



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

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GENERAL QUESTIONS

1. **Why does the CAP require an IQCP for nonwaived testing previously covered by Equivalent Quality Control (EQC) requirements? When did this change occur?**

The Centers for Medicare and Medicaid Services (CMS) implemented IQCP and discontinued recognizing EQC as an acceptable QC option for non-waived testing effective January 1, 2016. To be in compliance with CMS, the CAP revised its checklists in July 2015 to introduce IQCP and remove language allowing EQC as a daily QC option. The requirements for IQCP provide laboratories with the framework to implement IQCP, when appropriate, and offer flexibility to design a QC plan that meets the needs of the laboratory. The overall intent is to help ensure that CAP-accredited laboratories remain in compliance with CLIA and CMS regulations.

2. **Do the checklist requirements for IQCP apply to laboratories that are not subject to US regulations?**

Yes, the changes to the checklist relating to quality control and IQCP apply to all participants in the Laboratory Accreditation Program, whether or not they are subject to US regulations.

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

Five specific IQCP requirements are included in the All Common Checklist, along with introductory material and notes in the customary format. Additional requirements in the discipline-specific checklists (eg, Chemistry, Point-of-Care Testing) also reflect the replacement of EQC with the IQCP option.

4. **What does the CAP require for IQCP?**

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 a specific CAP form to maintain a list of IQCPs.



Master and custom versions of the checklists are available for download from cap.org through e-LAB Solutions Suite (log in required).

5. Is there a specific model and/or forms that I need to use to create my own IQCP? Can I use a commercial product to develop an IQCP?

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

No specific forms are required when creating an IQCP; however, the CAP does require the use of a special form to list all IQCPs in use to facilitate the inspection process. Refer to the List of Individualized Quality Control Plans form located in the IQCP Toolbox on cap.org in e-LAB Solutions Suite (log in required).

6. Can I submit an IQCP developed by my laboratory to the CAP Central Office or to one of the CAP's scientific resource committees for review and approval prior to implementation?

No. The College of American Pathologists (CAP) 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. 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 (refer to [FAQ #58](#) for a list of CAP and other resources).

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ELIGIBILITY TO USE IQCP

7. 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) **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 IQCP eligibility requirements, the minimum daily QC requirements and default CLIA regulations, as defined in the CAP checklist 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. It is available in the IQCP Toolbox on cap.org in e-LAB Solutions Suite (log in required).

8. 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.

9. Is Microbiology testing eligible for IQCP?

The following types of microbiology testing are eligible for IQCP:

- Molecular-based infectious disease testing and direct antigen testing performed using nonwaived instruments or devices that have internal control processes.
- Microbiology testing performed using media, identification systems, and susceptibility test systems.

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 must be followed.

Refer to the Microbiology Testing section ([FAQs #41 - 50](#)) for additional questions and answers on this topic.

10. 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?

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.

11. Do all states allow IQCP?

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 QC requirements defined in the CAP checklist requirements, CLIA regulations, and applicable state requirements, whichever is the most stringent.

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TESTS/INSTRUMENTS

12. Are there any test systems or instruments that are exempt from IQCP?

The CAP has not categorized any specific instruments or test systems as exempt from



IQCP.

The use of an IQCP is voluntary and there are specific eligibility criteria defined for use. If an IQCP is not implemented for eligible tests, laboratories must follow the minimum daily QC requirements and default CLIA regulations for daily QC of nonwaived testing, as defined in the 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.

13. 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).

14. If my instrument has a control process that uses liquid control materials on-board the instrument or within a test cartridge, or uses a device, such as an optical filter or electronic control simulator, do I need to implement an IQCP to meet daily QC requirements?

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 have a similar matrix to that of patient specimens, be treated in the same manner as patient specimens, and go through all elements of the analytic process as applicable. It must also be a different type of material or from a different lot number than used to calibrate the instrument (42CFR493.1256(d)(9)). Function checks, instrument/electronic checks, and procedural controls do not meet the definition of an external control material. Those types of checks only verify electronic components or detect function of the instrument and may only monitor a portion of the analytic process. Laboratories must carefully evaluate the control processes used to determine if they control the full analytic testing process.

If the control process 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. For on-board instrument controls that meet the above definition of an external control material, but vary in the preanalytic portion, such as with sampling of the control, an IQCP is not required. The laboratory can periodically verify proper sampling through proficiency testing, competency assessment, the use of other types of external control materials, and following processes defined in the manufacturer's instructions, as applicable.

