Topic: **Individualized Quality Control Plan (IQCP) Frequently Asked Questions**

Date: May 5, 2015 (last updated August 17, 2015)

GENERAL QUESTIONS

1. **Why is the CAP implementing the IQCP option and eliminating the Equivalent Quality Control (EQC) or internal control process-related checklist requirements? (UPDATED)**

   The Centers for Medicare and Medicaid Services (CMS) has implemented IQCP as an acceptable QC option. **As of January 1, 2016**, the CMS will no longer recognize EQC as an acceptable option to meet Clinical Laboratory Improvement Amendments (CLIA) requirements for QC of nonwaived testing. Because of the CAP's deemed status as an accrediting organization, the CAP revised its checklists for the 2015 edition to address these changes. These changes apply to all participants in the Laboratory Accreditation Program, whether or not they are subject to US regulations. The 2015 edition introduces IQCP and removes language from requirements that allow for the use of EQC as an acceptable daily QC option. The new requirements for IQCP provide laboratories with the framework to implement IQCP and offer flexibility to design a QC plan appropriate for the laboratory. These changes will ensure that CAP- accredited laboratories remain in compliance with the CLIA and CMS regulations.

   The use of an IQCP is optional. These changes only apply to nonwaived testing.

2. **When will the checklist changes relating to IQCP occur? (UPDATED)**

   New requirements for IQCP were published on July 28, 2015 in the 2015 edition of the All Common Checklist. Existing requirements in the discipline-specific checklists (eg, Chemistry, Point-of-Care Testing) were also revised at that time to remove provisions for EQC. **As of January 1, 2016**, all laboratories performing nonwaived testing must follow the minimum CAP requirements and default CLIA quality control regulations or implement an IQCP, if eligible, as defined in the 2015 CAP checklist for the QC of nonwaived testing.

3. **Where can I find the CAP checklist requirements for IQCP? (UPDATED)**

   Five new requirements for IQCP are included in the 2015 All Common Checklist, along with introductory material and notes in the customary format. Revisions to additional requirements in the discipline-specific checklists (eg, Chemistry, Point-of-Care Testing) were also made to remove provisions for EQC and introduce the option for IQCP.

4. **What does the CAP require for IQCP? (UPDATED)**

   The 2015 edition of the All Common Checklist contains the requirements for IQCP, including Risk Assessment, Quality Control Plan, and Quality Assessment Monitoring. The checklist also requires the use of specific CAP forms to maintain a list of IQCPs and a summary of each IQCP.

   Master and custom versions of the 2015 edition checklists are available for download and review from the CAP website through e-Lab Solutions Suite.

5. **Is my laboratory required to have an IQCP?**

   No. The use of an IQCP is voluntary. However, without an IQCP, laboratories must follow the minimum daily QC requirements and default CLIA regulations for daily QC of nonwaived testing, as defined in the 2015 CAP checklist. This will primarily impact laboratories that are using

instruments or devices (eg, test kits) where an internal control process (electronic, procedural, or built-in) has been used for daily QC in lieu of an external quality control sample, especially those that use multiple identical instruments or devices.

6. **Do I need to implement an IQCP if I am currently running at least two levels of external QC for a nonwaived test each day of patient testing (or following more stringent requirements as defined in the CAP checklist and CLIA regulations)?**

   No. There is nothing further you must do. If a test is eligible for an IQCP, the laboratory is NOT required to implement an IQCP, but has the **option** to implement an IQCP **or** follow the default QC requirements of at least two levels of external QC each day of testing (or more frequent as specified in a discipline or subdiscipline).

7. **If my instrument has an internal control process that uses liquid control materials, do I need to implement an IQCP to use this material to meet daily QC requirements? (NEW)**

   The default CLIA regulations were written for the traditional daily testing of two levels of external control materials. To be considered an external control material, the control material must follow the entire testing process, from sample introduction through the analytic pathway. It must also be a different type of material or from a different lot number than used to calibrate the instrument. With the advancements in technology, manufacturers produce test systems that include a variety of different types of internal monitoring systems. If the internal monitoring system does not meet the criteria described for external control materials, the laboratory must either perform additional QC testing using appropriate external control materials or implement an IQCP to meet daily QC requirements.

