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I. Introduction

The following Frequently Asked Questions are presented as a supplemental document to the CAP Point-of-Care Testing Checklist. They are intended to serve as an interpretive reference for laboratories, inspectors, representatives of government and industry, and others who seek clarification of issues raised within the current Point-of-Care Testing Checklist (March, 2004). CAP is an accreditation organization that has been granted deeming authority by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). By virtue of this appointment, the CAP is legally obligated during its inspections to adhere to the statutorily mandated guidelines set forth in 42 U.S.C. §§ 263a – a7 (2001), and to the regulations enumerated in 42 C.F.R. § 493.1 – 493.2001 (2003) by the CMS as provided for by Congress in the CLIA. Thus, the standards enforced by the CAP through its Laboratory Accreditation Program must at a minimum enforce those regulations as promulgated by the CMS. However, please note that as the world’s leading organization for the promotion of high quality laboratory testing, the CAP’s requirements in some instances go beyond those set forth in CLIA and its accompanying regulations. In so doing, our goal is to educate, to instruct, and to otherwise ensure that we provide our patients with the best possible laboratory testing. This Frequently Asked Questions Document is in keeping with that spirit.

II. Applicability

1) How does the CAP define point-of-care testing?

The CAP defines point-of-care testing as testing that is performed outside the physical facilities of the clinical laboratory, in proximity to the patient on whom the testing is performed. The central feature of POC testing is that it does not require permanent, dedicated space. The Point-of-Care Testing Checklist is used to inspect testing that falls within this definition. Laboratories that oversee point-of-care testing programs are responsible for ensuring that their POCT programs fulfill the requirements outlined in the CAP POCT Checklist.

2) Does the CAP Point-of-Care Checklist apply to point-of-care testing that is performed at sites removed from the medical facilities?

The CAP accredits point-of-care testing that occurs outside the traditional physical limits of medical facilities. Point-of-care testing that is associated with a CAP accredited laboratory’s CLIA number must be inspected and accredited by the CAP. If point-of-care testing is performed under a different CLIA number, an institution may elect to have the College accredit this testing, to have another accrediting agency accredit this testing, or to have licensure and inspection conducted by the CMS or...
its agents. Facilities that provide point-of-care testing, regardless of physical context, must either be inspected and accredited by a private accrediting agency, or inspected, accredited, and licensed by CMS or one of its agents.

3) Our hospital’s central laboratory is CAP accredited. Our point-of-care glucose testing is performed under a separate nursing CLIA certificate. Are we required to have the CAP inspect our point-of-care glucose testing, or can we choose to have this testing inspected by another accrediting organization?

CAP defines a single accreditation unit (laboratory) by all testing that is associated with a particular CLIA number. Therefore, if your institution has a different CLIA number for testing that is performed under the direction of the nursing service, the CAP will not inspect this testing unless the nursing service submits a separate CAP accreditation application. Your institution can select any Centers for Medicare and Medicaid Services (CMS) approved accrediting organization to inspect and accredit the testing associated with the CLIA numbers it holds. A list of CMS approved accrediting organizations can be found in the current Federal Register, or on the CMS website at http://www.cms.gov.

4) Is each location that performs patient testing outside the central laboratory required to maintain a copy of the POCT checklist?

Laboratories that oversee point-of-care testing programs are responsible for ensuring that their programs meet the requirements outlined in the POCT Checklist. If the records for a POCT program are not centrally stored, each location in the POCT program will be inspected as an independent section of the main laboratory. Conversely, if the records for a POCT program are centrally maintained, the program will be inspected as a single unit. In this latter instance, the inspector will visit only a sample of POCT sites. The POCT Checklist defines the criteria that are used by CAP POCT inspectors to inspect POCT programs. Laboratories are not required to maintain copies of this Checklist at specific locations.

III. General Topics

Proficiency Testing

5) If our central hospital laboratory performs a Proficiency Testing Survey for an analyte that is also tested at the point-of-care, are our POC test sites required to independently subscribe to proficiency surveys?

For analytes that are tested both in a central laboratory and in point-of-care settings that operate under the same CLIA number, the central laboratory and POC sites need not enroll in separate proficiency surveys. Please note
that point-of-care whole blood glucose testing and plasma or serum glucose testing do not measure the same analyte.

Also, there is a general POCT Checklist requirement to compare the performance of all instruments that measure the same analyte at least twice per year. This comparison should be done using fresh human samples (not QC materials).

6) Is participation in proficiency testing required for POC sites that perform urine hCG and dipstick testing?

Proficiency testing is required for urine hCG and dipstick testing for each method that is performed under a single CLIA number. Therefore, an institution need only purchase separate proficiency testing kits for POC urine hCG and dipstick testing if the POC sites are using different methods than the central laboratory, or if they operate under a separate CLIA number.

7) Does the CAP provide proficiency survey materials for whole blood cholesterol meters?

Whole blood cholesterol proficiency testing materials are available through the CAP’s Excel program. Excel surveys L6, WL6, and L17 are compatible with whole blood cholesterol testing meters. You can obtain additional information about these products by contacting the CAP Customer Service Department at 800-323-4040, option #1.

8) Nurses in our labor and delivery suite perform urine dipstick testing for pH and protein. Are we required to enroll in proficiency surveys for this testing?

If point-of-care urine dipstick testing is performed by the same method and under the same CLIA license as the central laboratory, the point-of-care sites are not required to independently enroll in a proficiency testing program for the testing.

9) We perform pH testing using nitrazine paper in our emergency department. Are we required to enroll in a proficiency testing program for this testing?

The CAP requires laboratories to participate in biannual external proficiency testing programs of the CAP or a CAP approved alternative provider for all tested analytes if external proficiency testing materials are available. If external proficiency testing materials are not available for an analyte, the laboratory must establish an in-house method of proficiency testing. Examples of in-house methods include the use of blind specimens and split sample testing. The results of the proficiency testing must be
reviewed, and corrective actions in response to unacceptable results must be documented.

