The information listed below contains excerpts from the CAP’s July 2015 edition for the CAP Laboratory Accreditation Program checklists, a copyrighted work of the CAP, relating to the individualized quality control plan (IQCP) option. The CAP is providing this document as a tool to assist laboratories in developing an IQCP. Please refer to the published checklists for a complete listing of all of the CAP accreditation requirements.

**ALL COMMON CHECKLIST**

**REVISED**       07/28/2015

**COM.04200** Instrument/Equipment Record Review Phase II

**REVISED**       07/28/2015

**COM.30625** Function Check Tolerance Limits Phase II

**INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)**

This section applies to laboratories using an IQCP approved by the laboratory director for nonwaived testing to reduce external control analysis to a frequency less than the limits defined in the CLIA regulations and CAP checklists. Note that development of an IQCP only impacts quality control requirements. All other checklist requirements remain unchanged and applicable.
This section does not apply to tests where an IQCP was implemented, but the type and frequency of quality control defined in the plan already meets or exceeds minimum quality control requirements defined in the CLIA regulations and CAP checklist requirements. Quality control requirements in other sections of the All Common Checklist and discipline-specific checklists will be used for inspection in those situations.

If a laboratory is located in a state that does not accept IQCP as an option for reducing the frequency of external quality control, the laboratory must follow the state regulations and perform external daily quality control following the frequency defined in the state regulations and CAP checklists.

Eligibility for use of an IQCP is limited to testing meeting all of the following criteria:

- Nonwaived tests that employ an internal (electronic/procedural/built-in) quality control system
  - Exception: Microbiology media and reagents used for microbial identification and susceptibility testing may implement an IQCP as defined in the checklist
- Tests performed in specialties other than Anatomic Pathology and Cytopathology
  - Exception: If an Anatomic Pathology or Cytopathology test can be assigned to a different CMS subspecialty, it may qualify (e.g. FISH testing may be classified as either a histopathology or a cytogenetics test).

Laboratories may develop their own model for designing an IQCP or use the Clinical and Laboratory Standards Institute (CLSI) Guideline EP23-A, the Centers for Medicare and Medicaid Services guidance, a manufacturer protocol, or use other commercially available products.

NOTE: A laboratory may not implement an IQCP that allows for quality control to be performed less frequently than indicated in the manufacturer's instructions. The components of the quality control plan must meet regulatory and CAP accreditation requirements and be in compliance with the manufacturer instructions and recommendations, at minimum.

The following table contains information on quality control related requirements that are eligible for IQCP under CAP’s accreditation program and the related CLIA regulations (Title 42CFR):

<table>
<thead>
<tr>
<th>QC Requirement</th>
<th>Related CLIA Regulation (Title 42 in the CFR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative testing includes two levels of quality control at different concentrations at least daily</td>
<td>493.1256(d)(3)(i)</td>
</tr>
<tr>
<td>Qualitative testing includes positive and negative controls at least daily</td>
<td>493.1256(d)(3)(ii)</td>
</tr>
<tr>
<td>Semi-quantitative testing with graded or titered results include a control material of graded or titered reactivity at least daily</td>
<td>493.1256(d)(iii)</td>
</tr>
<tr>
<td>Tests with an extraction phase include two levels of quality control, one of which goes through the extraction phase at least daily</td>
<td>493.1256(d)(iv)</td>
</tr>
<tr>
<td>Tests with molecular amplification procedures include two control materials and a control material capable of detecting inhibition, as applicable</td>
<td>493.1256(d)(3)(v)</td>
</tr>
<tr>
<td>Fluorescent stains are checked for positive and negative reactivity each time of use - Fluorescent in situ hybridization only</td>
<td>493.1256(e)(3)</td>
</tr>
<tr>
<td>Each new lot and shipment of reagents, disks, stains, antisera, and identification systems (systems using two or more substrates or two or more reagents, or a combination) are checked for positive and negative reactivity, as well as graded reactivity, if applicable</td>
<td>493.1256(e)(1)</td>
</tr>
<tr>
<td>Each batch of commercially prepared media is checked for sterility, if sterility is required for testing, before or concurrent with initial use</td>
<td>493.1256(e)(4)(i)</td>
</tr>
</tbody>
</table>
Each batch of commercially prepared media is checked for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response, before or concurrent with initial use.

Antimicrobial susceptibility tests include appropriate control organism(s) to check the procedure each day tests are performed.

Antifungal susceptibility tests include appropriate control organism(s) to check the procedure each day tests are performed.

Blood gas testing includes one control (combination of low and high values used) every eight hours of patient testing and one control sample each time a specimen is tested unless the method is auto-calibrated every 30 minutes.

Automated coagulation testing includes two levels of controls every 8 hours of patient testing and when a reagent is changed.

Inspector Instructions:

- Policies and procedures for the implementation of an IQCP
- Sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years for the following:
  - Risk assessment, including laboratory data and summary of findings
  - Manufacturer's product inserts and published data
  - Signed quality control plan defining all aspects monitored
  - Ongoing quality assessment monitoring records for QC, instrument/equipment maintenance and function checks, complaints, errors, and corrective actions
  - Reassessment of quality control plan at least annually

If an IQCP is in use, the laboratory is required to complete the following forms provided by the CAP and provide a copy to the inspector:

- List of Individualized Quality Control Plans by Instrument/Device/Test - identifies all tests, instruments and devices using an IQCP
- Individualized Quality Control Plan Summary - provides key information on implementation and monitoring of the IQCP

Use the completed forms to identify an appropriate sampling of records to review.