8. **If an IQCP is not used, what are the CAP's minimum requirements and default CLIA regulations for daily external QC for nonwaived testing?**

   Generally, the CAP and CLIA require at least two levels of external QC each day of patient testing. Different CAP and CLIA requirements exist in some discipline and subdiscipline areas (eg, coagulation, blood gases, and microbiology). The QC requirements for nonwaived testing, as written in the 2015 CAP checklists and CLIA regulations, must be followed if an IQCP is not implemented by January 1, 2016.

9. **What are the QC requirements if I have *multiple* identical instruments/devices/cartridges in use but do not wish to develop an IQCP?**

   The existing CLIA and 2015 CAP checklist requirements will apply; generally, at least two levels of external QC for **each device and cartridge**, each day of testing (or more frequent as specified in a discipline or subdiscipline).

10. **Can an IQCP be used to reduce the frequency of calibration, AMR verification, or instrument comparison?**

    No. IQCP is applicable to QC only. The results and data from the above functions may be useful when conducting the Risk Assessment for an IQCP.

11. **Can I use an IQCP for some analytes on a test platform and not others?**

    Yes. The Risk Assessment may indicate that an IQCP is a viable option for some analytes, but may not be suitable for others due to identified risks.

12. **If an instrument or device is used to perform multiple tests, is a separate IQCP required for each test?**

Many of the same risks will apply to all tests performed on an instrument or device; however, risks may vary for specific tests. The Risk Assessment performed must address all potential areas of risk for **each test, as well as the instrument or device**. Based on the outcome of the Risk Assessment, a single IQCP may or may not be appropriate for the instrument or device.

13. Are there specific IQCP forms that I need to use to create my own IQCP? (NEW)

There are no specific forms required to create an IQCP. A laboratory may develop its own model in designing an IQCP or use resources, such as those listed in FAQ #43.

Once an IQCP is implemented, information from each IQCP must be added to CAP required forms to be used during the CAP inspection process - 1) IQCP List and 2) IQCP Summary. These forms are located on the CAP website in e-Lab Solutions Suite, under CAP Accreditation Resource, Accreditation Forms and Instructions.

14. Can my laboratory submit an IQCP developed by my laboratory to the CAP Central Office for review and approval prior to implementation? (NEW)

The College of American Pathologists (CAP) is an accrediting organization and does not offer this type of consulting service. It is the laboratory director's responsibility to review the IQCP risk assessment and approve the quality control plan prior to implementation. In addition to ensuring that the quality control plan ensures the quality and reliability of patient test results, the laboratory director must also ensure it meets the CAP's accreditation requirements, as well as federal and state regulations. For CAP-accredited laboratories, records for IQCPs implemented will be reviewed for compliance during the laboratory's next onsite inspection.

The CAP provides a number of resources to aid in the development and implementation of an IQCP, including the checklist requirements in the 2015 edition (refer to FAQ #43 for a list of CAP and other resources).

ELIGIBILITIY TO USE IQCP

15. Does IQCP apply to all types of testing? What are the CAP's IQCP eligibility requirements?

IQCP does not apply to waived testing. Laboratories must continue to follow manufacturer's instructions for QC for both waived and nonwaived test systems, at a minimum.

For nonwaived testing, the CAP has defined eligibility requirements for IQCP. Eligibility is limited to tests meeting **both** of the following criteria:

1. The testing is performed in a discipline other than Anatomic Pathology (ANP) or Cytopathology (CYP). (Exception: tests in ANP or CYP that can be assigned to another discipline, such as FISH) **and**
2. The test system has an **internal control process** (electronic, procedural or built-in). (Exceptions exist in microbiology for media, ID systems and susceptibility testing, which qualify for IQCP even though there is no internal QC.)

For tests that do not meet the CAP's IQCP eligibility requirements, the minimum daily QC requirements and default CLIA regulations, as defined in the 2015 CAP checklist, of at least two levels of external QC each day of patient testing (unless more stringent requirements exist), must be observed.

The CAP has developed an **Eligibility Determination** tool to assist in the determination of eligibility of a test system for a CAP IQCP.

16. Is Microbiology testing eligible for IQCP? (UPDATED)

Microbiology testing, including molecular infectious disease testing and direct antigen testing, performed using nonwaived instruments or devices that have internal control processes are eligible for IQCP. In addition, microbiology testing performed using media, identification systems, and susceptibility test systems are eligible for IQCP. Laboratories must have an IQCP to define the use of reduced QC, even if following manufacturer's instructions or Clinical and Laboratory Standards Institute (CLSI) guidelines. Previous data collected by the laboratory and manufacturer certificates of analysis may be used in the Risk Assessment. Without an IQCP, the minimum CAP checklist and default CLIA QC requirements are applicable.