An exception to the above rule is made for physician performed testing on analytes that are included in the CAP Physician Performed Testing (PPT) section. Consequently, the answer to your question depends upon who is performing the pH testing. If nurses or other non-physician personnel are performing nitrazine testing, you must enroll in proficiency testing for that testing. If the testing is exclusively performed by physicians, it would be considered as PPT. You would not be required to enroll in a proficiency testing program for this testing, although it would be subject to inspection with the CAP POCT Checklist if it is performed under a CLIA license for which the license holder’s accreditation is provided by the CAP.

10) Multiple sites within our hospital perform urine hCG, fecal occult blood, and other POC testing under the same CLIA number. Do we need to enroll in a proficiency survey program for each site that performs POC testing?

Only one proficiency survey kit is required for each analyte and method that is tested under a given CLIA number. The kits may be rotated among your POC test sites. After reserving an aliquot of PT material for possible follow-up testing in the event of an unacceptable result on initial testing, you should consider distributing aliquots of the remaining sample to additional test sites. The results of testing at these sites can be compared to the results of your evaluation. Note your performance and any corrective actions that you take.

11) Does the CAP require proficiency testing for fecal occult blood testing that is performed by nurses?

The CAP does not require proficiency testing for fecal occult blood testing. However, the laboratory must perform some type of validation of the testing every six months. Most laboratories find proficiency testing to be a simple way to meet this requirement.

12) There are no commercially available proficiency testing samples for our HDR (Heparin Dose Response) or our HPT (Whole Blood Heparin Assay) instruments. The HDR is a modified ACT test in which the patient’s blood is incubated with varying levels of heparin – 1.5 and 2.5 U/L – to estimate the patient’s response to heparin. The analyzer provides an average baseline ACT, the projected heparin concentration required to reach the target ACT, and the bolus dose required to reach the projected heparin concentration. The whole blood heparin assay is used to ensure that a patient’s heparin level is within a certain range. A red cartridge detects heparin levels of 0.0 – 0.9 mg/kg. A white cartridge detects heparin levels of 2.5-5.0 mg/kg. The white cartridge is used while the patient is heparinized and
on bypass. The red cartridge is used at the end of the procedure to establish whether or not the effect of the heparin has been reversed.

Because samples for both assays must be analyzed immediately after they are drawn, it is not possible to exchange samples with other institutions. CAP’s “liquid plasma” based heparin assay is not a suitable reference for the whole blood assay. Please describe some possible alternative proficiency testing methods for the whole blood heparin assay that will satisfy CAP requirements.

For tests that do not have graded external proficiency testing material available, your laboratory must develop an in-house procedure for proficiency testing. This procedure must be implemented at least twice per year, and the results must be recorded and reviewed by the medical director or his or her designee. You must demonstrate that corrective action has been taken as needed. Methods can include split sample analysis, enrollment in ungraded proficiency testing programs, exchange of specimens with other laboratories, or equivalent procedures that are approved by your medical director. Spiking bloods with various levels of heparin and monitoring the cartridges’ reactions for adequate responses, blind testing of unknowns, and comparisons with alternative test methods are all acceptable for in-house proficiency testing programs. Some laboratories have used external quality control materials as “blind specimens,” or have used pooled or adulterated specimens. The CAP does not provide specific procedures for in-house proficiency testing. Your in-house proficiency testing program should include specimens with analyte values that are in the clinically reportable ranges for the cartridges that you use, although the total number of specimens that you test is within the discretion of your laboratory director.

13) Under what conditions can POCT sites and main hospital laboratories share proficiency samples?

Proficiency testing kits may be shared between your main laboratory and point-of-care testing sites as long as the laboratory is administratively responsible for POCT. Proficiency testing kits can be shared for analytes that are tested in both the main laboratory and at the POC. The results from sites that share proficiency testing materials must be recorded and evaluated against the peer data in the Participant Summary Report. You must have documentation of corrective action taken in response to any unacceptable results.

Quality Control and Quality Improvement

Procedure Manuals

14) What is the required content of a procedure manual for a new instrument?
The purpose of a procedure manual is to provide guidance to operating personnel on all aspects of the testing process, including instrument operation. The complete procedure manual should be written in substantial compliance with, and meet the intent of, NCCLS GP2-A3. The procedure manual should be available to, and used by, personnel at the workbench. The procedure for each analyte must include: the principle of the assay, its clinical significance, the specimen types on which it may be performed, the required reagents, the calibration and quality control procedures, the procedural steps for performing the assay, as well as the necessary calculations, reference ranges, and guidelines or methods for interpretation of the results. The inspection team will review procedure manuals in detail to understand a laboratory’s standard operation procedures, and to ensure that all significant information and instructions are included. The inspection team will also examine the laboratory for proof that a laboratory’s actual practices match the contents of its procedure manuals.

Manufacturers’ procedure manuals for instrument/reagent systems may be acceptable as components of departmental procedures, but should not substitute for institution specific procedures. Any modification to, or deviation from, a manufacturer’s procedure manual must be clearly documented. All laboratory procedures must have documentation of annual review, either with each procedure, or on a list of all procedures within the manual that contains a corresponding signature for each. A single signature on a Title Page or Index of all laboratory procedures is not sufficient documentation that each procedure has been carefully reviewed. It is not required that a signature or initials be present on each page of a procedure.

Reporting of Results

15) What is meant by the term “verified” in The Laboratory General Checklist requirement that point-of-care testing results that are entered into the LIS must be verified?

