COLLEGE of AMERICAN PATHOLOGISTS

FAQs

Topic: **CMS Directive Regarding Testing PT Samples on Secondary Instruments/ Methods**

Date: October 28, 2015

As 2016 order renewal for the Surveys proficiency testing (PT) programs begins, the College of American Pathologists (CAP) would like to provide additional guidance about secondary (or multiple) instrument testing and alert you to some important changes:

1. The Centers for Medicare & Medicaid Services (CMS) has reiterated that **laboratories are not permitted to test PT samples on multiple instruments unless that is how the laboratory routinely tests patient specimens**. A laboratory's standard operating procedures must be written to reflect that process.

2. Recently, the CMS communicated to approved PT providers that **this directive applies to all analytes**, including those not listed in Subpart I of the Clinical Laboratory Improvement Amendments (CLIA) regulations, as well as analytes/methods categorized as waived tests (such as whole blood glucose meters).

The CAP is committed to providing comprehensive solutions that allow you to effectively monitor the quality of testing across the laboratory, ensuring accurate results for your patients, while complying with all regulatory requirements. As such, **the CAP will expand its CAP Quality Cross Check offering in 2016 to include additional analytes**. The new programs include: Coagulation, Limited (CGLQ), Clinical Microscopy (CMQ), Activated Clotting Times (CTQ, CT1Q, CT2Q, CT3Q, and CT5Q), Body Fluid Chemistry (FLDQ), Hemoglobin A_{1C} (GHQ), and Occult Blood (OCBQ). These programs will allow you to augment your instrument comparability efforts, while delivering additional opportunities to fulfill competency assessment requirements.

It should be noted that in 2016, laboratories will be able to purchase multiple kits of the Whole Blood Glucose Surveys (WBG/ WB2) to test all their glucose meters, but with some important changes in the timing of testing and reporting of results. See the FAQ's below for more details.

The details of these new offerings are currently being finalized and will be available in the next few weeks. At that time, the CAP will provide additional guidelines and information to help you make all necessary changes to your laboratory's order.

To help you better understand this directive, refer to the FAQs below.

CMS DIRECTIVE

It is clear that the directive to not test PT samples on multiple instruments applies to regulated analytes, but does it also apply to nonregulated analytes?
Yes, it applies to all analytes, including nonregulated, as well as analytes/methods classified as waived tests such as whole blood glucose meters.

My laboratory currently orders WBG/WB2 and reports on multiple instruments. Will we be able to continue to use this program to evaluate all of our point-of-care whole blood glucose meters?
Yes, you will be able to use these Surveys to evaluate all of your point-of-care whole blood glucose meters. While the recent communication from the CMS regarding multiple instruments applies to waived analytes/ methods such as whole blood glucose meters, we understand that this PT program is unique and important to a laboratory's quality management initiatives. The CAP has made changes to the time of testing and reporting of results that are permissible under CMS and CLIA guidelines such that you can use these Surveys to test all of your whole blood glucose meters.

The CAP is proceeding with an interim solution for 2016 in which we allow laboratories to test whole blood glucose PT samples on secondary instruments after the PT event cut-off date and **submit the results online only**. Full instructions on how to perform the testing in a CLIA compliant manner will be included in the kit instructions. In 2017, we will introduce a more comprehensive solution for whole blood glucose.

How does this new directive from the CMS impact how large laboratories, with multiple testing sites or separate locations in which all are under one CLIA number, order Surveys other than Whole Blood Glucose? For example, previously laboratories such as these would have been able to order a Chemistry Surveys kit for four different sublevels (-01, -08, -10, and -11) for use in different departments. Is this still an option, or will they only be able to order one Chemistry Surveys kit for their single CLIA license?
If a large laboratory has multiple testing sites or separate locations in which all are under one CLIA license, then they will only be able to order one Chemistry Surveys kit unless they are testing multiple instruments, all with different analytes. The CAP Chemistry Quality Cross Check program (CZQ) can be used as an alternative to purchasing multiple Surveys kits and will reduce the risk of noncompliance associated with purchasing multiple proficiency testing kits.

One PT result per analyte per type of specimen (serum, whole blood, urine, etc.) is allowed for each individual CLIA-licensed laboratory. If a laboratory routinely uses more than one primary method/instrument for reporting the same analyte, PT can be rotated among the primary methods/instruments. This is similar to personnel rotation for PT**.** According to the CMS, a central laboratory with more than one instrument or methodology for the same test may alternate methods or instruments from one testing event to the next as long as both are routinely used to test patient specimens. All samples for one analyte within a shipment must be tested with the same instrument.