The CAP, the American Society of Microbiology (ASM) and the CLSI are working collaboratively to produce templates that may be used in developing an IQCP for susceptibility and identification testing, as well as for media. Templates are currently available for susceptibility testing and disk diffusion testing on the CAP website in e-Lab Solutions Suite. Additional examples will be added as they become available.

Refer to the Microbiology Testing section (FAQs #34-36) for additional questions and answers on this topic.

17. Why did the CAP limit the eligibility to use an IQCP to tests with internal control processes?

While many of the elements of IQCP are not new for laboratories, the overall concept is a significant change. The CAP will limit the use of an IQCP to instruments or devices with an internal control for the 2015 checklist edition (with the exception of microbiology susceptibility, media, and identification systems; see FAQ #16 above) and will reevaluate this decision as we gain more experience with IQCP. This meets or exceeds the CLIA/CMS requirements and was approved by the CMS.
The use of internal control systems has been accepted by the CAP previously. Laboratories may continue to use internal control processes, but **must** implement an IQCP to do so. For the microbiology tests mentioned above, the CAP has accepted alternative quality control practices that followed microbiology guidelines from the CLSI. These practices may continue to be used **if** an IQCP is implemented.

18. How do I determine if an internal control process used by my instrument or device is sufficient to meet the CAP's eligibility criteria to implement an IQCP? (UPDATED)

The sufficiency of an internal control process must be evaluated by the laboratory as it performs a risk assessment. The laboratory must evaluate the manufacturer's information to identify potential areas of risk, processes to mitigate risk (eg, internal control processes) and other sources of information, as available, and perform its own studies in its own environment to confirm that the defined control processes, frequency, and associated risk is acceptable. Retrospective data may be used in the risk assessment.

19. Which states do not allow IQCP? (NEW)

State regulations may vary from state to state. Laboratories that are unsure of IQCP acceptability in their state should contact the state CLIA office to confirm acceptability of IQCP in the state or determine if there are any limitations. If state law does not allow for the use of the IQCP option, laboratories must follow the default to QC requirements defined in the CAP 2015 checklist requirements, CLIA regulations, and applicable state requirements, whichever is the most stringent.

RISK ASSESSMENT

20. What are the components of a Risk Assessment?

The required components of a Risk Assessment include evaluation of:

1. Five required elements: reagents, environment, specimen, test system, and testing personnel
2. All phases of testing: pre-analytic, analytic, and post-analytic
3. Data from the laboratory's **own** environment, instrument/equipment performance, and testing personnel
4. All variations in test performance (eg, multiple test sites, devices, types of testing personnel, etc)

21. Can a single Risk Assessment be used for multiple laboratories with multiple CAP numbers?

No. **Each** laboratory with a ***separate CAP number*** must conduct its own risk assessment. Affiliated laboratories (or systems) may use the same or similar format and some of the same resources (eg, manufacturer's information) when evaluating the risks, but the data collected and risk assessment must be specific to the laboratory for ***each separate CAP number***. This is required to ensure that variations in use and practice are evaluated.

22. Is a separate Risk Assessment required for each site if the same instrument/device/test is used in multiple areas *within a CAP number*?

No. The laboratory has an option. Individual assessments may be performed **or** a single risk assessment (RA) may be used when there are multiple sites performing testing ***under a single CAP number***. If a single RA is performed, all variations in the required components must be taken into account when conducting the RA (eg, differences in sites, environments, or personnel). A laboratory can then develop one IQCP that accounts for all of the differences in the RA or can develop individual IQCPs to address differences by site. Each device used must be monitored in some way, as well as each location.

23. Do I have to perform all new studies to gather data/information for my Risk Assessment? (UPDATED)

No. Historical data accumulated during the laboratory's routine operations may be used.

If the laboratory is implementing a new test, instrument, or device, it will need to gather information on the laboratory-specific risks associated with the test, including evaluation of laboratory-specific data. This may be done during the test method verification process prior to use for patient testing. Alternatively, the laboratory may choose to begin using the test after the test method is verified and perform quality control using external quality control materials following the default CLIA and CAP checklist requirements, until sufficient data can be collected to perform the risk assessment and implement a quality control plan.

