



Introduction to Antimicrobial Susceptibility Testing (AST) Individualized Quality Control Plan (IQCP)

Updates and changes are noted in *red font* below.

The “Individualized Quality Control Plan” (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) policy that **became** effective as an alternative QC option for all laboratory tests on January 1, 2016. What does this mean for antimicrobial susceptibility testing (AST) in your laboratory?

- You can either develop an IQCP or perform daily QC as described in current CLIA regulations.
- It is no longer acceptable for your laboratory to follow CLSI AST guidelines alone for converting from daily to weekly testing of QC strains.
- Your laboratory is required to develop an IQCP (or perform CLIA mandated QC) regardless of when weekly QC of AST was implemented in your laboratory.
- As you develop an AST IQCP for your laboratory, you must take into consideration all the activities that are in place to ensure quality AST results for your patients.
- Your IQCP may demonstrate that daily QC is not necessary and less frequent QC (e.g., weekly QC) is sufficient to ensure quality AST results for your patients.
- Although there are certain elements that must be included in each IQCP as defined by CMS (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP), CMS is not prescriptive and each laboratory director must customize their own AST IQCP according to test method, patient population, environment, and personnel competency.
- The QCP (Quality Control Plan) developed in your IQCP may not be less than that required by the manufacturer.

Representatives from American Society for Microbiology (ASM), College of American Pathologists (CAP), and Clinical and Laboratory Standards Institute (CLSI) have jointly prepared materials you can use as a guide in development of an AST IQCP in your laboratory for a commercial automated AST system and **disk diffusion AST system**. Specifically, the following are available ASM’s website:

- **Word document templates** that describe the components that should be included in an IQCP for a commercial MIC AST system and for disk diffusion
- Example of **completed risk assessments for IQCP**
- Listing of Q&A’s

Additional materials **have been** developed to help you address IQCP for other tests in your clinical microbiology laboratory ([ASM/CLSI/CAP templates](#)). Please be sure and check the CMS website (link shown above) to obtain additional information about the IQCP program.

Please note that a ‘frequency of occurrence’ table and a ‘severity of harm’ table are included in these materials. Although it is not mandated by CMS, once the laboratory has identified sources of potential failures, it may be helpful to define and include a ‘frequency of occurrence’ table and a ‘severity of harm’ table to link the process of the Risk Assessment to the Quality Control Plan. Including this process will address what CMS does mandate, “the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error.”

Reference: CMS letter Ref: S&C: 13-54-CLIA August 16, 2013 letter