COLLEGE of AMERICAN PATHOLOGISTS

Webinar Q&A

Topic: **Q&A from CAP Webinar: Stay in Compliance With the CMS Directive Regarding PT Testing on Multiple Instruments**

Date: November 12, 2015

The questions below were received from attendees of the CAP webinar held on November 12, 2015. Please contact CAP Customer Contact Center at 800-323-4040 option 1 for more information.

Clarification of the CMS Directive

Customer Question	CAP Response
1.) Can you rotate proficiency testing (PT) events on multiple analyzers throughout the year or do you always need to run PT samples on the primary analyzer?	PT should be performed on the lab's primary instrument. If there are multiple instruments designated as primary, PT can be rotated among the primary instruments.
2.) How do we determine if two analytes are different? Is it by activity code, number of results fields on current CAP result forms, subdiscipline, method and units of measure, or different clinical use and different reference ranges (LDT)?	Please contact the CAP Customer Contact Center at 800-323-4040 option 1 for more information about the specific situation in your laboratory. Generally, if the PT program codes are different, the material is different. Exceptions to this include a number of the chemistry and blood gas programs.
3.) We have two chemistry analyzers and both are primary. We order one survey and run it on one of the analyzers only. For future surveys do we only run on that same analyzer or can we switch to the other analyzer as long as we run all samples on that analyzer?	Your current practice is in compliance with the CMS directive. The PT must be run on the primary instrument. If you wish to rotate PT on the other analyzer, it is acceptable as long as it is performed on only one instrument. Always make sure that the PT Result Form is populated with the appropriate instrument/method codes so that your laboratory results are evaluated in the appropriate peer group.
4.) Can you test a PT sample on another instrument if it meets laboratory repeat testing criteria to repeat on second instrument?	A laboratory should not test PT samples on more than one instrument/method unless that is how it tests patient specimens. Repeated analysis of PT samples is not appropriate unless patient specimens are similarly tested.
5.) Can you provide the exact CLIA rule in your follow up?	https://www.cms.gov/Regulations-and-

	Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html
6.) If point of care (POC) is under the same CLIA number as laboratory, do you consider POC primary and laboratory secondary?	If more than one instrument is used for patient testing, the laboratory should designate one instrument as primary and perform PT on that instrument. For future PT mailings, you may rotate PT on other primary instruments.
7.) Can we run the same analyte on a CAP Survey and a CAP-approved vendor survey if only one is reported to the CMS?	Yes, but it is the responsibility of the laboratory to communicate with the CAP and the Laboratory Accreditation Program-accepted PT vendor regarding who is reporting results to the CMS.
8.) Is it correct that the laboratory can test multiple analyzers if two different kits are used? If so, which result will be submitted to the CMS?	Multiple kits of the same PT program can be ordered from the CAP, but the laboratory has the responsibility to ensure the same analyte is not tested more than once during an active PT event, inclusive of all kits (on the same or different instruments). If the multiple kits are from different PT programs utilizing different material, then it is allowed; and the laboratory would need to designate which result is submitted to the CMS.
9.) Can you split a PT kit between two different instruments (three samples on one and two samples on another)?	In this situation even though no PT sample is run more than once, there is no way to report differing methodologies by sample. It is advised to run the entire kit on one instrument, and rotate instruments over PT mailings.
10.) Why can't you run the same material, on the second analyzer after the reporting deadline?	You are allowed to run the same material on a second analyzer after the PT due date has passed. Laboratories need to be aware of specimen stability and will need to perform a self- evaluation on any secondary results.
11.) If you run ABC analytes on one instrument and CDE on another (sharing the C analyte), how do you order/report PT?	Analyte C may only be run one time on one instrument during the PT event. Ordering for PT depends upon the specific analytes and/or instruments in question.
12.) If you have three identical analyzers and currently use three of the same PT kits testing—one kit on each analyzer once/year—is that still acceptable or do we only run PT on one "primary" analyzer?	If more than one instrument is used for patient testing, the laboratory should designate one instrument as primary and only perform PT on that instrument. For future PT mailings, you may rotate PT on other instruments.
13.) We have two separate CLIA numbers, one for POC testing and one for the main laboratory. We perform urinalysis in both	No, your current practice is in compliance with the CMS directive because there are two separate CLIA numbers.