15. If I perform tests where there are no external control materials available, do I need to implement an IQCP?

No, if no external control materials are available, the laboratory must establish its own procedures for detecting errors and monitoring test performance. An IQCP is not required, although the risk assessment process may aid a laboratory in identifying potential risk and developing an effective QC plan. Some examples of tests without external control materials include tests for cold agglutinins and for platelet function testing using methods in which normal donor samples are the only source for verifying the



system's performance. Laboratories must follow manufacturer's instructions for quality control at minimum.

16. 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 subspecialty areas (eg, coagulation, blood gases, microbiology). The QC requirements for non-waived testing, as written in the CAP checklists and CLIA regulations, must be followed if IQCP is not implemented.

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

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

18. Is an IQCP needed in flow cytometry for leukemia/lymphoma panel testing?

No. An individualized quality control plan (IQCP) is not required for leukemia/lymphoma immunophenotyping performed using flow cytometry. The Flow Cytometry Checklist requirement FLO.23737 defines the quality control requirements and the types of controls that may be used. As long as a laboratory has written guidelines defining criteria for acceptable performance of these controls and records of periodic performance, the CAP will consider the laboratory in compliance.

19. Is an IQCP needed for molecular-based testing performed by my laboratory?

The IQCP option is limited to test systems that employ an internal (electronic/procedural/built-in) quality control system. These are methods that would have previously qualified for the equivalent quality control (EQC) option. A limited number of molecular-based methods qualify for the IQCP option, namely those commonly used for molecular infectious disease testing and a limited number of genetics tests that employ disposable single-use cartridges. It includes the use of test systems that have the internal control processes that are used for daily QC in lieu of external controls.

The IQCP option is not available for other types of molecular-based testing, such as in situ hybridization (ISH), microarray, Sanger sequencing, and next generation sequencing under the CAP's accreditation programs. These include methods that do not have an internal (electronic/procedural/built-in) control system, but have specialized control processes and quality metrics to monitor the performance of the test. The quality control requirements for these methods are defined in the method specific sections of the applicable checklists. The control measures used must ensure accuracy and reliability of patient results and must follow manufacturer's instructions (as applicable), as well as the CAP Checklist requirements.

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

Prior to implementation of the CMS IQCP option, the CAP previously accepted the use



of internal control systems for daily QC for certain types of instruments and devices, as well as the microbiology exceptions involving media, identification systems, and susceptibility testing that were based on CLSI guidelines. Based on the CAP's experience with these methods, the CAP decided to allow laboratories to continue to use alternative quality control practices to detect errors in the testing process for these types of instruments/devices and testing processes.

The CAP has re-evaluated expanding its IQCP eligibility criteria but has decided not to make any changes at this time. The CAP will continue to re-evaluate its criteria as it gains more experience with IQCP.

21. Do I need to implement an IQCP for my blood bank antibody identification panels?

No, IQCP is not required for antibody panels used in the transfusion service laboratory. An antibody panel is considered a critical material and is subject to TRM.31241 for inspection and testing, as applicable, of new lots before use. This involves visual inspection of new lots and shipments for appropriate physical characteristics (e.g. no hemolysis) and quality control following manufacturer's instructions described in the product insert. If the manufacturer does not provide specific instructions for QC, the laboratory must define its own mechanisms to detect errors and monitor test performance. Because antibody panels are not used alone for identification of an antibody, laboratories typically have a variety of other control processes that are being used as part of the work-up, such as having specific rules for ruling in or ruling out antibodies based on panel reactions, correlating the results of the antibody screen to the antibody panel, and performing antigen typing on the patient to confirm the absence of the corresponding antigen. The control criteria used must be defined in the procedure.

22. 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.

23. If an instrument or device performs 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.

24. Can I add an additional test performed on the same instrument, an identical new or replacement instrument, or an additional test site onto an existing IQCP?

A laboratory may modify an existing IQCP to include additional tests performed on the same instrument, an identical new or replacement instrument, or additional test sites; however, there may be new or different risks not previously addressed by the existing risk assessment and quality control plan. The following actions should be taken:

- Review and modify the existing risk assessment to ensure that risks specific to the new test, instrument, or test site have been properly evaluated for each of the five components of IQCP (reagents, environment, specimen, test system, testing personnel) and the three phases of testing.



