FAQs

Topic: Q&A From Webinar: Monitor Performance of Multiple Glucose Meters and Stay in Compliance
Date: October 17, 2016

CAP Accreditation Program Proficiency Testing (PT) Requirements for Whole Blood Glucose Testing

Is enrollment in an external PT program required for waived whole blood glucose testing using glucose meters?
Beginning in 2017, PT for waived whole blood glucose on glucose meters will no longer be required for laboratories accredited by the CAP. Laboratories will be required to perform alternative performance assessment (APA).

Is PT required for other instruments that test for waived whole blood glucose, such as the iSTAT?
Yes, PT requirements will only be discontinued for waived whole blood glucose by meter (strip). PT will still be required for other waived whole blood glucose methods such as iSTAT, Hemocue, and Piccolo.

Many laboratories have multiple iSTAT instruments. Why is PT still required?
While iSTAT uses a whole blood sample, it uses a blood cell separation microfluidic system and essentially tests plasma. Additionally, Hemocue and iSTAT are FDA approved for quantitative glucose measurement without restrictions, whereas meters do not have FDA approval for critical care use. The CAP offers a Quality Cross Check program (AQ4Q) for laboratories that want to verify the accuracy and perform comparability studies for additional iSTAT instruments.

What about laboratories that use glucose meters off label to test critically ill patients? Would they need to enroll in PT at a frequency of five challenges/three times per year?
The use of a waived whole blood glucose meter off label would classify it as a nonwaived method (high complexity); therefore, it would be subject to all the requirements for nonwaived methods in the CLIA regulations, including verifying the accuracy of the method twice per year. Quality Cross Check—Whole Blood Glucose (WBGQ) can be used to meet this requirement. In addition, laboratories can enroll in the Waived Test Combination (HCC2) to meet the requirement.

Alternative Performance Assessment (APA) for Whole Blood Glucose Testing Using Meters

What type of specimens can be used for APA—split sample, controls, linearity, external PT materials? Would instrument comparison qualify as alternative assessment?
Semiannual APA options for waived whole blood glucose testing on glucose meters are as follows:
- Participation in an external PT program or the Quality Cross Check—Whole Blood Glucose (WGBQ) program
- Split sample analysis with reference or other laboratories
- Split samples with an established in-house method (for example, Chemistry analyzer, iSTAT, etc)
- Use of assayed materials (for example, blinded QC and/or linearity material
- Other suitable and documented means
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**Are laboratories required to perform APA on each meter in their laboratory?**
No, APA is required at the analyte level and is not required for each instrument/method. Similar to PT, a laboratory should rotate APA among glucose meters.

**Should alternative performance assessments be performed by end users, just as PT samples are performed by end users?**
Yes, a laboratory should rotate APA among glucose meters and personnel.

**Can the laboratory director delegate the duty of APA review or does the laboratory director have to sign all the APAs?**
It is the responsibility of the laboratory director to define such alternative assessment procedures and the criteria for successful performance in accordance with good clinical and scientific laboratory practice.

APA review may be delegated, in writing, to other qualified individuals.

**Quality Cross Check—Whole Blood Glucose (WBGQ)**

**My hospital has more than 30 glucose meters. What are my options for verifying the accuracy of all of these meters?**
A single WBGQ kit may be used to test 30 meters, and laboratories may rotate meters between shipments. Alternatively, you may order multiple WBGQ kits to test additional meters.

**Can I test more than 30 meters per WBGQ kit by testing each of the three specimens on different meters?**
No, the WBGQ kit is intended to test up to 30 meters. It contains three specimens each with a different level, and every meter used in testing will report a value for each of the three levels.

**Can one operator perform testing for all 30 meters using the WBGQ kit?**
No, a laboratory should rotate testing among glucose meters and personnel.

**How will I receive results from WBGQ?**
Participant evaluations and a Participant Summary Report (PSR) will be available online at cap.org in e-LAB Solutions Suite. In addition, reports will be mailed to participating laboratories.

**How will the CAP monitor Quality Cross Check?**
Quality Cross Check is not a form of proficiency testing, and as such will not be formally monitored by the CAP’s Laboratory Accreditation Program. Laboratories will be required to provide Quality Cross Check reports, evaluation of results, and any subsequent corrective actions performed during their on-site inspection.

**Will laboratories need to write another policy/procedure to cover the assessment of Quality Cross Check or will PT procedures cover this?**
Quality Cross Check is not a form proficiency testing, and it is important that laboratories distinguish PT from Quality Cross Check in their procedures. Similar to PT, the Quality Cross Check program provides an evaluation of results, and as such the written procedure can reflect a similar process to how laboratories evaluate graded PT.