laboratories. How would this change affect us? Would we be out of compliance reporting two surveys, even though we have separate CLIA numbers?	
14.) Can I purchase a kit for each machine and submit each one as a primary machine?	No, you need to designate one instrument as primary and perform PT on that instrument. For future PT mailings, you may rotate PT on other instruments, or your laboratory may opt to purchase a CAP Quality Cross Check program, if available for your instrument/method.
15.) If you order more than one PT kit, can you share the kits among multiple departments (ie, POC, etc)?	Multiple kits of the same PT program can be ordered from the CAP, but the laboratory has the responsibility to ensure the same analyte is not tested more than once during an active PT event, inclusive of all kits (on the same or different instruments).
16.) Can we test PT event A on analyzer #1 and then PT event B on analyzer #2 (analyzer #1 and #2 are the same type of equipment and run the same analytes)?	Yes, PT kits may be rotated between instruments every mailing.
17.) What is included in the list of specimen types that will allow us to order more than one PT for the same analyte?	Generally, different PT program codes indicate different specimens and, as such, can be used to test the same analyte. Please contact the CAP Customer Contact Center at 800-323-4040 option 1 with specific Survey questions.
18.) If the backup instrument is rarely used and not in use during the PT event, do you have to run PT on it twice a year?	Proficiency testing is required for the primary instrument. Comparability testing is required for any other instrument performing patient testing. CAP Quality Cross Check can be utilized to meet this requirement.
19.) Just to clarify, if you have instruments in different locations, do you no longer have to order a kit for each location if under the same CLIA number? Can you now rotate the kit each time the Survey comes in?	The CMS directive prohibits a laboratory from running multiple kits of the same PT material during the active PT period. Surveys may be rotated amongst instruments every mailing, or you can utilize the CAP Quality Cross Check programs where applicable.

Questions Concerning Blood Gas Surveys

Customer Question	CAP Response
20.) Can the five Critical Care Aqueous Blood Gas (AQ) Survey samples be performed on five different analyzers not repeating any one sample?	It is best that all PT challenges are analyzed on one primary analyzer. There is no way to report potentially different analyzer codes by sample. You can designate other analyzers as primary for subsequent PT events.

21.) Give an example between AQ versus AQ4 Survey for blood gas.	AQ and AQ4 have different specimens and, as such, can be ordered together for testing the same analyte. AQ3 and AQ4 programs are specifically designed for i-STAT methods. AQ and AQ2 have the same specimens, so they should not be ordered together to perform the same testing. Similarly, AQ3 and AQ4 have the same specimens and should not be ordered together to perform the same testing.
22.) If a hospital has multiple blood gas analyzers in various locations all under one CLIA certificate, which one is the primary?	If more than one instrument is used for patient testing, the laboratory should designate one instrument as primary and perform PT on that instrument. For future PT mailings, you may rotate PT on other instruments. You can also subscribe to the CAP Quality Cross Check Blood Gas programs.
23.) We have three blood gas machines of different series, one of which reports lactates. Currently we report for two different machines the lactate and one of the other two, but I switch the reporting machine for every other AQ and SO. Should I always keep the same analyzer for reporting?	This situation as described is somewhat unclear. Under no circumstances can the same PT samples be run more than once for any analyte. The PT kit may be rotated amongst different instruments per PT event or you can subscribe to the CAP Quality Cross Check programs.
24.) If you order a CAP AQ Survey for a 01 site, do you need to still order an AQ Survey for a 05 site? It's the same primary CAP number but different site numbers.	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 run one AQ Surveys kit unless they are testing multiple instruments all with different analytes. The CAP Cross Check Critical Care program (AQQ) 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.
25.) Can you order separate PT materials for GEM 4000, Epoc blood gas, and IL GEM OPL separately under the same CAP #?	Because these instruments require the same PT programs, it would not be allowed to report the same analytes on both instruments.
26.) If multiple instruments, for example main lab and POC performing same tests such as blood gas using different PT Surveys, can the different Surveys for blood gas be reported?	It is acceptable to order different PT programs to test the same analyte, as long as those programs contain different specimens (different labeling, target values, etc). AQ and AQ2 cannot be ordered together to perform the same analyte testing, but AQ and AQ3 (or AQ2 and AQ4) can be ordered together.
27.) Can I order PT material from a different vendor for blood gases and run it on the same instrument but at different POCT sites, both under the same CLIA license?	Yes; but unlike the CAP Quality Cross Check programs, you will have to perform comparability analysis yourself. It is important to note, if a lab would order PT from different PT providers, the lab would need to ensure each PT provider knows which analytes to report to CMS.
28.) We have four blood gas analyzers in four areas of our hospital.	No, unless the PT programs are different.

We order four PT programs one for each machine because each machine is considered the primary instrument for that area. Are we compliant?	