- Evaluate laboratory-specific data (historical or new) relating to the modification and include a summary of the evaluation with the risk assessment.
- Obtain laboratory director approval of the modifications to the quality control plan.
- Retain records of the risk assessment and changes to the quality control plan.
- Ensure that appropriate ongoing quality assessment processes are in place for the added test or testing site.
- Update the laboratory's List of Individualized Quality Control Plans form for inspection readiness.

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RISK ASSESSMENT

25. 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)

26. 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.

27. 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.

28. Do I have to perform all new studies to gather data/information for my risk assessment?

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.

29. How much in-house data is needed to show that the internal control process used by my instrument or device is sufficient? The 2014 checklist edition allowed my laboratory to perform a 20-consecutive day study to validate the use of my internal control for daily QC; can we do a 10-day study instead?

The time period over which the data from an in-house study is collected and the amount of data evaluated to assess the performance and stability of the test is dependent on the maximum interval that the laboratory selects for performing external quality control. The study must support the QC frequency and elements defined in the laboratory's quality control plan and include data representing, at a minimum, the maximum interval between runs of external quality control. The use of data from studies conducted over a period of time allows the laboratory to take into account variances in performing the test (eg, environmental changes, reagent stability, and different personnel). The laboratory may use historical data during the risk assessment for tests already in place.

30. 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.

31. Do I need to use a probability chart like the one described in the CLSI's EP-23A guideline when performing my risk assessment?

No. The CAP does not require the use of a probability chart when evaluating the risks identified. As stated in COM.50300 (Risk Assessment), the intended medical uses of the test and impact if inaccurate results are reported (clinical risk) need to be evaluated for the potential sources of error; however, the checklist requirement is not prescriptive on how this must be done. The CLSI's EP23-A guideline describes the use of the probability chart and many laboratories find this a useful tool in determining if the level of risk is acceptable. Other processes may be acceptable. It is the role of the laboratory director to confirm that the level of risk is acceptable prior to approving the quality control plan for an IQCP.

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QUALITY CONTROL PLAN DEVELOPMENT

32. What elements are required in the written quality control plan for a test with an IQCP?

The written quality control plan must include the following, at a minimum:

- The number, type (internal, electronic, external, etc.) and frequency of testing for QC and the criteria for acceptable performance
- Use of external QC with each new lot and shipment of reagents
- Laboratory director signature and date approving the plan prior to implementation (initial approval may not be delegated)



The data from the risk assessment must support the rationale for the quality control plan. The laboratory may not define a quality control plan that is less stringent than the manufacturer's instructions.

33. Can the quality control plan for my IQCP be included in the written procedure for my test instead of creating a separate plan?

Yes. The quality control plan may be part of a test procedure or be on a separate written plan, as long as the required components are included and the plan is signed and dated by the laboratory director and reapproved by the laboratory director or designee at least biennially.

34. In previous checklist editions, COM.50500 required external controls to be run at least every 31 days if an IQCP was in place. Why was this provision removed in the 2017 edition?

The CAP decided to remove the statement requiring external QC to be performed at least every 31 days based on experience that the CAP has gained through laboratory inspections. This change allowed laboratories more flexibility in designing their own quality control programs. Laboratories must continue to have risk assessment records demonstrating that the QC frequency defined in the laboratory's quality control plan is appropriate and supported by the in-house QC study. **The QC study data used in the risk assessment to assess performance and stability must cover the maximum interval between runs of external quality control.** In addition, external controls must be performed for each new lot and shipment and following manufacturer's instructions.

35. Is there a minimum number of levels of external controls that need to be run? If multiple devices are in use, can we run the external QC using a subset of devices?

The laboratory must define its control procedures based on its risk assessment. 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. The laboratory director is ultimately responsible for the control procedures and must approve the quality control plan before it is implemented. 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.

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

No. At a minimum, laboratories must follow all manufacturer instructions for internal and external quality control.

37. Do 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 error, 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.

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ONGOING IQCP ASSESSMENT

38. 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 on an ongoing basis for effectiveness and revised, as necessary. An example form is available on cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox that may be used for recording ongoing assessments of the IQCP (log in required).

39. In previous checklist editions, COM.50600 required IQCP reapproval at least annually. Why has this changed to biennial reapproval?

In prior checklist editions, the CAP took a more stringent approach than the CMS in this area to encourage laboratories to more closely evaluate effectiveness of the quality control plan that was implemented. Based on experience gained through laboratory inspections, the CAP decided to modify the frequency for reapproving the IQCP from annual to biennial to be more consistent with existing procedure review requirements.