24. My instrument (or kit) manufacturer provides risk assessment information for implementing an IQCP. Is this acceptable to use?

Yes. It is acceptable to use information provided by an instrument or kit manufacturer as a supplement in the risk assessment. However, it does **not** replace the need for a laboratory to perform its own evaluation of all five elements of risk and **cannot** be used alone.

QUALITY CONTROL PLAN DEVELOPMENT

25. What is required in the written Quality Control Plan for a test with an IQCP?

The written Quality Control Plan must include, at a minimum, the number, type (internal, electronic, external, etc) and frequency of testing for QC, and the criteria for acceptable performance. The data from the Risk Assessment must support the rationale for the plan. The plan may allow for less than the CLIA requirements, but cannot be less than the manufacturer's requirements for QC.

Additionally, the CAP will require external QC to be performed at least every 31 days and for each new lot and shipment. The laboratory will determine if the external QC must be run on each device or instrument or on a subset of devices, based on the manufacturer's instructions and the findings of the risk assessment and define the requirements in the written quality control plan.

The written plan must be signed and dated by the Laboratory Director prior to implementation. This approval cannot be delegated.

26. Why is the CAP requiring external controls to be run at least every 31 days if an IQCP is in place? (NEW)

While many of the elements of IQCP are not new for laboratories, the overall concept is a significant change. The CAP decided to define a minimum frequency for performing external quality control to include new lots and shipments of reagents and at least every 31 days. Laboratories must also follow manufacturer's instructions at minimum. The CAP will reevaluate this decision as we gain more experience with IQCP.

27. For the external QC at least every 31 days, how many levels of controls need to be run? If multiple devices are in use, can we run the external QC using a subset of devices? (NEW)

The laboratory must define the control procedures to be followed based on the risk assessment performed. The decision on the number of controls needed and the use of subsets of devices using the same reagent lot if multiple devices are used may be defined by the laboratory in the quality control plan, if appropriate, and be approved by the laboratory director based on the risk assessment evaluation and the supporting data used in the risk assessment. The laboratory director is ultimately responsible for the control procedures defined. The effectiveness of the control measures defined in the quality control plan must be evaluated on an ongoing basis as part of the quality assessment monitoring process.

28. Can I use my IQCP to reduce the type and/or frequency of QC to be less stringent than the manufacturer's requirements?

No. You must continue to follow all manufacturer instructions for internal and external QC. These instructions should frame the evaluation of Risk Assessment data and development of an IQCP.

29. Will the checklist requirements for more frequent QC for some types of testing still apply (eg, coagulation, blood gases) if a laboratory implements an IQCP?

During the Risk Assessment process for a test that is eligible for IQCP, the laboratory must evaluate the potential sources of errors, manufacturer's instructions, and historical test performance to identify the appropriate control processes. The laboratory's Quality Control Plan may define a frequency less than the minimum frequency defined in the CAP checklist if it is determined to be acceptable based on the risk assessment.

If an IQCP is not implemented, the minimum QC frequency defined in the CAP checklists and default CLIA requirements must be followed.

In all cases, manufacturer's requirements for QC must be followed, at a minimum.

30. Can I use a commercial product for development of my IQCP? (UPDATED)

The CAP does not require a specific format for the IQCP. Laboratories may develop their own model for designing an IQCP or use other resources, such as the CLSI Guideline EP23-A, Laboratory Quality Control Based on Risk Management, CMS guidance and brochures, a manufacturer protocol, or other commercially available products.

The CAP will require the use of specific CAP forms to maintain a list of the IQCPs and a summary of each. These forms are intended to be used as an inspector tool and will not meet the checklist requirements for documenting the IQCP risk assessment or quality control plan. These forms are located on the CAP website in e-Lab Solutions Suite, under CAP Accreditation Resource, Accreditation Forms and Instructions.

31. What are the QC requirements if I have *multiple* identical instruments/devices/cartridges in use but do not wish to develop an IQCP?

Without an IQCP, the existing CLIA and 2015 CAP checklist requirements will apply; generally, at least two levels of external QC for **each device and cartridge**, each day of testing (or more frequently as specified in a discipline or subdiscipline).

