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MANAGEMENT > QA/QC

## Dear API Abby

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The American Proficiency Institute (API), a global leader in proficiency testing programs, is dedicated to improving the accuracy and efficiency of clinical laboratory testing. Known for its constant innovation in the field, API offers technical expertise and checklists to help its laboratory customers become more proficient. Below, API's Technical Support Manager, Anita Hoeksema; Quality and Compliance Manager, Sue Styles; and Technical Support Specialist, Danielle Casey offer a series of commonly asked questions with responses aimed to improve laboratory quality.

### Dear API Abby:

Our main hematology analyzer, we nicknamed it Oscar, is ready to retire. Our laboratory is seeking an instrument replacement. Will we need to switch our proficiency testing program?

Thank you,

Lost Without Oscar

**Dear Lost Without Oscar:**

It can be challenging when those stalwarts we have worked with for so long meet their expiration dates. As you investigate those new instrument opportunities, you will need to ensure you have the correct proficiency testing program to match. Most hematology analyzers that test complete blood count with differential will require a proficiency program specific to that analyzer. When you are ready to make the switch, contact your proficiency testing provider to make certain you are enrolled in the correct program.

**Dear API Abby:**

I received my proficiency testing evaluation today and, to my dismay, a failure was received! After taking deep breaths and going for a walk, I found my resolve to dive into the cause of this failure. Please help, what do I do now?

Anita Pass

**Dear Anita Pass:**

You took a positive first step already — when embarking on any stressful situation, it is important to be calm and ready to think rationally. Next, be sure to involve your testing personnel and laboratory director in the investigation, remedial action, and documentation process. Failures can occur for a variety of reasons. API provides a “Corrective Action Checklist,” which will help walk you through investigating sample handling, clerical errors, quality control matters, calibration issues, instrument problems, and reagent concerns. Remember, it is important to review past patient results that were reported during the period when your proficiency testing was unsatisfactory! You need to ensure that patient results were not affected or potentially affected during this time. Work closely with your medical director to make certain you have addressed the issue, once identified, and have taken the appropriate mitigation measures going forward.

**Dear API Abby:**

My co-worker and I are having a disagreement that we hope you will resolve. On our last proficiency test evaluation, we received a score of 100% in the performance summary for our urine adulteration testing. Yet, looking at the comparative evaluation, it shows our result is “not graded.” My co-worker believes we should do something with this analyte since it was not graded. I think, since we received a performance score of 100%, we do not need to do anything additional. Who’s right?

Resting on My Laurels

**Dear Resting:**

Your co-worker is 100% correct. You do need to review the comparative evaluation and assess your result. You should compare your results to the expected result(s). If your result falls within the expected range, document that your laboratory obtained the correct response. If your result(s) does not fall within the expected range, you should troubleshoot to determine the cause of the failure. If the expected results are not available, you may need to complete an alternative assessment.

**Dear API Abby:**

Sorry, but I really dislike doing proficiency testing. I feel this is a waste of our time and resources. Why do we have to do so many?

Ima Bizzle

**Dear Ima:**

Proficiency testing is used to verify the accuracy and reliability of the analytes for which you are testing. It can identify subtle shifts and trends that may not be as evident with quality control. Proficiency testing may be used to validate pre-analytical, analytical, and post-analytical processes, which helps to assess too the competency of testing personnel. Importantly, if problems linger, patient results may be affected.

There are certainly times in life when we must complete tasks we do not like, but knowing that accurate laboratory results are so critical to patients is something that motivates me to action. If that's not enough, remember that proficiency testing is required by the federal government and laboratory accreditation agencies.

**Dear API Abby:**

Our medical director just approved the use of ten point-of-care (POC) devices that will be used for reporting patient INR (international normalized ratio) results. Ten! How am I going to perform proficiency testing on all of these point-of-care devices?!? We already perform proficiency testing on the main laboratory coagulation instrument, and now I have these additional ones. What should I do?