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

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
- Ongoing assessment of the effectiveness of the IQCP.

Some of these items may already be included in the QM plan. The laboratory may consider including ongoing assessment of these items as quality indicators.

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MICROBIOLOGY TESTING

41. Do I need an IQCP for my microbiology testing?

The 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 (MIC.21540), the testing of new lots and shipments of certain tests described in MIC.21624 (eg, PYR, catalase, coagulase, latex coagulation tests, optochin, bacitracin, indole, and Streptococcal grouping reagents), or the QC of typing antisera described in MIC.21628 (e.g. Salmonella, Shigella).

Non-exempt media that is routinely checked per batch/lot/shipment for sterility, ability to support growth, and biochemical reactivity (if appropriate) would not need an IQCP, as the CLIA default QC is already being performed.

A tool, "IQCP in Microbiology", is available on cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox to help identify when an IQCP is needed for microbiology testing (log in required).

42. Can I still use the CLSI documents as a basis for my quality control criteria for antimicrobial susceptibility testing, identification systems (eg. streamlined QC), and media?

The CLSI documents (M2, M7, M22, M50, M100) may not be used as the sole criteria for establishing the control criteria. If the defined frequency of quality control is less stringent than the CAP checklist requirements and default CLIA quality control regulations, the laboratory must implement an IQCP. If the risk assessment performed justifies the quality control criteria as spelled out in the CLSI documents, it may be part of your quality control plan.

43. If there is a change in my antibiotic panel such as the addition of a new antibiotic, do I need to change my IQCP?

The validation data for the new antibiotic may be added to the existing risk assessment. Your IQCP should address this type of change and how it will be handled. For example, your IQCP may state that you will follow CLSI criteria for changes in susceptibility testing. It will be up to your director to determine whether the level of risk has changed and if a modification to the quality control plan is necessary.

44. Are specific tools available for developing an IQCP for microbiology tests or media?

Members from the CAP, the American Society of Microbiology (ASM), and the CLSI have worked collaboratively to produce templates that may be used to develop an IQCP for antimicrobial susceptibility testing, microbiology identification systems, and microbiology media. Templates and examples can be downloaded from cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox (log in required). Other resources are described in [FAQ #58](#).

45. Does my laboratory need to create a risk assessment for bacterial cultures?



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.

46. Do I need to perform a risk assessment on each type of media used or can I group them as agar/plated media and broth media?

The Microbiology Checklist requirement MIC.21240 contains the requirements for media QC and the use of an IQCP. Not all media has an equal risk for failure; therefore, if more than one type of media is included a single IQCP, the IQCP documents must clearly list all types of media covered. The risk assessment must show an evaluation of the risks for all types of media listed, 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.

47. Do I need an IQCP for blood cultures?

There are no CLIA regulations or CAP checklist requirements for daily QC on blood culture instruments. Laboratories must follow manufacturer's instructions for function checks and maintenance. However, a laboratory may implement an IQCP for blood culture media listed as exempt in the CLSI/NCCLS Standard M22-A3 if it wishes to accept quality control performed by the media manufacturer in lieu of performing its own end user quality control. Media quality control is addressed in the Microbiology Checklist requirements MIC.21240 and MIC.21420. A visual inspection is required and without an IQCP each new lot/shipment of blood culture media must be quality controlled.

48. If my laboratory (satellite lab) does microbiology culture set up and blood culture collection and sends the cultures to an affiliated laboratory for testing, do we need an IQCP for the media involved?

If the satellite laboratory is receiving the media from the laboratory that will be performing the testing, it is not responsible for the end user quality control of the media. The reference laboratory is responsible for quality control of the media, including the use of an IQCP, when appropriate. The satellite laboratory is responsible for a visual examination of the media as stated in MIC.21420 to confirm that the media was not adversely affected during transport. The satellite laboratory may also have an IQCP for the extent of their handling of the media.

Any laboratory that orders and receives media directly from the manufacturer is subject to quality control requirements for the media, including IQCP, as listed in MIC.21240 and MIC.21420, regardless of whether it performs testing on cultures or refers it to another laboratory.

If any culture result, such as findings of "no growth", are reported by the satellite laboratory, it is responsible for the quality control of the media involved, including the use of an IQCP when appropriate, regardless of whether it receives the media directly from the manufacturer or from another laboratory.