Questions Concerning Chemistry Surveys

Customer Question	CAP Response
29.) We have an automated line in chemistry with three duplicate chemistry instruments and two duplicate special chemistry instruments connected. If we run the PT specimens like a patient by barcoding the specimens and loading them on the front of the automated line, then there is no way to designate which instrument they will be performed on—and there will most likely be multiple instruments used on a single Survey shipment. Is it possible to front-load the PT specimens, even though this is not the primary way we perform patients? How should we manage this?	You can put your PT specimens in your automated line as long as each analyte for each specimen is run and reported only once.

Questions Concerning Coagulation Surveys

Customer Question	CAP Response
30.) Four lab sections perform fibrinogen: three sections test for fibrinogen activity and one tests for fibrinogen antigen. Different methods are used. Should we be running PT for both the fibrinogen activity and fibrinogen antigen?	Yes, the laboratory needs to ensure that only one result for fibrinogen activity and fibrinogen antigen is tested and reported across all sections. Additional testing can be performed after the PT due date.
31.) In the point-of-care areas, we have three different methodologies for activated clotting times. Will the CMS rules require only one methodology reported? Is this also applicable for POC blood gas and CO-oximetry?	This depends upon which specific Activated Clotting Time (CT) Surveys are being used. If the methodologies are under different CT Surveys, then PT can be run for each methodology. As an alternative, in 2016 new CAP Quality Cross Check CT series programs are available. Multiple kits of the same PT program can be ordered from the CAP, but the laboratory has the responsibility to ensure the same analyte is not tested more than once during an active PT event, inclusive of all kits (on the same or different instruments).
32.) If you use two different methods for ACT and there are two different Surveys that are ordered, can you continue to do so or do you only need to submit one Survey for ACT?	This depends upon which specific CT Surveys are being used. If the methodologies are under different CT Surveys then PT can be run for each methodology. As an alternative, in 2016 new CAP Quality Cross Check CT series programs are available.

Questions Concerning Hematology Surveys

Customer Question	CAP Response
33.) Similar to another question, we have two different hematology instruments and we currently order two different PT Surveys for them. One instrument runs a three-part differential and one runs a five-part differential, but the other CBC analytes are the same. Can we continue to do this? Or would utilizing CAP Quality Cross Check be the more appropriate option; and if so, does the CAP Quality Cross Check program allow the comparison of two different instruments, whereas with PT we can't use the same product?	Yes, as long as two different Automated Hematology Differential Series (FH) PT programs are ordered. CAP Quality Cross Check can be utilized as another option. The hematology CAP Quality Cross Check programs are instrument specific. Please consult the catalog for more information.
34.) Can we run the same analyte on two different CAP Surveys if we only select one to be reported (for example, HE kit for whole blood hemoglobin [2937] while another section orders FH for whole blood hemoglobin [197])?	In general multiple, identical kits cannot be run unless they are reporting on different analytes and/or materials. However, HE and FH series can be run because they are different materials.
35.) If the hematology analyzers report different differentials (five-part diff versus three-part diff), do you need to drop the three-part diff proficiency test?	No, as long as two different Automated Hematology Differential Series (FH) PT programs are ordered. CAP Quality Cross Check can be utilized as another option.

Questions Concerning Whole Blood Glucose Surveys

Customer Question	CAP Response
36.) In 2017 if we have more than 19 glucometers, how do we assess the rest?	When you receive the WBG Survey in 2016, you will be allowed to report from one glucometer. However, after the due date of the first event has elapsed, you will be able to access online a new Result Form for the remaining glucometers and report all results. There is absolutely no cost for additional reporting. In 2017, we will introduce a CAP Quality Cross Check program for whole blood glucose that will provide a more comprehensive solution.
37.) We have a total of 30 glucose meters and 19 blood gas analyzers. What is your ordering recommendation for this scenario?	As described during the webinar, there is an interim solution in 2016 for WBG/WB2 Surveys. (see above) With regards to your blood gas analyzers, only one PT kit may be run during the active period. CAP Quality Cross Check programs are available for your additional blood gas analyzers.
38.) Is it required to run the WBG Survey on all of the glucometers in	No, only one PT result is required to meet LAP requirements for PT.

addition to the linearity?	Linearity programs are not impacted by the CMS Directive.
39.) What will the time interval be for the second entry of the 19 glucose meters?	The primary event (single site/meter) of WBG (WB2) will have 15 days for testing. The secondary event (multiple sites/meters) will be available online for reporting on day 16 through 22.