Counting POC in My Sleep

**Dear Counting:**

It's good of you to be concerned when considering proficiency testing for multiple instruments. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations state that if a laboratory uses multiple methods to test an analyte, then one instrument/method should be designated as the primary method. Proficiency testing should be performed on that specific analyzer. This scenario may match what you have with your coagulation instrument in your main laboratory, and your POC devices throughout the hospital.

Laboratories should not test proficiency samples during the proficiency testing event with more than one instrument — unless that is how they test all patient specimens. After the primary test due date, your ten POC devices may have proficiency testing performed. API offers verification programs just for this purpose. Laboratories are directed to test verification samples after the proficiency testing due date and submit results online. Verification evaluations are available online when the evaluations for proficiency programs are also released.

The convenience of using proficiency samples and statistics to verify secondary instruments and method, all while remaining compliant with CLIA regulations, is beneficial to busy laboratorians like you. Plus, you may assign the proficiency test to personnel performing the testing on the hospital floors to help document their competency when performing testing.

**Dear API Abby:**

I hear so much about wildfire season in the west and hurricane season along the coasts. What happens during these natural disasters if laboratories are unable to do proficiency testing? How can I be prepared if something like this threatens my lab?

Nervous Nellie

**Dear Nellie:**

We applaud you for thinking of risks ahead of time. Risk management is very important! Regardless of the situation, if you are still testing patients, you still must perform proficiency testing. Proficiency testing providers do not have the authority to excuse you. You will usually have at least two weeks to complete your proficiency testing. Be aware of when your proficiency testing is coming, and don't leave it until the last minute.

If the natural disaster has a significant impact on your area and patient testing is down for the whole period, communicate and document the situation. CLIA requires that you notify your state or accreditation agency and your proficiency testing provider for consideration to be given. Since you already sound like a planner, you could add their contact information and your proficiency testing schedule to the packet of emergency contact information.

If you are able, access your proficiency testing provider's website, complete your result reporting, and indicate that your testing was down for a period of time. This will prevent the 0% scores that proficiency testing providers are required to issue if they do not hear from you. Also document the communication made to your state or accreditation agency. Keep records of when testing was down and when it resumed, the impact of the disaster

(e.g., power outage, flooding), and your laboratory's subsequent capabilities. This documentation will be reviewed at your next inspection. Hopefully these tips will help you have your proficiency testing covered.

### **Dear API Abby:**

My laboratory switched proficiency testing providers this year. My friend works at a laboratory that did the same and they had some trouble at first. She can be a bit negative, so it's tough to tell if it was sour grapes or if she truly had problems. Do you have any tips for things to watch out for during this transition?

Hopeful for Smooth Transitions

### **Dear Hopeful:**

A positive and "can-do" attitude is always helpful in approaching any change. From our experience, most laboratories are aware that they should first read sample storage instructions and testing instructions carefully. Reviewing method lists from your new provider to make the correct choice for each of your tests is also kind of obvious, but plan time to ask questions because method choice can affect how your results are evaluated. Also, while you are likely to read website instructions the first time you submit results, be sure you get a confirmation screen acknowledging results have been received! The confirmation should have a date and time listed, or some sort of record that looks like a "receipt" for your transaction. If you aren't sure, submit your results early and call your new provider to confirm receipt. This will avoid getting a failure to participate for your first event due to something small and easily preventable.

What might trip you up may relate to any samples you still receive from your old provider and reviewing your evaluation reports from your new provider. If you are still receiving samples from your old provider, make sure you tell them about any analytes you will not be reporting to them anymore. If you don't, they may continue to expect results from you and could issue you a 0% score. This is considered a clerical error that they cannot remove, so make sure to keep in touch with them ahead of time.

Regarding evaluations from your new provider, make sure you understand how any “not graded” samples are indicated so you may follow up on them. Ask for a tutorial or webinar that may go over the features of the report or how to find any statistical information you need. This may help you complete any internal documentation so you may put that successful proficiency testing behind you and move on to the next item on your to-do list!

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