# Quality Cross Check SARS-CoV-2 Testing

September 18, 2020

**Julie McDowell:**

In the current pandemic, the microbiology laboratory plays a central role in testing to meet the demand for SARS-CoV-2 molecular testing. Many laboratories have expanded testing capacity by adding multiple molecular instruments. However, this has left laboratories with questions regarding proficiency testing or PT requirements for these additional instruments, as two CAP members, Dr. Bobbi Pritt and Dr. Lauren Pearson, explained in this CAPcast interview.

Just a little background on both Dr. Pritt and Dr. Pearson before we get to the interview. Dr. Pritt is the chair of the Clinical Microbiology Laboratory and a professor of laboratory medicine and pathology at Mayo Clinic in Rochester, Minnesota. She currently serves as the chair of the CAP Microbiology Committee. Dr. Pearson is assistant professor of pathology at the University of Utah and laboratory director of the University of Utah Health Sciences Center Clinical Laboratories. She serves as chair of the CAP Instrumentation Committee.

Dr. Pritt, let's start with you. With the rise in demand for SARS-CoV-2 molecular testing, can you talk more about what microbiology laboratories are doing to address this need?

**Dr. Bobbi Pritt:**

Yes, I'd be happy to. Laboratories have been in a very challenging situation during the COVID-19 pandemic because we've been experiencing global shortage of test kits and reagents. Because of this, most labs have not been able to get enough supplies for any one test to meet their patient's needs. They've had to bring in multiple different tests and test systems from different manufacturers, thus necessitating having multiple instruments, multiple different tests, and multiple different vendors that they need to work with.

Many labs have implemented 3, 4, 5, or even more SARS-CoV-2 molecular tests. Here at Mayo Clinic, in my laboratory, we're actually bringing in our eight SARS-CoV-2 tests. It's really a unique situation. This is very different than the normal situation in which a laboratory would usually have a single test for a virus like SARS-CoV-2 and then perform the test on a single instrument with perhaps another instrument as backup. Definitely an unusual situation.

**Julie McDowell:**

Dr. Pritt, could you also speak to the challenges that microbiology laboratories encounter when testing volumes increase?

**Dr. Bobbi Pritt:**

Yes. There are many different challenges associated with this. First of all, laboratories need to ensure that they can get a regular supply of reagents and materials to perform the test. That would be from start to finish, including things like the nasal pharyngeal swabs that are used to collect the specimen in the transport media. Being creative and having a robust supply chain has been essential during this pandemic, especially for identifying alternative options for supplies and negotiating favorable pricing agreement.

Another challenge is that COVID-19 testing sometimes competes with other laboratory testing that is being performed in the laboratory, either because COVID-19 testing takes time away from our staff, so they don't have time to perform alternate testing or because the COVID-19 testing is performed on the same instruments. Pathologists and other laboratory leaders have had to make difficult decisions about which tests they're going to continue to perform and which ones they might have to take down or send out to a reference laboratory.

Then, importantly, there are all the challenges that come with performing high-volume testing on multiple different testing systems. Each test needs to first thoroughly be evaluated and then validated before being used for patient care. Then, all the technologists have to be trained on each system. The laboratory has to perform regular competency assessments to ensure that the technologists remain competent.

Also, each system has to have ongoing quality control testing and other quality assurance measures, such as doing comparison testing of the different systems every six months to ensure they're giving equivalent results. Then, lastly, each test needs to be periodically evaluated through the use of proficiency testing in which positive and negative specimens are tested in a blinded manner in the same method as patient specimens to determine if the expected results are obtained.

Many laboratories will subscribe to external proficiency testing products to do their proficiency testing. Fortunately, these are available through various organizations, such as the College of American Pathologists. In this case, the college responded very quickly to the pandemic and produced an excellent proficiency testing product for SARS-CoV-2 molecular testing that laboratories can use, but there's some very specific regulatory requirements about proficiency testing that may pose some challenges during the COVID-19 pandemic because laboratories are using these multiple different systems. Many laboratories may be unaware of the regulatory jeopardies that they face.

**Julie McDowell:**

Regulatory risk is an interesting question. Dr. Pearson, what are the PT requirements for laboratories doing molecular testing?

**Dr. Lauren Pearson:**

That's a great question. In the context of this discussion, it's important to know that laboratories may not test proficiency testing samples more than once during a proficiency testing event. That is a general rule that applies to all assays in a laboratory. But it's important to understand that this includes testing proficiency testing samples on multiple instruments or ordering multiple proficiency testing kits to challenge instruments in the given laboratory in the situation where a lab might have multiple instruments for a specific assay like SAR-CoV-2. Testing proficiency testing samples more than once is taken very seriously by CMS.

**Julie McDowell:**

Why is this a problem?

**Dr. Lauren Pearson:**

In August 2015, the Centers for Medicare and Medicaid Services or CMS, as I referred to it just a moment ago, reiterated that laboratories are not permitted to test proficiency testing samples on multiple instruments unless that is how the laboratory tests patient specimens. The interpretation was expanded beyond regulated analytes to include analytes not listed in the Clinical Laboratory Improvement Amendments regulations. This includes waived methods.

**Julie McDowell:**

What can the laboratory do to address this?

**Dr. Lauren Pearson:**

One option is to utilize a product such as the Quality Cross Check program, such as CoV-2 Q. What this program allows a laboratory to do is to stay in compliance with the regulations around proficiency testing while also being able to meet additional regulatory requirements in the area of inter-instrument comparison that Dr. Pritt referred to earlier in this podcast.

**Julie McDowell:**

Finally, Dr. Pearson, can you please tell us a little more about the Quality Cross Check program's design?

**Dr. Lauren Pearson:**

Sure. I want to be very clear, first of all, that it's not proficiency testing. The shipments are spaced between proficiency testing events so that the laboratory can monitor performance across multiple instruments and maintain compliance with the CMS directive. The kit allows the lab to assess performance of up to three instruments by peer group comparison. In the situation where a laboratory has more than three instruments in use, such as in Dr. Pritt's lab at Mayo, for example, multiple kits may be purchased. But the key take-home message about this product is that it provides opportunity for inter-laboratory comparison of instruments, or, in other words, inter-instrument comparison, which is a requirement for laboratory accreditation.

**Julie McDowell:**

Great. Well, thank you, Dr. Pritt and Dr. Pearson. If your laboratory could benefit from this Quality Cross Check program, more information is available on the CAP website. Go to cap.org and click on the shop link in the upper right corner to visit our online store. The program code is COV2Q. Interested participants can enroll for 2020 participation. The shipping date will be October 26th. For 2021 enrollment, interest laboratories can add this program to their 2021 PT Order Renewal.

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