Antimicrobial Susceptibility Testing IQCP Questions and Answers

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.

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 located in different locations in the healthcare facility, the QCP must be developed for each one.

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.

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. 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.

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.

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.

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.

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 QCP 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.

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

Q. When is the deadline for implementation of IQCP?

A. After the IQCP Education and Transition Period ends on December 31, 2015, laboratories have two options; 1) follow CLIA regulations, or 2) implement IQCP by January 1, 2016.

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