Verification is the process of reviewing a POCT result for clerical or other errors and, upon a determination of acceptability, posting the result to the patient’s medical record. In addition to verification, an audit trail must be maintained that permits all individuals who were involved in the process of testing and reporting the POCT results to be retrospectively identified.

Controls

16) The CAP Checklist requires laboratories to define tolerance limits for control procedures. Please explain the meaning of this requirement.
The CAP POCT Checklist requires that laboratories determine appropriate quality control ranges. For unassayed quality control materials, this must be accomplished prior to placing the controls into use. It is preferable to validate manufacturers’ quality control ranges for assayed materials prior to placing new control lots into use. However, for assayed materials this validation may be performed as the control lots are used, if time constraints do not allow for earlier validation. After a laboratory has validated the manufacturer supplied range for a lot of control materials, the necessity of adjustment to that QC range is within the discretion of the laboratory director.

**Instruments and Equipment**

17) Does the CAP classify a microscope as an “instrument” for the purposes of the maintenance requirements of the POC Checklist?

The CAP classifies microscopes as instruments that require documentation of routine maintenance. All instruments and equipment should be on routine maintenance schedules. Maintenance records, including date of purchase, serial number, and all repairs and routine service procedures, must be available and must be periodically reviewed on a scheduled basis by qualified laboratory personnel. Routine and “as needed” maintenance procedures are most often specified by the manufacturer. Contact your microscope manufacturer to obtain the maintenance procedures, and the frequencies at which those procedures should be performed.

18) We keep our regular instrument maintenance records next to the instruments at their testing sites. However, our Biomedical Engineering Department maintains all of the repair records for our instruments on computers within the Biomedical Engineering Department. Must we retain copies of our instrument repair records within the laboratory?

The laboratory is encouraged to keep maintenance and repair records at or near instruments. However, off-site storage is acceptable if the records can be promptly retrieved, and such a system is approved by your laboratory director. If records are stored in another department, your laboratory should have a written agreement that is signed by both directors, and stipulates that maintenance records will be promptly retrieved according to a laboratory defined timeline for laboratory troubleshooting purposes.

**Other**
19) Our organization maintains physician office laboratories that have previously been accredited by another organization. We would like these laboratories to become CAP accredited. How do we initiate the CAP accreditation process?

You can initiate membership in the CAP Laboratory Accreditation Program by submitting an application request form and a deposit. An application will be mailed to you at the location that you specify in your application request form. Applications can also be downloaded in pdf format from the CAP website at [http://www.cap.org/apps/docs/laboratory_accreditation/lap_info/appaccred.html](http://www.cap.org/apps/docs/laboratory_accreditation/lap_info/appaccred.html).

20) Does the CAP define numeric values for “acceptable” compliance with CAP guidelines (e.g., 80% compliance with an institution’s panic value policy)?

The CAP POC Checklist requires laboratories to document the presence of formal, written policies that ensure compliance with CAP guidelines. Compliance is expected. For example, the CAP General Checklist requires laboratories to have policies that ensure that appropriate clinical personnel are notified of critical values. Documentation of notification is also required. Moreover, the laboratory must have in place a quality improvement program that provides for monitoring and continuous improvement in the quality of laboratory testing from the pre-analytic through the post-analytic phases. This program should encompass compliance with CAP guidelines. A laboratory that does not document notification of critical values 100% of the time risks receiving a deficiency during a CAP inspection.

21) Does the CAP have suggestions on policies for reinstatement of POCT privileges following suspension?

Your institution should have a formal, written policy that clearly states the criteria for POC compliance, as well as the criteria for revocation and reinstatement of privileges. The restatement of privileges will likely vary in accordance with the reasons for suspension of privileges. Possible requirements for the reinstatement of privileges include: completion of operator re-training, acceptable performance of proficiency testing for a specified time period, or additional competency assessments.

Personnel

22) What competency testing is required for physicians’ assistants and nurse practitioners who perform fecal occult blood tests as part of the physical examinations that they provide? What documentation is required?
While the CAP does not require periodic competency assessment of physicians who perform testing such as fecal occult blood testing that is within the scope of the practice of medicine, this exemption from regular competency testing for fecal occult blood testing applies only to physicians, and is not extended to other healthcare providers. Records of personnel competency assessment must allow an inspector to determine the skills that were assessed, and the methods by which those skills were evaluated. Some elements of competency assessment include, but are not limited to: directly observing routine patient test performance, including patient preparation, if applicable; specimen handling, processing and testing; monitoring the recording and reporting of results; reviewing intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; directly observing performance of instrument maintenance and function checks; testing previously analyzed specimens, internally blind samples, or external proficiency samples; and evaluating problem solving skills.

23) What are the educational requirements for individuals who perform Provider-Performed Microscopy (PPM) Procedures.

Certificates for Provider-Performed Microscopy are available for laboratories in which only individuals designated as “Providers” in the Federal Register perform the testing. These individuals include: physicians, midlevel practitioners under the supervision of physicians or in independent practice authorized by the state in which they are practicing, and dentists. Other personnel are required to meet the CLIA mandated qualifications for individuals who perform tests of the applicable complexity level (personnel requirements are listed in the Federal Register) under the appropriate CLIA licenses.

For example, urine dipstick testing may be performed under a PPM certificate by a provider (MD, DO, nurse practitioner, etc.) during the medical examination of the patient. Urine dipstick testing may also be performed by a non-provider (e.g., a nurse) under a Certificate of Waiver. Because visual urine dipstick testing is classified as a waived test by the CMS, non-providers who perform this testing must possess a high school diploma, and must provide documentation of adequate training and competence to perform the testing.

24) We have an employee who has a BS in Biology, whom we would like to train to perform and report the results of Giardia direct testing. The testing is considered to be high complexity. Does her education qualify her to perform this testing?