Questions Concerning Other Surveys

Customer Question	CAP Response
40.) On the Virology Culture Survey (VR1) there is a box below the culture result to put the molecular result if you perform molecular testing. Is this a no-no now? Should we just report the culture result and get another Survey offered for the molecular test?	PT must be run and reported to the same extent as patient testing. Nucleic acid amplification test results should only be reported when this testing is performed to confirm culture results on patient specimens per your laboratory's standard operating procedures.
41.) If performing visual urine dipstick and urine dipstick testing using a Clinitek analyzer under the same CLIA number, can two CAP Surveys be ordered?	No, this would be prohibited because visual urine dipstick and automated urine dipstick testing utilize the same material and is considered the same analyte. The laboratory should report PT from the primary method and consider enrolling in the CAP Quality Cross Check program for clinical microscopy (CMQ) for the additional method.
42.) My lab orders two PT kits: one for Olympus Au400 and another for LC/MS confirmation of urine. Both instruments perform one test in common THc-COOH. This is the way we test all patient samples. Au400 e for screening/validities and LC/MS for confirmation. Is it OK as per new directive?	It depends on which PT kits are being ordered. A laboratory is prohibited from ordering two of the same kits, but CAP/AACC Urine Drug Testing, Screening (UDS) and CAP/AACC Forensic Urine Drug Testing Confirmatory (UDC) could both be ordered since they are different materials and specifications.
43.) We order the Blood Parasite Survey for our hematology department and the Parasitology Survey for microbiology. We always receive a slide for malaria identification in hematology, and we occasionally have a malaria specimen in microbiology. How should we address this potential double reporting for malaria?	Generally, if the PT program codes are different, the material is different. In this situation, BP and P are different materials and can be used.
44.) Transfusion medicine orders both the J (manual) Survey and the JAT (automated testing) Survey that tests for the same analytes by different methodologies. Can we continue to order both?	Yes, because the Transfusion Medicine, Comprehensive/Limited (J) and Transfusion Medicine Automated Testing (JAT) Surveys utilize different materials and specifications.
45.) Since the CAP required PT testing for waived testing, how would we stay compliant for testing like urine dipstick and urine pregnancy testing? The main laboratory would be performing the PT and	Products like CAP Quality Cross Check can assist with the laboratory ensuring the accuracy of your testing on additional kits/instruments. For CAP-accredited laboratories, comparability studies are only

reporting to the CMS. Are comparisons required for waived testing?	required for nonwaived tests.
46.) For waived testing performance at the main laboratory, ie, Urine (hCG) and for the same test performance at different POCT sites, does the CAP requirement to run proficiency testing on waived testing apply to the Main Lab only and not to the different POCT sites?	If both sites, the main laboratory and POCT are under the same CLIA number and both are considered primary methods, the lab can rotate PT events among the different areas.
47.) We screen PSAs on a Centaur and break down the free and total PSAs on a DXi. Both are chemilum technology. We currently order two PT kits. Would we be compliant?	Total PSA and free PSA may only be run and reported once during the active PT period.
48.) I order multiple UA, occult blood, whole blood glucose, and Strep screen kits to take to point-of-care settings—both at a local clinic and two outside clinics. Can I continue to order these kits?	If these clinics fall under the same CLIA number, then the same PT program cannot be used to perform the same testing. The CAP Quality Cross Check programs are not considered PT and would be an acceptable testing alternative for this situation.
49.) Is it still possible to order multiple linearity kits?	Linearity kits are not considered proficiency testing; therefore, they can be ordered and submitted in multiple quantities.

Questions Concerning i-STAT

Customer Question	CAP Response
50.) Is AQ3 considered a different kit from AQ4?	Both AQ3 and AQ4 are for i-STAT instruments. They are similar with the exception of AQ4, which offers additional analytes (BUN, creatinine, and glucose). The CAP offers CAP Quality Cross Check programs for i-STAT as Critical Care Aqueous Blood Gas (AQ3Q) and (AQ4Q). AQ3Q and AQ4Q can be used for any purpose as those are not PT programs but offer individual instrument evaluations and instrument comparisons.
51.) We use two different i-STAT cartridges in different areas of the hospital. One cartridge has blood gases plus lactate; the other has blood gases plus glucose. If I need to do PT on both lactate and glucose, how can I do this because I cannot hide the blood gas results?	There is a way to disable analytes on cartridges or enable test selection. Please consult with Abbott for directions.
52.) Are the AQ and AQI considered the same Survey? We use one for I-STAT in surgery and the other for our respiratory analyzer?	AQ and AQI are different programs.
53.) We have multiple departments that run the i-STAT. Some only	The laboratory should report PT results on the most comprehensive