49. What can I use for historic data when developing an IQCP for media listed as



exempt in the CLSI/NCCLS Standard M22-A3 when I have not been doing end user quality control at my laboratory?

While there must be assessment of laboratory-specific data included in the risk assessment, the IQCP option is not prescriptive on the amount of data or evidence required for the risk assessment. It is the laboratory director's responsibility to determine the acceptable amount of data. The following are examples of historical sources of data that may be used as part of the risk assessment:

- Records from visual quality checks of media upon receipt
- Data regarding transport and storage conditions of media
- Problem logs
- Manufacturer's quality certificates.

There is an example of an IQCP for microbiology media available on the CAP website that was developed in collaboration by members of the CAP, ASM, and CLSI that may provide additional guidance. This example along with other microbiology tools can be found on cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox (log in required).

50. Is MALDI-TOF eligible for IQCP?

Currently, MALDI-TOF instruments do not meet the CAP's IQCP eligibility criteria because they lack an internal control process. Laboratories must follow the QC requirements as defined in the Microbiology Checklist (MIC.16605 – Mass Spectrometer Controls) and no less than what the manufacturer requires.

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RECORD RETENTION

51. 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).

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CAP INSPECTIONS

52. What happens if my laboratory has been performing external QC at a reduced QC frequency without an approved IQCP?

If the laboratory does not have an IQCP in place and has not been performing external quality control at the frequency required in the default CLIA regulations and CAP checklist requirements, the laboratory must:

- Take immediate action to begin performing external quality control at the frequency defined in the default CLIA regulations and CAP checklist requirements.
- Perform and record a lookback of testing performed during the period without appropriate quality control, including notifications to physicians if the lookback identifies problems with the quality of the results.



- Develop and implement an IQCP if the laboratory wishes to reduce the frequency of external QC.

If the laboratory is cited with a deficiency relating to reduced QC performance and the lack of an IQCP, the laboratory will have 30 days to respond to the deficiency with its corrective actions. It is possible that there will be citations against the director for lack of director oversight if the appropriate quality control is not being performed and abbreviated quality control has been in use.

53. How is IQCP inspected?

Inspectors look for compliance with the CAP checklists provided for inspection.

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

- **Risk assessment**, including evaluation of all of the following:
 - All five required elements (Reagents, Environment, Specimen, Test System, Testing Personnel)
 - All phases of testing: pre-analytic, analytic, and post-analytic
 - Data from the laboratory's own environment, instrument/equipment performance, and testing personnel
 - All variations in test performance (eg, multiple test sites, devices, types of testing personnel)
- 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.
- **Approval** of the written IQCP by the laboratory director prior to implementation (signed and dated)
- Ongoing **quality assessment** of errors, QC failures, and complaints, including the need to reassess the risk assessment and quality control plan
- **Biennial reapproval** of each IQCP
- Use of the CAP **List of Individualized Quality Control Plans form**

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.

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FORMS

54. Where can I find the IQCP form mentioned in the All Common Checklist requirement COM.50200 (List of Individualized Quality Control Plans)?

The Individualized Quality Control Plan List form and instructions can be found on cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox (log in required)

55. Do I need to submit the List of Individualized Quality Control Plans form to the CAP?

No, the form is not submitted to the CAP unless specifically requested. The form must be available to inspectors at the time of inspection; it may also be requested by the inspection team ahead of time. The form should be updated between inspections to ensure readiness for inspection.

56. Do I need to make changes to the IQCP form if my laboratory modifies an existing



IQCP, such as adding tests or test sites?

Yes. The form needs to be updated to ensure inspection readiness and to provide inspectors with accurate information. Changes can be noted directly on the IQCP Form indicating what was changed and the date changes were made.

57. Am I still required to use the CAP List of Individualized Quality Control Plans form if I used a software program for the development of my IQCP?

Yes. If one or more IQCPs are in use, laboratories must complete the CAP's List of Individualized Quality Control Plans form and provide a copy to the inspection team during the laboratory's next on-site inspection.

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OTHER RESOURCES

58. Where can I find other sources of information on IQCP?

The CAP website has a variety of information available on cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox (log in required). The CAP checklists are also a valuable resource accessible by logging into e-LAB Solutions Suite.

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 IQCP Resources:

All CAP IQCP resources may be found on cap.org through e-LAB Solutions Suite under Checklist Resources, IQCP Toolbox (log in required).

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 guidance and brochures](#)
- [CDC CLIA IQCP Resources](#)
- Manufacturer tools, if available

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