Under CLIA, personnel who perform high complexity testing must possess an MD, DO, DPM, PhD, MS or BS “…in a chemical, physical,
biological or clinical laboratory science, or medical technology from an accredited institution.” [42 C.F.R. § 493.1489] In accordance with this standard, a BS in Biology would qualify the individual in question to perform high complexity testing such as direct giardia testing. As with all employees, you should maintain documentation of the employee’s initial training and ongoing competency assessments for the testing that she performs.

25) Our hospital utilizes a significant number of temporary agency nurses. The agency is responsible for training the nurses in the use of our hospital’s POC instruments. Is it acceptable for multiple temporary agency nurses who perform POC glucose testing to use a generic glucose meter user ID#, e.g. 55555? Must we retain records of these temporary agency nurses’ glucose meter training?

The CAP requires that POC testing protocols contain provisions that permit the unique identification of analysts who perform patient testing. The use of a generic identification number that would be shared among multiple instrument users does not allow for the unique identification of testing personnel, and therefore, would not meet CAP requirements if used without additional means of uniquely identifying the individual who performs each test.

The CAP also requires that institutions provide documentation of specific training and competency assessment programs for all employees who perform point-of-care testing. Therefore, you must retain records of the training and competency assessment that is performed by temporary agencies.

26) Are we required to complete individual competency forms annually for each employee who performs POC testing?

Your institution must have a documented competency program to ensure that every individual who performs POC testing maintains satisfactory levels of competence. The records must make it possible for your inspector to determine what skills were assessed, and how those skills were evaluated. The program must be approved by your POC medical director. The format that you use to document personnel competency is at the discretion of the laboratory director. However, your records should at a minimum include the following elements of competency assessment as described in the CAP POCT checklist:

1. Direct observations of routine patient test performance.
2. Monitoring the recording and reporting of test results.
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

IV. Qualitative Testing

27) What section of the CAP POCT Checklist contains questions that are specific for nitrazine (NBT) testing in the labor and delivery suite?

The CAP POCT Checklist does not contain a section that specifically addresses NBT testing. Since NBT testing is classified as “Qualitative Testing,” the questions in this Checklist section apply to NBT testing. The Physician Performed Testing section would apply to NBT testing that is performed by physicians.

28) A manufacturer recently changed the package insert that accompanies a waived test kit that contains internal positive and negative quality controls. The package insert previously stated that laboratories “must” run external quality control every twenty-five tests. The insert now “recommends” that laboratories run external QC every twenty-five tests. *Must* we now run QC every twenty-five tests, *should* we run QC every twenty-five tests, or is this within our discretion as long as we run external QC with each new lot or shipment of kits and follow the manufacturer’s other guidelines?

To satisfy basic CAP requirements for quality control, actual testing personnel must run, review for acceptability, and document the results produced by positive and negative controls on each day of use before testing patient samples. Corrective action must be taken and documented for unacceptable QC results. Controls can be internal and/or electronic, or external, or a combination of these techniques. Laboratories must follow a manufacturer’s quality control instructions. Failure to do results in a use that extends beyond the scope of a test system’s FDA approved indications, and places the kit in the CLIA designated “high complexity” test category.

Laboratories are strongly encouraged to follow manufacturers’ recommendations, although this is not an absolute requirement. If a laboratory chooses not to follow a manufacturer’s recommendation, the laboratory should provide documentation of the studies it has performed that provide justification for exceeding the recommendation.

29) At our institution nurses perform Hemoccult® testing on our hospital floors. There are multiple kit and developer lots in use within our nursing units.
Consequently, developer lots are not always used with their designated kit lots. Are we required to monitor and document Hemoccult® kit and developer lot numbers?

The CAP requires that each laboratory develop new reagent lot acceptance criteria. New reagent lots must be verified prior to their use in clinical testing. Specifically, new reagent lots must be compared to previously used reagent lots to ensure comparability between the newly received lots and lots that have already been in use. Documentation of this verification process is required. Therefore, at a minimum you need to monitor and document Hemoccult® kit and developer lot numbers for this purpose.

Please note that the CAP restricts the use of reagent kit components to the kit in which they were originally contained, unless otherwise specified by the manufacturer. It is unacceptable to use Hemoccult® cards and developer from different lots together for patient testing unless this practice has been approved by the manufacturer of the reagents.

V. Quantitative Testing

30) Is calibration verification required for ACT instruments?

Calibration verification is not applicable to coagulation testing that reports patient results in units of time (i.e., ACT, PT/INR, aPTT).

31) Are establishment of the analytic measurement range (AMR) and the clinically reportable range (CRR) required for coagulation test instruments?

Neither calibration nor AMR verification are applicable to coagulation test instruments that report patient results in units of time. The CRR for such instruments can be established using previously analyzed patient specimens, control materials, and/or other standards.

32) Does regular calibration verification need to be performed on all i-STAT® instruments, or can it done on one instrument for each new lot number? For example, can we perform calibration verification on one unit at each campus and then compare i-STAT® units?

Single-use devices such as i-STAT® instruments or glucose meters are exceptions to the rule that calibration verification must be performed on all instruments. Since large numbers of such devices may be in use at a given time within an institution, it may be impractical to perform calibration verification using a special set of specimens for each device. In these situations, alternative approaches for calibration verification of instruments are acceptable. If calibration verification materials include low, midpoint, high values that are near the stated analytic measurement
range (AMR), and calibration verification data are within a laboratory’s acceptance criteria, the AMR has also been verified.

One possible approach is to perform calibration verification on each instrument when it is put into use and after maintenance or servicing. Calibration verification can be performed on representative devices every six months. Acceptable performance of the other devices can be demonstrated by satisfactory QC results. If an institution has more than one device type, lot of reagent strips, or lot of cartridges in service, the process should be repeated for each combination.