perform a BUN and creatinine. If we report that one time, will we get "dinged" the next time if we report more results?	cartridge to ensure there is a PT result for all required analytes. If necessary there is a way to disable analytes or enable test selection on the i-STAT. It is important to ensure only one PT result is reported for each analyte.
54.) Can you use two different i-STAT handhelds to test two different cartridge types that span the range of analytes?	Yes, as long as there is no duplication of analytes. There is a way to disable analytes on cartridges or enable test selection on the i-STAT. Please consult with Abbott for directions.
55.) We run different i-STAT cartridges in multiple POC settings across the hospital. We currently order the AQ Survey for each site. Some of the analytes in each cartridge are duplicated. Can we continue this practice in 2016?	You can order multiple kits as long as only one kit is reported to the CAP and the other kits are run after the due date. The lab must ensure there is no duplication of analytes. In addition, laboratories have the option to enroll in the CAP Quality Cross Check programs for Critical Care Aqueous Blood Gas (AQQ).
56.) How do I order/result PT in the case of same type of instrument but with different cartridges that have shared analytes. For example, our i-STAT cartridges, Chem8 and CG8, both report electrolytes, but have other, different analytes. How should we handle this type of situation?	There is a way to disable analytes on cartridges or enable test selection. Please consult with Abbott for directions.
57.) If we have same CLIA # and we run the same analyte on primary analyzer as well as POC (i-STAT), do we only run the Survey on one of these instruments rather than ordering a separate Survey?	PT should be reported on the primary method.
58.) Does the exception for Survey WBG/WB2 for multiple glucose meters also apply to Survey AQ for multiple i-STATs?	The AQ/AQI includes reporting for only one instrument. Laboratories have the option to enroll in a Quality Cross Check program for Critical Care Aqueous Blood Gas to report results for additional meters.
59.) For the i-STAT analyzer, is it acceptable to alternate PT samples for an analyte being tested on two different cartridge types (ie, glucose on the G and CG8 cartridges)?	Yes, it is acceptable to rotate PT amongst the different cartridge types by mailing.
60.) How is i-STAT proficiency addressed if multiple i-STATs are under the same CLIA number as the main laboratory, report all of the same analytes as the main laboratory, and use different methodology?	If the analytes are reported in the main laboratory on the Chemistry (C) Survey, there is no need to also run and report PT results for these analytes on the i-STAT as long as comparability requirements are followed (if nonwaived). Whole blood glucose, ethanol, and INR are analytes that have separate programs for whole blood and serum/plasma and should be run on both matrices. These analytes' methodologies and reference intervals often differ between whole blood and serum/plasma, which may further complicate comparisons between matrices.
61.) We order PT for our i-STAT analyzers for troponin and aqueous	Yes, because the materials are different.

blood gas testing. Those PT materials are specifically for those analyzers. We also order PT material for those same analytes that are run on our chemistry analyzers. Those PT materials are not the same as those for our i-STATs. Can we still order both of those materials?	
62.) We order AQ3 and AQ4 for i-STATS. Some analytes are on both Surveys (Na, K, H&H). How should results be submitted? We also do Na, K, H&H on lab analyzers. We use the pH, PCO2, and PO2 for primary instruments for blood gases. What should we order?	It is acceptable to order different PT programs to test the same analyte, as long as those programs contain different specimens (different labeling, target values, etc). AQ and AQ2 cannot be ordered together to perform the same analyte testing, but AQ and AQ3 (or AQ2 and AQ4) can be ordered together.
63.) We have two blood gas analyzers, Radiometer ABL90 and i-STAT. They currently have two different CAP Surveys AQ and AQI, respectively. Can we continue using them?	Yes, because the materials are different.
64.) I have I-STATs and Rapidpoint 500, and I order AQC and AQi, Surveys for blood gas chemistries. Would that be compliant?	The PT material for i-STATs and Radiometers is different, and both programs can be ordered.
65.) For point-of-care and main lab kits that are the same and give results for the same assays, such as SO co-oximetry for I-STAT and ABG instruments, what should we do?	It is acceptable to order different PT programs to test the same analyte, as long as those programs contain different specimens (different labeling, target values, etc). AQ and AQ2 cannot be ordered together to perform the same analyte testing, but AQ and AQ3 (or AQ2 and AQ4) can be ordered together.
66.) I have i-STATs at two different locations, one does Chem 8 and the other uses the EG7. Can I purchase two sets, although some of the analytes are the same?	Yes, as long as there is no duplication of analytes. However, the laboratory can test both cartridges using the samples provided in one kit. If there is duplication of analytes, there is a way to disable analytes or enable test selection on the i-STAT.
67.) If we have I-STATS in multiple locations using different cartridges, do we need multiple kits (for example, creatine cartridge in radiology and a chem 8 cartridge in emergency department)?	If the i-STAT is the primary method for reporting, then the cartridge with the most analytes should be reported on the PT ensuring all analytes are covered. The laboratory can use the Quality Cross Check product to assist with comparability studies.
68.) What if your CLIA number performs multiple different i-STAT cartridges with tests that duplicate in some cases? What is the correct way to run and submit results *without* having to change the analyzer's settings and customization just to run a PT sample?	Testing cannot be duplicated. Please consult with Abbott for specific instructions on how to do this.
69.) There is a separate blood gas survey for i-STATs. Can you submit both the i-STAT blood gas Surveys AQI and the AQ2?	Yes, AQ and AQI are different programs.
70.) If there is more than one platform for blood gases, eg, ABL90 and i-STAT, do we order a Survey for each, or do we order only one and designate one platform as a primary even though these devices	You are not required to order a Survey for each platform. If the laboratory wants to select the ABL 800 as its primary analyzer, the other analyzers would need to ensure comparability requirements are

