A CONVERSATION WITH THE CAP ON OSMOMETER QUALITY CONTROL

ABSTRACT

On March 8, 2021, Advanced Instruments had a conversation with the College of American Pathologists (CAP) on osmometer quality control. During the conversation, CAP addressed key topics including how CAP approaches osmometer QC, what CAP looks for during an inspection, the importance of following manufacturer instructions and guidance for QC monitoring.

INTRODUCTION

Welcome to our conversation with the CAP on Osmometer Quality [Control], brought to you by Advanced Instruments, the leader in osmolality testing in clinical chemistry, in collaboration with the College of American Pathologists, a global leader in laboratory accreditation. To find out more, please visit aicompanies.com. And now, here's your host, Julie MacKenzie.

Julie MacKenzie (Advanced Instruments):
Hi everyone. This is Julie MacKenzie. I'm the Senior Manager for our Clinical Product Portfolio at Advanced Instruments. I'm here with Stacy Meyer, Senior Technical Specialist for Accreditation Services at the College of American Pathologists. Thank you so much for being here today Stacy.

Stacy Meyer (College of American Pathologists):
Hello All. I'm looking forward to our discussion today.

Julie MacKenzie (Advanced Instruments):
Stacy, today we're going to talk about osmometer quality control. But first, can you tell me about your role at CAP?

Stacy Meyer (College of American Pathologists):
Sure. I am one of the technical specialists in the Laboratory Accreditation Program section of the College of American Pathologists also known as CAP. Our group works with laboratories to help understand the regulatory and compliance needs as defined in our checklists as well as post-inspection review processes for all CAP accredited laboratories.

Julie MacKenzie (Advanced Instruments):
Great! What was your background before joining CAP?

Stacy Meyer (College of American Pathologists):
I have worked in laboratories for more than 15 years now. I started doing data entry while finishing up my MLT degree. I then went on to get my bachelor's degree and became an ASCP certified MLS. I have worked in both clinic and large hospital laboratories doing every part of the job from phlebotomy on up. I have now been with the CAP for over 3 years and love working with laboratories from the regulatory and compliance perspective. I have experience in all areas of the laboratory including use of Advanced Instruments osmometers.

Julie MacKenzie (Advanced Instruments):
Great! To start, what section of the CAP checklist does osmolality quality control fall under?

Stacy Meyer (College of American Pathologists):
Most laboratories will have this fall under the CAP Chemistry checklist. We do have some laboratories that will use the Limited Services Checklist but either way the requirements are the same for daily quality control of non-waived testing. For example, in the Chemistry checklist it would be CHM.13900 whereas in Limited Services checklist, it would be LSV.37078. The verbiage is exactly the same though.

Julie MacKenzie (Advanced Instruments):
Great! Can you tell me about how CAP approaches osmometer QC? What do you look for during an inspection?

Stacy Meyer (College of American Pathologists):
Quality control or QC is a very important process to ensure that the patient results being reported are accurate. QC is one way to ensure that the instruments generating results are in good working condition and results can be

relied upon. It is critical that laboratories follow both the requirements defined by CLIA as well as the manufacturer of the instrument and the reagents used. When looking at laboratories during an inspection, a good understanding of the testing being done is critical as well as any package inserts or instruction manuals.

If I am inspecting, I like to look at several months of QC records in conjunction with package inserts and manuals as well as laboratory policies with maintenance and calibration records to ensure the instrument is maintained as required.

Julie MacKenzie (Advanced Instruments):
That's good to know. Is it correct then that CAP does not require use of third-party controls?

Stacy Meyer (College of American Pathologists):
Correct – CAP does not require any specific type of QC to be utilized. This is where the manufacturer's instructions will come into good use. If a manufacturer states that a specific QC product must be utilized, any modification to that process changes the testing complexity as well as other validation requirements.

For non-waived tests that are FDA cleared or approved, like osmos, these are considered moderately complex tests by the FDA. If a laboratory chooses not to follow the manufacturer instructions, the testing now becomes high complexity testing, and a complete and full validation is required. This can be a lengthy process involving the laboratory performing studies to prove not only accuracy, precision, and reportable range but also specificity and sensitivity as well. By following the manufacturer instructions, the process is much simpler, and these lengthy steps can be avoided.