Another method of ensuring ongoing acceptable instrument performance is to monitor the extent of agreement between POCT results and parallel blood specimens that have been sent to the main laboratory for analysis. Note that there may be some discrepancies in results in depending upon the analyte concentration and a patient’s condition. This type of comparison is facilitated when the POCT results are downloaded to a central data management computer. Comparisons should be conducted regularly such that over a six month period each POCT device is included in a comparison at several concentrations. This latter approach can also concurrently document correlation between POCT devices and the main laboratory method.

Other approaches for calibration verification of multiple single-use devices may be acceptable as long as the process documents calibration verification for the POCT instruments. Manufacturers’ instructions for calibration verification and AMR verification must be followed.

33) How often must we re-calibrate the glucose meters that we use for point-of-care testing?

Your glucose meters should be calibrated in accordance with a frequency that is established by the instruments’ manufacturers. Calibration of POC glucose meters is typically set at the factories prior to shipment of the instruments. With such instruments calibration verification, as opposed to calibration, must be performed on a representative sample of devices every six months. Calibration verification must include three points (low, mid, and maximum) that span the analytic measurement range (AMR). The materials used must be matrix appropriate (blood-based, not aqueous). Please contact your manufacturer to obtain recommendations for calibration frequency if you have a calibratable meter. You must, at a minimum, follow manufacturer requirements for calibration frequency.

34) We are having difficulty correlating the results of blood gas analytes between our several i-STAT® instruments because the samples are not stable. Do you have any recommendations on how to correlate these instruments?
Generally, all instruments must be included in instrument-to-instrument and method-to-method comparisons. Such comparisons are ordinarily performed with fresh human samples. Institutions that utilize large numbers of identical instruments, particularly when such instruments, measure unstable analytes, typically perform comparisons on subsets of instruments, using representative instruments to perform batch-to-batch and method-to-method correlations.

Single-use devices such as i-STAT® and glucose meters are an exception to the general rule that all instruments must be included in instrument-to-instrument comparisons. For institutions that utilize large numbers of these devices, alternative procedures may be used to document correlation of patient results among the devices and with the central laboratory. One approach is to document the agreement between patient results produced by a laboratory method and representative POCT devices for a lot of reagent strips or cartridges, while concurrently collecting results for QC materials that are run on the POCT devices. In addition, users can correlate POCT single use devices by comparing quality control results from meters that have used identical lots of reagent strips or cartridges and identical QC materials to perform their analyses. Another method of instrument correlation is to monitor the agreement between analyte measurements performed at the POC on whole blood samples, and those from simultaneously collected blood that has been sent to the central laboratory for analysis. Blood that is collected within thirty minutes of a POCT measurement generally provides acceptable agreement if the specimen is immediately processed by the central laboratory. However, there may be some discrepancies in results depending upon the particular analyte concentration and a patient’s underlying medical condition. Other correlation schemes may be acceptable. An appropriate correlation method will document the agreement between POCT devices and the central laboratory’s analyzers.

35) What are the CAP requirements for validation of new reagent lots for our glucose meters and other POC instruments?

The procedures and materials that are appropriate to validate new reagent lots must meet minimum manufacturer requirements, but are otherwise within the discretion of your laboratory director. Most often, two or three levels of control materials are run for multiple days on new lots of reagents. The means from each level are compared with those of the preceding lot numbers to validate the new reagents.

36) Please explain the difference between the analytic measurement range (AMR) and the clinically reportable range (CRR).
The analytic measurement range (AMR) is the range of analyte values that a method is capable of directly measuring for a given specimen type. In contrast, the Clinically Reportable Range (CRR) is the range of analyte values that the method can report as quantitative results. Thus, the AMR describes the limits of the method’s ability to measure an analyte, while the CRR can represent an extension of the AMR that is generated by dilution, concentration, or other pretreatment of specimens.

37) Can control materials be used for calibration verification?

Routine control materials generally are not suitable for calibration verification unless their manufacturers have specifically designated the materials as valid for calibration verification. The use of control materials ordinarily does not allow for verification over the entire analytic measurement range.

In order for control materials to be used for calibration verification they must be matrix specific, and have analyte values that reflect the minimum, middle, and maximum points of the analytic measurement range (AMR). It is unusual for quality control materials to meet these requirements.

38) According to the manufacturer of our POC glucose meters, the lower limit of these instruments’ AMR is 10 mg/dL. However, 32 mg/dL is the minimum concentration of the materials that are included in our linearity verification kits. Can we extend the AMR beyond that achieved with the linearity kit using materials from sources other than the linearity kit?

The analytic measurement range (AMR) of an instrument-reagent system is the range of values that can be achieved without the use of dilution or concentration protocols. The most common way to establish the AMR is through linearity testing, although the AMR can be verified by a number of different procedures. If the linearity materials you are using to establish the AMR do not verify the range of values that you desire, you may include additional data points to extend the AMR beyond that which you are able to verify with your linearity kit. This data may be obtained with previously tested patient samples (either neat or diluted), compatible materials from other vendors, previously tested proficiency samples, or other reference materials. The AMR must be validated every six months. If you were to use only your linearity kit for AMR verification, any result below 32 mg/dL should be reported as < 32 mg/dL.

39) For instruments that utilize electronic quality control to satisfy the CAP’s daily QC requirement, does the electronic QC need to be run by the personnel who actually perform patient testing?
The CAP requires the personnel who perform patient testing to run quality control testing. This requirement applies to systems that utilize electronic quality control in combination with external, i.e., “wet,” control materials. Quality control testing establishes that an instrument/reagent system is functioning properly, and that it is producing accurate results. It is the instrument operator’s (testing employee’s) responsibility to ensure that an instrument/reagent system produces correct patient test results before he or she tests actual patient samples.

40) What is meant by the term “matrix appropriate” materials as used in the CAP POCT Checklist?