are compared to the laboratory's gold standard blood gas analyzer (ABL800)?	followed. Because the PT materials for the ABL90 and i-STAT are different, it would be permissible to order kits for each instrument.
71.) I have blood gas analyzers in the main laboratory as well as i-STATs at POC sites. Are AQ2 and AQ4 considered two different Surveys programs?	Yes, AQ2 and AQ4 are different programs.
72.) For i-STAT testing when cartridges are considered a test system, which CAP Quality Cross Check program would be appropriate?	Please refer to the CAP Quality Cross Check programs in the 2016 Surveys catalog.
73.) On a critical gas Survey, must someone run all five samples on the same i-STAT meter? Normally when techs are assigned a sample they choose an instrument, ensure maintenance and QC has been run, and then analyze the sample.	This is at the discretion of the laboratory. However, if samples are split and rotated among instruments, the value of PT may be lessened. A laboratory would not be able to detect if one instrument was not functioning appropriately unless it was very deliberate about recording which sample was reported on which instrument; and it would be difficult to detect if a failure was due to random error versus a systemic issue. The better option would be to rotate “mailings” among the staff. If a laboratory were trying to use PT for competency, then a program like CAP Quality Cross Check would be a better option.

Questions Concerning CAP Quality Cross Check Programs

Customer Question	CAP Response
74.) We have ordered multiple SO and AQ Surveys in the past to accomplish the competency assessment requirements for our respiratory techs. We ordered two extra Surveys of each, the SO and AQ, which provided another 30 specimens annually. The CAP Quality Cross Check kits are only configured with six specimens per year. This means we will need to order five kits in order to cover our 60 respiratory techs. Do you all have any suggestions for minimizing our costs under the new CMS directive for PT?	CAP Quality Cross Check programs are available at a lower price than proficiency testing programs; and although you might get fewer specimens, you have the ability to report up to three instruments for the same kit. In addition to that, CAP Quality Cross Check provides you comparability analysis, saving you valuable staff time and resources. Surveys programs may be used for competency as long as the competency testing is completed after the PT event due date.
75.) Can we use the CAP Quality Cross Check material on two different instruments from different manufacturers?	Different instruments/manufacturers can be used with most CAP Quality Cross Check kits with the exception of the Hematology Automated Differential (FHQ) series, the Activated Clotting Time (CTQ) series, and Critical Care Aqueous Blood Gas (AQQ/AQIQ), which are instrument-specific programs. Please note that while each submission will be evaluated against its appropriate peer group, intralaboratory comparisons will not be evaluated.