Can multiple PT programs be ordered for the same analyte if the programs have different specimen types (for example, CGL for plasma prothrombin time and WP4 for whole blood prothrombin time)?
Yes, multiple PT programs can be ordered for the same analyte if the programs have different specimens (either in type or formulation). These programs have different target values and are not comparable to each other.

I currently purchase multiple kits for excess material to provide competency assessment for laboratory staff or for troubleshooting. Will I be able to order multiple kits in 2016 for these purposes?
Yes, you will still be able to purchase multiple kits for these purposes. If multiple kits are ordered for this purpose, then you should only return results for the kit that is tested on the primary instrument. The remaining kits will not be penalized for unreturned results.

The CAP advises you to exercise caution with regards to how you utilize these samples. You should never test these kits on multiple instruments during the PT event, but instead wait until after the submission due date to use this material for competency purposes.

What if my laboratory is a non-CLIA or international laboratory?
If your laboratory is **not** subject to United States CLIA regulations, your laboratory can run tests on both your primary (first) and secondary (backup) instruments at the same time. Multiple kits of the same program can be purchased and tested, and their results returned at the same time.

ORDER RENEWAL 2016

How will this change affect my order renewal for 2016?
The CAP is expanding its Quality Cross Check program in 2016 to include additional analytes. Order renewal packets are currently in the mail, and these packets do not include information regarding the new CAP Quality Cross Check program offerings. The preprinted order form included in these packets will reflect the Surveys and quantities ordered in 2015. The details of the new programs are currently being finalized and information will be available in the next few weeks. As this becomes available, the CAP will provide additional guidelines and information to help you make all necessary changes in your Surveys order.

In addition, you can order whole blood glucose meter testing for multiple instruments in 2016, with the restriction that only one result may be submitted in the PT testing period and that any additional quality testing is performed only after the due date for PT results. Quality testing after the due date will be limited to online reporting.

If a laboratory has already placed their Surveys order for 2016, they should review their order to make sure they are in compliance with the CMS directive.

What are the new CAP Quality Cross Check Programs for 2016?
Coagulation, Limited (CGLQ), Clinical Microscopy (CMQ), Activated Clotting Times (CTQ, CT1Q, CT2Q, CT3Q, and CT5Q), Body Fluid Chemistry (FLDQ), Hemoglobin A_{1C} (GHQ), and Occult Blood (OCBQ)

Details on these programs will be finalized and communicated in the next couple weeks.

ACCREDITATION

Will this new directive affect our laboratory's accreditation?
As long as a laboratory follows this directive, no impact on your laboratory's accreditation status will result.

Will this directive affect my activity test menu?
No changes are needed to a laboratory's activity menu as a result of this directive. The activity menu should reflect your laboratory's testing.

Will this affect my Analyte Reporting Selections (ARS) report?
This will not affect your laboratory's ARS report. New functionality is being introduced for 2016 that will ensure selection of the kit that has submitted results.

Will laboratories receive a proficiency testing compliance notification (PTCN) if they don't return results?
If multiple kits are ordered for purposes such as competency assessment or excess material, then results should only be returned for the kit that is tested on the primary instrument. The remaining kits will not be penalized for unreturned results.

If CAP PT is not reported for a secondary instrument, what type of assessment should be done?
Biannual comparison studies must be performed if more than one instrument/method is routinely used for patient testing. The CAP's Quality Cross Check program offerings may be used for compliance with the CAP accreditation requirement for COM.04250 (Comparability of Instruments/Methods) for tests performed on the same instrument platform with reagents of the same manufacturer and lot number. The Quality Cross Check programs CZQ and SOQ can be utilized in this capacity as well as all new CAP QCC program offerings developed for 2016.

What specific checklist questions address this issue?
Many laboratories have used PT as a means to compare results between non-waived instruments/methods. With this new directive, PT cannot be used for this purpose and, therefore, another alternative must be sought. The CAP Quality Cross Check program may be used in assessing comparability of instruments/methods. Review the Notes section of COM.04250 for more information. In addition, COM.01000 applies, as the laboratory must have appropriate procedures for PT. COM.01600 refers to the integration of PT into the routine workload and also has bearing on using multiple kits. Please review the notes on each of these requirements as well.

COM.01000 PT Procedure Phase II
The laboratory has written procedures for proficiency testing sufficient for the extent and complexity of testing done in the laboratory.

COM.01600 PT Integration Routine Workload Phase II
The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by the personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples.

COM.04250 Comparability of Instruments/Methods Phase II
If the laboratory uses more than one non-waived instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for comparability of results.

CONTACT INFORMATION

If we have questions, who do we contact at the CAP?
Call the CAP Contact Center at 800-323-4040 or 847-832-7000 option 1, or email us at contactcenter@cap.org for assistance.