As used in the CAP POCT Checklist, matrix appropriate materials refer to solutions or suspensions in which analytes are suspended or dissolved, that are expected to exhibit identical or nearly identical measurement properties as the patient specimens on which clinical laboratory testing is performed. Samples that are spiked to yield identical concentrations of an analyte, but that contain solvents with different matrix characteristics, can display different analyte concentrations upon measurement. These discrepancies in measurement are known as matrix effects. Measurement deviations of this type that occur in prepared samples when they are compared with actual patient samples, are attributable to such matrix effects. Optimally, comparisons between instruments and other quality control measures are performed with matrix identical materials in order to avoid such errors. For example, comparisons between instruments that test whole blood patient samples should be made with actual whole blood samples. At a minimum materials that have been demonstrated to be matrix appropriate should be used in instrument correlation studies and other quality control activities.

41) Please define “when applicable” in the checklist question “When applicable, are all patient results reported with accompanying reference (normal) or interpretive ranges?”

The CAP requires age and/or sex-specific reference ranges (normal values or interpretive ranges as applicable) to be reported with all patient test results. This is important to encourage proper interpretation of patient data. The “when applicable” is intended to refer to the appropriate use of reference versus interpretive ranges. This latitude is purposeful and necessary to allow medical directors the flexibility to set meaningful, appropriate standards that reflect the unique needs of the physicians and patients served by individual laboratories. All tests should have defined reference or interpretive ranges reported with patient results. The sole exception to this rule is for test results that are reported as part of a treatment protocol, e.g. an insulin sliding scale, in which clinical actions are taken in response to test values.
42) We have developed a whole blood platelet function test that can be used at the point-of-care. The test produces quantitative values, but uses a numeric “cut-off” to define “positive” or “negative” results. The results are reported qualitatively, as either positive or negative. The FDA considers the reported results to be qualitative. Does initial validation need to include linearity testing, as with a quantitative test?

Given the information that you have provided, i.e. that the FDA considers the test to be qualitative and that you are reporting a result based upon a numeric cut-off, the test can be validated as a qualitative test. Therefore, linearity testing is not required for the assay. Laboratories will need to run controls that verify the accuracy of the cut-off point. As a qualitative test instrument, positive and negative controls should be run each day of patient testing, prior to testing patient samples. Laboratories must also devise proficiency testing methods for the test, which must be performed every six months. If multiple instruments are used within an institution, the instruments’ function must be compared using patient samples every six months.

43) We use the i-STAT® instrument to perform POC arterial blood gas measurements. The instrument design includes an electronic control regimen that is recommended for use by the manufacturer. What daily quality control requirements does the CAP have for this instrument?

Traditionally, laboratories have been required to run two levels of liquid controls on quantitative instruments, at a frequency within which the accuracy and precision of the measuring systems have been expected to remain stable. This frequency has been based upon manufacturers’ recommendations, but has not been less often than once each day of patient testing.

However, the daily use of two levels of liquid controls may not be required for a test system for which the use of instrument or electronic controls demonstrates that the calibration status of the system is maintained within acceptable limits. Thus, the CAP accepts the use of daily electronic or internal controls in lieu of liquid controls after a laboratory has verified the adequacy of electronic controls for monitoring instrument performance. The daily use of two levels of instrument or electronic controls as the sole quality control system is allowed only for unmodified FDA approved “waived” or “moderate complexity” systems.

The laboratory is expected to provide documentation of the validation that was performed on the test system to ensure the adequacy of the quality control regimen. This documentation must include the Federal complexity classification of the test system. It must also include data that
demonstrates that the calibration status of the test instrument is monitored. The laboratory must also have a quality control policy that specifies the type of quality control materials used and the frequency of their use. Documentation demonstrating that the policy has been implemented and is followed by the testing personnel must be maintained.

44) What performance verification does the CAP require on new lot numbers of reagents?

The CAP requires laboratories to verify the performance of new lot numbers of reagents, prior to using the new lots for patient testing. Your laboratory may determine the appropriate procedure for verifying new lot performance, e.g. performing QC, calibration verification, patient comparisons, etc.

45) How frequently must linearity studies be performed on an instrument?

Linearity studies are only required at the time of installation of a new instrument. Linearity studies may be used to establish the reportable range for the assay. By contrast, the analytic measurement range (AMR) must be established before the instrument is used clinically, and must be verified every six months. Calibration verification may be used to verify the AMR.

46) For testing of activated clotting times in our cardiac catheterization laboratory, we currently test two levels of liquid controls weekly, and two levels of electronic controls twice a day on Monday through Friday, our scheduled days of operation. For weekend emergencies, is it sufficient to use the electronic controls alone although more than twenty-four hours may have passed since controls were last tested?

The quality control requirements for coagulation testing are that at least two levels of control material must be tested every eight hours on each day of patient testing. The control material can be either electronic or liquid. In the situation that you have described, it would not be necessary to run liquid controls on the weekend unless this was your regularly scheduled time for doing so, or unless you were troubleshooting an instrument.

47) What are the meter-to-meter and method-to-method requirements for POC glucose meters?

Generally, all instruments must be included in instrument-to-instrument and method-to-method comparisons. Such comparisons are ordinarily performed with fresh human samples. Institutions that utilize large numbers of identical instruments, particularly when such instruments, measure unstable analytes, typically perform comparisons on subsets of
instruments, using representative instruments to perform batch-to-batch and method-to-method correlations.

