Antimicrobial Susceptibility Testing (AST) Individualized Quality Control Plan (IQCP) Questions and Answers

Updates and changes are noted in red font below.

AST Test System

Q. What constitutes a "test system"?

A. Test System means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results. (Note: EP-23A uses the terminology "measuring system" for test system)

Source of Answer: CLIA 493.2 and CLSI document EP-23A

Q. When performing AST and identification on a commercial automated MIC system, do you need a separate IQCP for the AST component vs. the ID component?

A. CMS is not prescriptive on this topic. It is at the discretion of the laboratory director whether or not to have separate IQCPs for AST and identification methods done on the same instrument.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. Is it acceptable to develop one IQCP to address both MIC and disk diffusion testing?

A. No. MIC and disk diffusion tests represent unique test systems despite the fact that several steps are common to each of these AST systems. Common risk assessments and risk-mitigation actions may be shared for common elements of the test systems, but separate IQCPs are required.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. We have both a MicroScan and a Vitek 2 instrument. Can we do one AST IQCP for both?

A. No. While MicroScan and Vitek may be similar procedures, they are different make and model. You would need one IQCP for MicroScan and another IQCP for Vitek 2 since they are different instruments with differing potential risks.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. We have three Vitek instruments in our laboratory. Can we do a single IQCP for all three?

A. If laboratories have multiple identical devices, one IQCP can be developed for the test system taking into consideration any unique environment or testing personnel, etc. However, there must be documentation that each instrument had a separate verification process at the time it was put into use. If the instruments are in different locations in the healthcare facility but under the same CLIA number, certain elements of the risk assessment portion of the QCP/IQCP must be developed for each one; alternatively, a separate IQCP may be performed for each of the instruments. If, however, the instruments are under different CLIA numbers, separate IQCPs must be performed.

Source of Answer: CMS letter Ref: S&C: 13-54-CLIA, Aug. 16, 2013. FAQs.

Specimen

Q. For susceptibility testing, what is the "specimen" evaluated in the risk assessment? Is it the primary clinical specimen or the organism isolated in culture?

A. CMS is not prescriptive on this topic. The specimen must be addressed; however, it is up to the laboratory director to determine what constitutes the specimen for an AST IQCP. The ASM/CLSI/CAP template encompasses the entire testing process, and (by implication) considers the primary clinical specimen as the 'specimen' in the AST IQCP.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

QC Frequency

Q. Will IQCP reduce the amount of QC testing that I have to perform with my laboratory testing?

A. It is possible that your IQCP will demonstrate that less QC than previously performed may be acceptable for your AST system. However, appropriate documentation must be provided to justify any QC testing schedule other than the CLIA-mandated daily schedule (each day of patient testing or more frequently if specified by the manufacturer). For many laboratories, historical records will likely justify your current QC testing schedule and additional data would be required to support a reduced QC testing schedule. If a laboratory wishes to perform daily QC, no IQCP is required.

Source of Answer: CMS letter Ref: S&C: 13-54-CLIA, Aug. 16, 2013. FAQs.

Q. What is the minimum amount of QC testing allowed with AST IQCP?

A. CMS does not set a minimum QC requirement. QC cannot be less than that recommended by the manufacturer, and must be supported by the risk assessment and QC data. Your accrediting organization may have more stringent criteria.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

General

Q. Can I use CLSI EP-23A "Laboratory Quality Control Based on Risk Management" (2011) to prepare my IQCP?

A. CMS guidelines are based on the general principles found in EP23-A. It may be helpful to review CMS IQCP guidelines and ensure that your laboratory QCP is based on risk management. The CMS IQCP was based on principles contained in EP23-A, but the two are not 100 percent identical. EP-23A would be a useful component of documentation of an IQCP but is not itself sufficient. A laboratory must supply local data.

Source of Answer: CLSI/CAP/ASM Clinical Microbiology IQCP WG

Q. Who is qualified to prepare the IQCP?

A. The laboratory director (individual whose name is on the CLIA certificate) has the ultimate responsibility to review, sign and date the IQCP. The laboratory director may assign, in writing, specific duties for the IQCP to qualified individuals.

Source of Answer: CLIA IQCP Brochure #13 Nov. 2014

Q. Does the risk assessment need to be done with a "Fishbone" type diagram?

A. No. CMS does not mandate any specific method for performing the risk assessment. There are many methods available for risk analysis. The ASM/CLSI/CAP template uses a tabular format.

Source of Answer: CMS letter Ref: S&C: 13-54-CLIA, Aug. 16, 2013. FAQs.

Q. What if the inspector does not agree with the IQCP approved by the laboratory director?

A. Surveyors will use the Outcome Oriented Survey Process for compliance. This means that he/she will review your IQCP to determine if your risk assessment includes all of the requirements, if the identified risks were evaluated, if the IQCP includes any risk(s) that the laboratory director has determined needs to be mitigated, and that quality assessment is occurring and ongoing. If these requirements are not met, the laboratory may be cited for deficiencies. If laboratory staff believe the decisions during the inspection were in error, they should utilize the appeal process of the inspecting agency.

Source of Answer: CMS letter Ref: S&C: 13-54-CLIA, Aug. 16, 2013. FAQs.

Q. What is the timeline for implementation of IQCP?

A. Since the IQCP Education and Transition Period ended on December 31, 2015, laboratories have had two options; 1) follow default CLIA QC regulations, or 2) implement IQCP by January 1, 2016. For new tests, ensure that your IQCP is fully approved before transitioning away from performing QC each day of patient testing.

Source of Answer: CMS letter Ref: S&C: 13-54-CLIA, Aug. 16, 2013.

Q. How often does the IQCP need to be reviewed or revised?

A. Whenever there is an indication of failure of one or more components of the system (e.g., QC issues or issues related to physician concerns/complaints), relevant portions of the IQCP should be reviewed and revised accordingly. If no changes or updates have been made to the system that might result in revision to the IQCP, the laboratory director or designee should reapprove the IQCP at least biennially.

Source of Answer: CDC IQCP Individualized Quality Control Plan. Developing an IQCP A Step-by-Step Guide, Page 7. Accessed April 6, 2021, and CAP COM.50600 (rev. 9/17/2019).