Julie MacKenzie (Advanced Instruments):
That's helpful information. Advanced Instruments recommends that laboratories testing serum and urine osmolality run Clinitrol™ 290, Protinol™ Protein-Based Controls and Renol™ Urine Osmolality Controls on days when patient testing is performed. Clinitrol confirms the calibration of the osmometer and Protinol and Renol verify instrument performance at clinically relevant normal and abnormal levels. This recommendation can be found in the user guide update we issued in October 2020.

Stacy Meyer (College of American Pathologists):
Per CAP requirements, this would meet the checklist requirements discussed earlier as two levels of QC would be required at least daily and should be at clinically relevant decision points.

Julie MacKenzie (Advanced Instruments):
Great! Osmolality results are vital to the diagnosis and treatment of body fluid disorders which is why our manufacturer-recommended controls, Protinol and Renol, are designed to challenge medical decision points. Protinol includes three levels- 240 (an abnormal low level), 280 (a normal level) and 320 (an abnormal high level) mOsm/kg H_2O. Renol includes two levels- 300 (a low level) and 800 (a high level) mOsm/kg H_2O.

Can you speak to CAP's recommendation regarding the number of quality control replicates a lab should test?

Stacy Meyer (College of American Pathologists):
Yes. It is up to the laboratory director to determine the number of replicates appropriate for their laboratory. CAP requirements state that for quantitative testing, at least two levels of QC are run each day of patient testing. QC must be run by the same personnel performing patient testing.

Julie MacKenzie (Advanced Instruments):
That makes sense. Protinol and Renol are both assayed controls. Does CAP guidance differ depending on whether controls are assayed or unassayed?

Stacy Meyer (College of American Pathologists):
Yes. For assayed controls like Protinol and Renol, the laboratory must verify the ranges supplied by the manufacturer for acceptability. They can do this simply by running the QC as intended by the manufacturer and verifying the QC is in those ranges. Some laboratories may choose to run a few replicates and establish a tighter range than the manufacturer but can never go beyond that manufacturer defined range.

This is different from unassayed controls. For unassayed controls, the laboratory must establish a valid acceptable range by repetitive analysis.

Julie MacKenzie (Advanced Instruments):
OK, it's clear how assayed control materials save laboratories time. We're able to help labs troubleshoot quickly with Protinol and Renol minimizing downtime. The acceptability ranges for Protinol and Renol are intentionally tight and consistent lot-to-lot. As a result, labs can have confidence that the controls will allow them to quickly spot shifts in instrument performance and labs may not need to do as extensive testing to determine their own QC ranges when transitioning to a new lot of control material.

Stacy Meyer (College of American Pathologists):
That's a good point. It may be an opportunity for labs when they use your assayed control material to update their procedures and reduce the amount of testing they are doing to validate new control lots since such extensive validation testing is not required by CAP.

Julie MacKenzie (Advanced Instruments):
That's great information. Can you speak to CAP guidance on QC monitoring?

Stacy Meyer (College of American Pathologists):
Yes. At least monthly, laboratories must have documented evidence of QC review. This includes statistical evaluation for imprecision in QC. So, looking at the data from the entire month to see if there are any shifts or trends in QC may indicate an issue with the instrument before any patient impact occurs.

Julie MacKenzie (Advanced Instruments):
That makes sense. We provide instant and monthly reports as part of our Advanced QC Peer Group Program. Registration for the peer group program is free and available at aicompanies.com/advanced-qc.

Stacy Meyer (College of American Pathologists):
Peer group data is a great tool that many laboratories participate in. It will not only show how your laboratory is performing and monitoring your required statistics but will also compare your laboratory to other laboratories using the same lot number. Sometimes these reports may show that your laboratory has a shift or trend that may be a first indicator of issues. These can be resolved then prior to impacting patients.

Julie MacKenzie (Advanced Instruments):
Great! Thank you for the informative discussion Stacy. We truly appreciate you being here today. This has been Julie MacKenzie, Senior Manager for our Clinical Product Portfolio at Advanced Instruments. Thanks to all for listening.

Stacy Meyer (College of American Pathologists):
Thanks for having me! Don't forget you can always call or email CAP if you have any questions.

Julie MacKenzie (Advanced Instruments):
Great, thank you so much!

CLOSING REMARKS:

You've been listening to, "Osmometer Quality Control." This was brought to you by Advanced Instruments, the leader in osmolality testing in clinical chemistry, in collaboration with the College of American Pathologists. To find out more, please visit aicompanies.com.