Glucose meters are an exception to the general rules that all instruments must be included in instrument-to-instrument and method-to-method comparisons. For institutions that utilize large numbers of glucose meters, alternative procedures may be used to document correlation of patient results among the devices and with the central laboratory. One approach is to document the agreement between patient results produced by a laboratory method and representative POCT devices for a lot of reagent strips, while concurrently collecting results for QC materials that are run on the POCT devices. In addition, users can correlate POCT glucose meters by comparing quality control results from meters that have used identical reagent strips and QC materials to perform their analyses. Another method of instrument correlation is to monitor the agreement between glucose concentration measurements performed at POC on whole blood samples, and those from simultaneously collected blood that has been sent to the central laboratory for analysis. Blood that is collected within thirty minutes of a POCT measurement generally provides acceptable agreement if the specimen is immediately processed by the central laboratory. However, there may be some discrepancies in results depending upon a patient’s blood glucose concentration and his or her underlying medical condition. Other correlation schemes may be acceptable. An appropriate correlation method will document the agreement between POCT glucose meters and the central laboratory’s glucose analyzer.

48) Is it necessary to perform precision checks on ACT instruments every six months?

Ordinarily, precision checks are only required as a component of the initial instrument and method validation that is performed at the time of an instrument’s installation. Your laboratory may need to perform precision studies for the purpose of troubleshooting, or to investigate possible changes in the precision of an instrument. As part of your ongoing quality control program, monthly QC statistics should be reviewed for accuracy and precision. Accuracy and precision are usually determined by analyzing the percent coefficient of variation and the standard deviation of the data.

49) The CAP requires that laboratories use repetitive analysis to establish a statistically valid QC range of acceptability for commercial controls that have assigned mean values. The analysis must be performed for each lot of quality control material. How many analyses must be performed in order to meet this CAP requirement?
The number of repetitions that laboratories must perform to establish QC ranges is within the discretion of their laboratory directors. The determination of a statistically valid range requires the inclusion of a sufficient number of values to minimize the impact of any single value on the results. It is common for laboratories to use the statistics that they gather during the first month of use to establish the QC ranges of acceptability for each lot of QC material.

50) Does the CAP really require the same individual who performs patient testing to perform the quality control testing?

Yes, individuals who actually perform patient testing must perform the quality control testing on the instruments that they use. This requirement ensures that the personnel who operate the instruments have verified that the instruments and reagents are performing correctly. The CAP believes that those individuals who are responsible for operating the instruments are best suited to assess their function, and from this evaluation to decide whether or not their use for patient testing is appropriate.

VI. Physician Performed Testing

51) Why has the CAP added a section on Physician Performed Testing (PPT) to the Checklist? Inspecting this testing increases the amount of work we have to do, and our physicians are upset about having their work addressed?

The CAP has added a specific PPT section because it has been difficult to locate the Checklist questions that applied to this type of testing when they were included in other sections of the Checklist. We believe that the addition of this section should improve the inspection process. The PPT section does not apply to all laboratories. For example, if a medical staff has its own PPM (Provider Performed Microscopy) certificate, it will not be inspected as part of its institution’s clinical laboratory, so the PPT section will not apply under these circumstances.

PPT applies only to a list of 14 tests, and only to physicians. If others such as nurses perform any of these tests or physicians perform tests in addition to these 14, the other sections of the Point of Care Checklist apply.

52) Is competency testing required for physicians who perform fecal occult blood tests as part of their physical examinations?

The CAP does not require competency assessment of physicians who perform testing that is within the scope of the practice of medicine as described in the Physician Performed Testing (PPT) section of the POCT Checklist. Physician performed fecal occult blood testing is among those
tests that are included in the PPT section. Under the most recent CAP POCT checklist, competency assessment of physicians who perform PPT testing has been deemed part of the medical staff credentialing process, and will no longer be included in CAP Point-of-Care inspections.

The CAP requires that all other healthcare providers, including nurse practitioners and physicians’ assistants, undergo periodic competency assessments. Finally, manufacturer quality control requirements and test instructions must always be followed irrespective of who performs a test.

53) How should we assess the competency of physicians who perform POC testing?

Your institution, with the participation of the medical director, should establish an institutional policy that addresses competency assessment for physicians who perform point-of-care testing. For tests that are included in the physician performed testing (PPT) section of the CAP POCT Checklist or are FDA classified waived tests, oversight of physician competency is the responsibility of your medical staff credentialing officials. Physician competency assessment for these tests will not be addressed during CAP inspections. For POCT tests that are not included within the Physician Performed Testing category and are FDA classified moderate and high complexity tests, the requirements for physician training and competency assessment will depend on the test under consideration. In some circumstances, physicians may be required to demonstrate competency in the same manner as other employees who perform these tests. Many institutions have outlined specific tests that physicians are deemed competent to perform on the basis of their training and educations. For those tests that have not already been included in the PPT section of the Checklist, no additional documentation beyond proof of completion of the requisite training is required.

Institutions have developed and implemented POCT training and competency programs for physicians. The administration of these programs need not be the responsibility of the point-of-care coordinator. Often the laboratory medical director or another designated physician supervises POCT training and competency programs for physicians.

54) We have Hemoccult® kits available for POCT testing in most of the units at our facility. Physicians perform the occult blood testing. What are our laboratory’s responsibilities for quality control testing?

Physician performed testing (PPT) is subject to CAP inspection only if the laboratory director maintains overall responsibility for the testing. Quality control must be documented for all tests that are subject to CAP inspection. Each PPT site must maintain a technical procedure manual
that includes specimen handling information, and the laboratory must have documented evidence of an effective quality improvement program that is appropriate for the nature of the testing performed (in this case fecal occult blood testing). The quality improvement program should at a minimum address daily quality control results, instrument maintenance, and corrective actions for QC and/or reagent failure. For tests that are included in the physician performed testing (PPT) section of the CAP POCT Checklist or are FDA classified waived tests, oversight of physician competency is the responsibility of your medical staff credentialing officials. Physician competency assessment for these tests will not be addressed during CAP inspections.