ONGOING IQCP ASSESSMENT

32. What is required for ongoing assessment of an IQCP?

Ongoing assessment must include evaluation of errors relating to the different phases of the testing process, QC failures and corrective action, and complaints from clinicians and other providers on the quality of results. It must also include a determination of the need to reassess and revise the IQCP.

Quality control and instrument/equipment maintenance and function check data must continue to be reviewed at least monthly.

Additionally, each IQCP must be assessed **annually** for effectiveness and revised, as necessary.

33. Does the quality assessment monitoring for IQCP need to be included in the quality management (QM) program? (NEW)

If used, IQCP must be incorporated into the quality management program. Ongoing quality assessment of an IQCP must include evaluation of errors relating to the different phases of the testing process, QC failures and corrective action, complaints from clinicians and other providers on the quality of results, and an annual assessment of the effectiveness of the IQCP. Some of these items are often included in the QM plan already. The laboratory may consider including ongoing assessment of these items as quality indicators. .

MICROBIOLOGY TESTING

34. Do I need an IQCP for my microbiology testing? (NEW)

The 2015 Microbiology Checklist includes a number of revisions based on changes in the CMS Interpretive Guideline. Along with the removal of the EQC option, the CMS also removed provisions from the CMS Interpretive Guideline that allowed laboratories to follow alternate frequencies for quality control of microbiology media, susceptibility testing, and identification

systems that were based on published guidelines from the CLSI. If a laboratory wishes to continue to follow the alternate QC protocols for exempt media, weekly QC for susceptibility testing, or streamline QC for identification systems, a laboratory must perform a risk assessment and implement an IQCP. These changes are described in the checklist.

For other types of microbiology testing that employ an internal (electronic/procedural/built-in) control system in lieu of external QC, such as direct antigen test kits or instruments for molecular infectious disease testing, an IQCP must also be implemented if external QC is not run following the requirements as defined in the CAP checklist and default CLIA regulations.

An IQCP is not needed for reagents where the checklist and other regulations define specific quality control requirements, such as weekly QC for gram stains or the testing of new lots and shipments of certain tests described in MIC.21624, such as catalase, coagulase, indole, and Streptococcal grouping).

The CAP, the American Society of Microbiology (ASM) and the CLSI are working collaboratively to produce templates that may be used in developing an IQCP for susceptibility and identification testing, as well as for media. Templates are currently available for susceptibility testing and disk diffusion testing on the CAP website in e-Lab Solutions Suite. Additional examples will be added as they become available.

35. Does my laboratory need to create a risk assessment for bacterial cultures? (NEW)

There are no requirements for a risk assessment or IQCP to be implemented for microbiology cultures. Neither the CLIA regulations nor the CAP Checklists define a specific QC requirement for microbiology cultures. The IQCP requirements apply to identification systems and media involved in this process.

36. Do I need to perform a risk assessment on each type of media used or can I group them as agar media on plates and broth media? (NEW)

The Microbiology Checklist requirement MIC.21240 contains the requirements for media QC and the use of an IQCP. Not all media have an equal risk for failure; therefore, if the laboratory decides to include more than one type of media in a single IQCP, the IQCP documents must clearly list all types of media included and the risk assessment must include an evaluation of the risks for all types of media included, including the use of a laboratory's own data (e.g. historical performance, problem logs) in this evaluation. In addition, please note that at a minimum, laboratories must follow manufacturer's guidelines for performing end user quality control. Some manufacturers require end user quality control for media while others do not.

If end user quality control is performed on media that meets the default CLIA regulations and CAP checklist requirements, an IQCP is not required.

RECORD RETENTION

37. What records are required? What is the retention time for this information?

All information, records, or data used in conducting the Risk Assessment (eg, previous QC data, manufacturer's package insert, information or instructions, instrument maintenance and function records, proficiency testing data, environmental data), and the Quality Control Plan must be maintained for the life of the IQCP plus two years (five years for Transfusion Medicine).

Records and data collected during the ongoing monitoring and assessment of the IQCP must be retained for two years (five years for Transfusion Medicine).

CAP INSPECTIONS

38. What if my laboratory is being inspected with the 2014 checklist edition after January 1, 2016?

All laboratories with CAP inspections occurring after January 1, 2016 will be evaluated for compliance with the QC requirements for nonwaived testing, **as published in the 2015 checklist edition**, regardless of the checklist edition being used for inspection.

