you in advance for sharing your questions in the Q&A and ahead of today’s meeting. If we don’t answer your question today, or if you have any questions after today’s meeting, feel free to send an email to OneLab@CDC.gov.

I’m going to start with our first question. I’ll just let our panelists know that they can feel free to jump in if they want to answer. And our first question for our panelists is, “what do we do when test materials are not commercially available, such as swabs or transport media? Can we still perform the test?”

I can start with that one, I suppose. So I think it depends on what is not available. If there are no swabs available, then it would be hard to do a swab test. But I think the question is probably getting at it if specific swabs are not available. For things like swabs and transport media, depending on the type of test, the authorization does not usually list a specific commercial product. It’s usually a type of product. So if there are alternatives available, you can certainly use those.

At different times during the pandemic, we’ve had on the FDA FAQ site lists of alternative products. We don’t have as much of that anymore as the supply chain issues have been relieved throughout the emergency.

Thank you, Toby. We have another question for you, actually. “What will happen when the EUA ends? Will everything eventually switch to FDA cleared/approved?” And we also had a similar question about what the future of EUAs for COVID tests are. You want to comment on that too?

Sure. So we have only authorized one test so far for beyond the emergency. That was the BioFire test that was granted a de novo earlier this year. We have been in conversations with other test developers about transitioning to full authorization, and we do hope that tests will move in that direction. We don’t have any timeline at this point. The public health emergency [AUDIO OUT] previous public health emergencies for which we’ve used emergency use authorizations are still open.

Zika, Ebola, they’re all still active. We can still entertain EUAs under those, and so we don’t expect to stop the EUA process anytime soon. And we have publicly announced that FDA is working on a transition guidance document that will talk about different options for transitioning to full authorization for tests that are under EUA or under [AUDIO OUT].

Great. Thank you. Next question is– and I know Monique need to talked about this– is “how can non-CLIA labs use CLIA and EUA tests?” This Monique.

How can non-CLIA labs utilize a EUA test?

Yes. A CLIA test. Yeah.

Well, I want to go back and [INAUDIBLE] that would be for if you modify the manufacturer’s instructions, and particularly for this. Any laboratory intending to modify a previously EUA authorized COVID-19 assay must be CLIA certified for high complexity testing. That was one thing. And changing a specimen type would actually default that to being changing the complexity of that test and would require the laboratory to establish performance specifications.

And so that’s one thing we wanted to go back and answer right now. And the second question is right now, this would actually be outside of the purview of CLIA for any changes that we would be making with a laboratory developed test. And so if you’re not actually CLIA certified, that would actually be not underneath our purview, for your second question there. And it’s not required to be CLIA certified for this.

Great. Thank you, Monique.

I can also address that from the FDA EUA perspective. The EUAs do specify that the authorized setting, which are unless it’s authorized for home use, the authorized settings are CLIA laboratories. So any laboratory– and Monique, please correct me if I state this wrong from the CMS perspective– but any laboratory that is performing clinical testing is required to be CLIA certified. And from that perspective as well, with the EUA authorizations. Those are authorized for use in a CLIA lab.

Yes. That’s true.

Awesome. Thank you. We’re down to the last minute of today’s session so I’m going to turn this back over to Dr. Henderson-Samuel. Thanks again to our speakers.

Thank you so much, Johanzynn, and thank you to our presenters for presenting today. And unfortunately, we had a shorter Q&A section, but the slides and the resources will be shared with you. Please look out for more information regarding our October 1 live event, in which we will discuss Lessons Learned from the Negative COVID-19 Effects on Supply Chain. As a reminder, all of these slides with links will be posted to [www.cdc.gov/onelab](http://www.cdc.gov/onelab) within the next two weeks. If we weren’t able to answer one of your questions please email one lab at cdc.gov. We’re looking forward to our continued collaboration and being able to assist you in all of your training needs. Thank you and enjoy the rest of your day.