76.) What is the point of using the CAP Quality Cross Check program when it doesn't meet CLIA criteria for correlation? There are no CLIA requirements for "compatibility" so why are you even creating a program for it?	CAP Quality Cross Check programs can be used for compliance with the CAP accreditation requirement for COM.04250 (Comparability of Instruments/Methods).
77.) If you rotate the PT Surveys mailings among different instruments, must you still run the CAP Quality Cross Check program?	CAP Quality Cross Check programs are not mandatory; but they provide a way to help you verify the performance of multiple instruments.
78.) Can the CAP Quality Cross Check programs be used for instruments under different CLIA/CAP #s?	Yes, CAP Quality Cross Check is not proficiency testing, and the results will not be sent to any regulatory agency.
79.) If we have two different instruments for POCT blood oximetry testing, would we order a CAP Quality Cross Check or two PT Surveys?	If both instruments are used under one CLIA license, it is recommended that you use PT for the primary instrument and CAP Quality Cross Check programs between PT events for both instruments.
80.) What is the order due date for the CAP Quality Cross Check material for 2016?	Orders for the CAP Quality Cross Check programs are due December 1, 2015, to ensure material availability. Orders received after December 1, 2015, will be fulfilled on a first-come, first-served basis as program material is available.
81.) Is it required to enroll in a CAP Quality Cross Check program?	No, CAP Quality Cross Check is not proficiency testing, and the results will not be sent to any regulatory agency. It is a program to help you verify the performance of multiple instruments.
82.) How soon will results from CAP Quality Cross Check be evaluated and returned to a laboratory?	CAP Quality Cross Check program evaluations are typically available two to three weeks after the due date.
83.) How many vials are included in the CAP Quality Cross Check for the AQ Survey?	The AQQ Aqueous Blood Gas program contains three specimens in triplicate, enabling use on up to three instruments.
84.) How do you do proficiency testing for Point of Care if I cannot order duplicate kits and CAP Quality Cross Check samples do not count for proficiency testing?	While the CAP Quality Cross Check programs are not proficiency testing, results will be evaluated in a similar manner providing valuable information to the laboratory as part of their overall quality assessment program, including alternate assessment.
85.) With multiple units in the hospital having the same analyzer it is possible that one or more units may not perform PT in the year. Will running CAP Quality Cross Check be acceptable?	PT may be rotated between analyzers and comparability performed for the non-reporting analyzers. CAP Quality Cross Check is one tool that can be used as part of comparability testing.
86.) Will CAP Quality Cross Check satisfy the requirement for range	CAP Quality Cross Check is not intended to verify the analytical

validation?	measuring range (AMR). The Calibration Verification/Linearity program is appropriate for AMR verification.
87.) If we order a CAP Quality Cross Check program, should we also include the primary instrument that we tested in the PT Survey?	It is not a requirement, but in practice most laboratories like to include their primary instrument in the CAP Quality Cross Check program.
88.) If one analyte is done in three sections of a laboratory and they are done by different methods, have different reference ranges, and get three different results. Can PT/AAP be done on all of these? If not, how can cross checks be performed?	During the PT event, you are not allowed to run multiple kits for the same analyte and material. The CAP Quality Cross Check programs may be an option for testing multiple methods.
89.) I was told in the past that the CAP Quality Cross Check material for blood oximetry instrumentation is for the *same* instrument make and model—only l. Is this not correct?	The SOQ material can be used on a wide variety of analyzers. Results will be evaluated against the appropriate peer group; intralaboratory comparisons would not be evaluated in this case.
90.) With your CAP Quality Cross Check order do you get three samples of each level for the three instruments that will do the testing (for example, in the AQ and SO Surveys)?	Due to the stability of the specimens, both the Critical Care Aqueous Blood Gas (AQQ) and Blood Oximetry (SOQ) programs contain three vials of each level. For the remaining CAP Quality Cross Check programs, enough material is provided to ensure that it can be used on up to three instruments.
91.) Will the Survey cycle for the main Survey and CAP Quality Cross Check Surveys be more evenly spaced across the 12-month period?	In most cases, the CAP Quality Cross Check program will ship approximately six months apart and be spaced between the mailings of the corresponding PT Survey.
92.) If we participate in PT and QCC from the CAP, do we still need to perform in-house data comparisons from different instruments every six months?	The CAP Quality Cross Check program may be used as part of your laboratory's twice per year comparison program.
93.) The CAP Quality Cross Check program includes only three samples. It has been my understanding that a minimum of five samples must be used for correlation purposes.	The CAP Quality Cross Check program may be used as part of your laboratory's twice per year comparison program. It is under the discretion of the laboratory director to determine the scope of comparison testing.

Questions Concerning Instrument Comparability and Correlation

Customer Question	CAP Response
94.) Can you use quality control (QC) material for the inter-instrument comparison?	Yes, QC material can be used.
95.) If you use a backup instrument, do you have to do inter-instrument comparisons between the primary and backup?	Yes, this is required.
96.) Can linearity material be used for correlation studies?	Yes, the linearity material can be used as part of the laboratory's overall correlation studies.