For laboratories that are being inspected with the 2014 checklist edition and the inspection window allows for inspection after January 1, 2016, the CAP will be providing a transition packet to alert them to this change and provide the revised requirements.

39. What happens if my laboratory is not able to complete all the necessary risk assessments and implement IQCP for all areas of the laboratory by January 1, 2016? (NEW)

The CAP must abide by the rules stipulated by Centers for Medicare and Medicaid Services (CMS). CMS has stated that there will be no extension to the January 1, 2016 implementation date. **If the laboratory does not have an IQCP in place for tests performed using instruments or devices where QC is performed less frequently than stated in the default CLIA regulations and CAP checklist requirements, the laboratory must perform daily external quality control at the required frequency until an IQCP can be implemented by the laboratory.** If the laboratory is cited with a deficiency relating to the performance of EQC and the lack of an IQCP during on onsite inspection conducted after January 1, 2016, the laboratory will have 30 days to respond to the deficiency with its corrective actions.

40. What if I am assigned to do an inspection after January 1, 2016 with the 2014 checklist edition?

Teams that are inspecting laboratories with the 2014 checklist edition after January 1, 2016, will be provided instructions, training, and the revised 2015 checklist requirements.

41. How will IQCP be inspected?

Inspectors will look for compliance with the requirements defined in the 2015 checklist for IQCP.

For **each** CAP number, requirements for compliance will include:

1. Risk Assessment, including evaluation of all of the following:
    a. All five required elements (Reagents, Environment, Specimen, Test System, Testing Personnel)
    b. All phases of testing: pre-analytic, analytic, and post-analytic
    c. Data from the laboratory's own environment, instrument/equipment performance, and testing personnel
    d. All variations in test performance (eg, multiple test sites, devices, types of testing personnel, etc)
2. Written Quality Control Plan defining types of control processes used, criteria for acceptable performance, and frequency evaluated. QC may not be performed less frequently than defined in the manufacturer's instructions.
3. Approval of the written IQCP by the laboratory director prior to implementation (signed and dated)
4. Ongoing assessment of errors, QC failures, and complaints, including the need to reassess the risk assessment and quality control plan
5. Annual review of each IQCP

6. Use of CAP forms to maintain a list of Individualized Quality Control Plans and a summary of each IQCP

Inspectors may cite deficiencies when any of the above elements are not in compliance with checklist requirements. The decision on whether the level of risk for any of the elements evaluated in the risk assessment is acceptable is left to the discretion of the laboratory director.

42. Where can I find the IQCP forms to provide to the inspector mentioned in the All Common Checklist requirement COM.50200 (IQCP Test List/IQCP Summary)? Do I need to submit these forms to the CAP? (NEW)

The forms for the IQCP List and IQCP summary are located on the CAP website in e-Lab Solutions Suite, under CAP Accreditation Resource, Accreditation Forms and Instructions.

If one or more IQCPs are in use, laboratories must complete the IQCP List and IQCP Summary forms and provide a copy to the inspector during the laboratories next on-site inspection. These forms should be updated between inspections to ensure readiness for inspection. These forms are not submitted to the CAP, unless specifically requested.

OTHER RESOURCES

43. Where can I find other sources of information on IQCP? (UPDATED)

The CAP website (http://www.cap.org) has a variety of resources and continues to be updated as new resources become available. Aside from the resources listed below, laboratories may also wish to contact the manufacturers of instruments or devices to determine if they provide any information or tools for conducting a risk assessment.

CAP Resources:

- 2015 Checklist Edition – All Common Checklist
- Eligibility Determination for Individualized Quality Control Plan (IQCP) Option
- CAP/ASM/CLSI Microbiology IQCP template and examples
- CAP forms and instructions for inspection
- CAP IQCP webinar presentation in August
  - Posted to CAP website approximately one month after the event
  - Rebroadcast with live Q & A in October

Other Resources:

- Clinical and Laboratory Standards Institute (CLSI) Guideline EP23-A, Laboratory Quality Control Based on Risk Management (www.clsi.org) and companion documents

- The Centers for Medicare and Medicaid Services guidances and brochures: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
- CDC/CMS Handbook: Developing an IQCP – A Step-by-Step Guide (http://wwwn.cdc.gov/CLIA/Documents/IQCP%20Layout.pdf)
- Manufacturer tools, if available