The Point-of-Care Testing Checklist requires that quality control be performed and the results documented each day of patient testing. In order to verify that a Hemoccult® card is working properly, the performance indicator should be tested for each card prior to reporting the patient result (refer to the manufacturer’s product insert for specific testing instructions and recommendations). Physician documentation of successful testing of the performance indicator can fulfill the requirement for daily quality control, as testing personnel must perform and record quality control results. Quality control results for PPT testing, as with all POCT must also be reviewed by the medical director or his or her designee, and there must be documentation of corrective action taken for any unacceptable quality control results.

55) Our physicians perform occult blood and rapid urease testing (CLO tests) during endoscopy procedures. Are we required to enroll in proficiency surveys for these tests?

The CAP classifies occult blood and rapid urease testing that is performed by physicians as part of their endoscopic examinations as Physician-Performed Testing (PPT). This testing is subject to CAP inspection only if the testing is performed under the laboratory’s CLIA certificate, or another CLIA certificate that is subject to CAP inspection. The CAP does not require proficiency testing for PPT, although such testing is subject to the requirements of the PPT section of the CAP Point of Care Checklist.

56) Our physicians perform KOH and Wet Prep testing in our clinics and in the hospital. Are they required to participate in proficiency surveys for this testing? If physicians are the only persons who perform this testing, are we required to maintain written procedures for it?

Procedure manuals and quality control are required for all tests that your facility performs, even those that are performed solely by physicians. The CAP does not require enrollment in proficiency surveys for PPT. However, because there are no commercially available quality control
materials for these two tests, many laboratories use proficiency testing as a way to satisfy this CAP requirement.

57) Physicians at our institution frequently perform bedside Hemoccult® testing. Do we need to document competency for these physicians. Must we document quality control results for the testing that they perform?

For tests that are included in the physician performed testing (PPT) section of the CAP POCT Checklist or are FDA classified waived tests, oversight of physician competency is the responsibility of your medical staff credentialing officials. Physician competency assessment for these tests will not be addressed during CAP inspections.

Physicians must document quality control for the tests that they perform. Specifically, in addition to patient results, daily positive and negative control results should be recorded. A requirement for external controls depends upon the presence of internal controls and manufacturer instructions. Please note that controls must be run as often as the manufacturer requires, but no less frequently than once each patient day. In the case of Hemoccult® cards, for example, internal positive and negative controls should be performed with each test card development.

VII. New Instruments

58) We have recently purchased a POCT bilirubin analyzer for use in our newborn units. Given the difficulty in obtaining neonatal samples for study purposes, what are the CAP’s validation requirements for this new instrument?

For all new instruments, the CAP requires that you assess the linearity (reportable range verification), accuracy, and precision of each instrument before reporting clinical results. You must also verify the sensitivity and specificity of, and the reference range for, each method that you perform. The laboratory director is responsible for determining the scope and extent of these activities. Your laboratory cannot use manufacturer provided data as a substitute for your own internal validation of an instrument. For further information, please read the Laboratory General Checklist “Method and Performance Specifications” section. The Laboratory General Checklist can be downloaded from the CAP website at http://www.cap.org/html/ftpdirectory/checklistftp.html.

The reference (normal) range may be established through a literature review, or a study that is performed internally or in conjunction with other institutions. Matrix appropriate materials must be used for all of the aforementioned studies. While patient materials may be preferred for many of these studies, this is not an absolute requirement, as long as the materials are matrix appropriate. Validated reference or standard
materials may be potential options for use in your efforts. The CAP no longer provides validated reference materials for neonatal bilirubin testing.

59) We just purchased new POCT analyzers as replacements for older instruments. The manufacturer has performed correlation studies with the old and new instruments. Is this data sufficient for validation of the new analyzers?

Your laboratory cannot use manufacturer provided data as a substitute for your own internal validation of an instrument. Please see questions 58, 60, and 61 for additional information regarding the validation of new instruments.

60) We are considering implementing a POC hemoglobin A1C analyzer. The instrument is designed for single use, and has built in electronic validation and quality control checks. What are the CAP’s requirements for correlation, frequency of quality control, and calibration verification for the instrument?

The necessary scope of method validation for a new instrument is determined by your laboratory director. It must encompass accuracy, sensitivity, and reportable range (AMR) verification for each instrument, and verification of the sensitivity, specificity and reference range for the method. The use of electronic controls in place of wet controls is at the discretion of the laboratory director for unmodified FDA classified moderate complexity and waived devices. If electronic QC is performed daily, the frequency of liquid QC is at the discretion of the medical director. However the frequency of liquid QC must meet the minimum requirements as set forth by the manufacturer in the package insert. Calibration verification is required every six months.

61) In setting up new instruments, are users always required to perform normal range studies, or are this required only if correlation studies demonstrate differences from old instrumentation? Are normal range studies needed for both serum and plasma if the manufacturer says they compare?

Normal range studies (reference range studies) ordinarily need to be performed on all new instruments at the time of their installation. However, if a new instrument is identical to one on which you have already performed reference range studies, i.e. the same make, model, and software version, you are not required to perform a complete reference study for the instrument. If the new instrument is not identical to your existing instruments, the reference range for the method must be evaluated. Your laboratory should also periodically review the appropriateness of its normal ranges at a frequency that is within the discretion of the laboratory director.
Whether or not you need to establish separate reference ranges for serum and plasma is within the discretion of your laboratory director. Distinguishing these sample types may be appropriate for some analytes, but unnecessary for others.

VIII. Alternative Test Systems

62) What are the laboratory’s responsibilities with respect to the transcutaneous bilirubinometers that are used by our neonatology departments? We have been told that the devices are CLIA exempt.

The Alternative Test Systems section has been eliminated from the most recent version of the CAP POCT Checklist. *In vivo* and alternative test systems such as transcutaneous bilirubinometers are no longer evaluated during CAP inspections.