97.) Please make a distinction between correlation and comparison and when quality control results can be used for either comparison and correlation.	CAP-accredited laboratories should refer to COM.04250 for comparability requirements.
98.) Do I have to order an Accuchek Survey as long as I am doing comparisons between Accuchek meters and between my Accuchek meter and my main chemistry analyzers?	Whole blood glucose, ethanol, and INR are analytes that have separate products for whole blood and serum/plasma and should be run on both matrices. These analytes' methodologies and reference intervals often differ between whole blood and serum/plasma, which may further complicate comparisons between matrices.
99.) Does the Roche Cobas E601 instrument that has two modules per loader and computer need inter-instrument comparison? I am able to run certain analytes on both modules.	If both modules report the same analytes then comparability requirements should be followed. The laboratory can decide which analytes to report on each module as long as there is no duplication of analytes.
100.) I have used the ANA Survey on two different instruments: One is our primary and the other is used for the Survey's unexplained fatigue panel. The ANA is run in different formats and reported in different fashions (primary gives the titer and pattern, while the second just gives a quantitative result). Do I have to do inter-instrument comparison of this analyte?	CAP-accredited laboratories should refer to COM.04250 regarding reportable results.
101.) Regarding the TEG analyzers where we need whole blood, how many specimens do we need? Currently we are using one normal and one abnormal since we need to get a person to volunteer their blood.	For CAP-accredited laboratories, alternative assessment is required for thromboelastograph results. Please see COM.01500 regarding alternative assessment.
102.) For CAP Quality Cross Check, are we required to run it on all 20 instruments or just a fraction to comply with comparability requirement?	If the question is regarding waived glucose meters, comparability between waived analyzers is not required. COM.04250 only pertains to nonwaived analyzers.
103.) What if I have two instruments that are not expected to correlate and I must submit them both under the same CLIA number, specifically intact PTH?	If the laboratory has two primary methods for intact PTH it would be advisable to rotate the PT among the two methods.
104.) Can you use the linearity material for inter-instrument comparison (for example, LN2 for general chemistry)?	The use of the linearity programs may be used as a material for comparison in the laboratory's processes or procedures. Use of the program alone does not guarantee compliance with the requirement. A laboratory must have a procedure, acceptance criteria, documentation, etc, to meet the intent of the requirement.

105.) Can we use the PT sample for the second instrument after submitting PT online for correlation studies?	Yes, the material may be used after the PT due date.
106.) Can we purchase more than one PT Survey in order to use material for correlation studies as long as the samples are not run until after the due date?	Yes, additional PT material may be used after the PT due date.

Questions Concerning LAP and Reporting to CMS

Customer Question	CAP Response
107.) How will the activity menu's "PT required" elements be handled when we must comply by use of a Q Survey?	Q Survey does not meet PT enrollment requirements and is optional for quality purposes. The Quality Cross Check programs can be used as a means to assist in comparability studies.
108.) Does the CAP Quality Cross Check meet CAP standard COM.04250 for instrument comparisons? Or is it required to use patient samples?	The use of the CAP Quality Cross Check programs may be used as a material for comparison in the laboratory's processes or procedures. Use of the product alone does not guarantee compliance with the requirement. A laboratory must have a procedure, acceptance criteria, documentation, etc, to meet the intent of the requirement.
109.) If you order multiple kits and only result one, will the CAP punish the laboratory for not submitting results? Will you fail the Survey for not turning in any results?	No, if additional kits are ordered and not returned, the CAP will not penalize the results. Each kit will receive a "blank" evaluation indicating that no results were returned, but this will not result in a 0/5 score. It is important, however, to submit one set of results. Multiple kits of the same PT program can still be ordered from the CAP, but the laboratory has the responsibility to ensure the same analyte is not tested more than once during an active PT event, inclusive of all kits (on the same or different instruments).

Questions Concerning Ordering Multiple Kits and Order Renewal

Customer Question	CAP Response
110.) We already placed our order for 2016. Can we revise the order and add the CAP Quality Cross Check program?	Yes. **If you already submitted your 2016 CAP Surveys order** but would like to revise it, please call the CAP Customer contact Center at 800-323-4040 option 1. If you have already submitted your 2016 CAP Surveys order and would like to include additional CAP Quality Cross Check programs, please email a completed QCC order form to CDM@cap.org to make the appropriate changes.

111.) Just to clarify, if we have multiple instruments for the same analyte, same methodology, can we order more of the same Survey materials *after* the initial Survey was submitted?	Multiple kits of the same PT program can be ordered from the CAP during order renewal, but the laboratory has the responsibility to ensure the same analyte is not tested more than once during an active PT event, inclusive of all kits (on the same or different instruments). Please note that the active PT period is live until the due date has passed, and is not based upon your laboratory's submission date.