Sampling of IQCP records to include: 1) a mix of manual and automated tests using an IQCP in the last two years; 2) a mix of tests using an IQCP where there are variations in the testing environment, personnel, multiple testing devices, etc.; and 3) a mix of tests using an IQCP that have had recurring problems with proficiency testing, quality control, instrument failure, errors, or physician complaints.

- What sources of information are used to perform a risk assessment prior to IQCP implementation?
- What steps were taken to ensure that tests already in place with internal quality control processes for daily QC (e.g. equivalent quality control) are in compliance with the IQCP requirements?
- How is the ongoing assessment of the IQCP quality control plan performed?
- How are physician complaints about the validity of test results for tests using an IQCP handled?
- What is the process to review errors for tests using an IQCP?
- Have there been any adverse patient events related to a test using an IQCP?
**NEW**       07/28/2015
COM.50200  IQCP Test List/Summary  Phase II

The laboratory has identified all tests using an IQCP and completed the CAP's forms for laboratories using an individualized quality control plan.

NOTE: The CAP requires the completion of the following forms if an IQCP is in use by the laboratory: List of Individualized Quality Control Plans and the Individualized Quality Control Plan Summary. The forms may be downloaded from the CAP website (http://www.cap.org) through e-LAB Solutions Suite.

The use of the forms is required, even if standardized forms and templates are used by the laboratory. The laboratory is responsible for maintaining the accuracy of the data on the form and for providing a current copy to the inspector during an on-site CAP inspection. The form is intended to be used as an inspector tool and does not meet the checklist requirements for documenting the IQCP risk assessment or quality control plan.

REFERENCES

**NEW**       07/28/2015
COM.50300  Risk Assessment  Phase II

The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include all of the following:

- Preanalytic, analytic, and postanalytic phases of the testing process
- Intended medical uses of the test and impact if inaccurate results are reported (clinical risk)
- Components of the tests including reagents, environment, specimen, testing personnel, and test system
- Variations in the components based on use of the tests (e.g. use in different environments, by different personnel, or multiple identical devices)
- Data from the laboratory’s own environment, instrument/equipment performance, and testing personnel
- Manufacturer’s instructions and recommendations

NOTE: The risk assessment must include a process to identify the sources of potential failures and errors for a testing process, and evaluate frequency and impact
of those failures and sources of error.

The laboratory director must consider the laboratory’s clinical and legal responsibilities for providing accurate and reliable patient test results. Published data and information may be used to supplement the risk assessment, but is not a substitute for the laboratory’s own studies and evaluation. The laboratory must involve a representative sample of testing personnel in the process of conducting the risk assessment. It is not necessary for all personnel to be involved.

The risk assessment for laboratories with multiple identical devices must show that an evaluation was performed if there are differences in testing personnel or environments where testing is performed, with customization of the quality control plan, as needed.

The QC study performed to assess the performance and stability of the tests must support the QC frequency and elements defined in the laboratory's quality control plan. The study must include data representing, at a minimum the maximum interval between runs of external quality control. The laboratory may use historical data during the risk assessment for tests already in place.

For affiliated laboratories (e.g. systems) with integrated procedures, each accredited laboratory must have its own IQCP approved by the laboratory director. There must be records demonstrating that risks specific to the site were evaluated involving a representative sample of local testing personnel to conduct the risk assessment and that laboratory-specific QC data were used in the study to support the defined frequency of quality control. Laboratories may use data from other sites to supplement risk assessments and to support their findings.

REFERENCES

**NEW** 07/28/2015
COM.50400 Quality Control Plan Approval Phase II

The IQCP includes a written quality control plan approved by the laboratory director prior to implementation.

NOTE: The quality control plan may be part of a test procedure or be a separate written plan. As an efficiency, a single plan may address multiple tests performed on one device. A separate, quality control plan approved by the laboratory director must be in place for each laboratory with a separate CAP and CLIA number.

REFERENCES
The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable:

- The number, type (external and internal quality control systems), and frequency of quality control
- Criteria for acceptable performance
- Monitoring of the testing environment and reagents
- Specimen quality
- Instrument calibration, maintenance, and function checks
- Training and competency of testing personnel
- Provisions for multiple identical devices and variation for uses covered under one IQCP

NOTE: The components of the quality control plan must meet regulatory and CAP accreditation requirements and be in compliance with the manufacturer instructions and recommendations, at minimum. The quality control plan must control the quality of the test process and ensure accurate and reliable test results.

External control material samples must be analyzed at least every 31 days and with new lots and shipments of reagents or more frequently if indicated in the manufacturer’s instructions.

REFERENCES

Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes the following:

- Review of quality control and instrument/equipment maintenance and function check data at least monthly
- Evaluation of errors relating to preanalytic, analytic and post analytic phases of the testing process
- Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing, and
- Evaluation of corrective actions taken if problems are identified
- Reapproval of the quality control plan by the laboratory director or designee at least annually

NOTE: If ongoing assessments identify failures in one or more components of the quality control plan, the laboratory must investigate the cause and consider if
modifications are needed to the quality control plan to mitigate potential risk.

REFERENCES

MICROBIOLOGY CHECKLIST

**REVISED** 07/28/2015
MIC.11018 QC Corrective Action

There are records of corrective action when control results exceed defined acceptability limits.

NOTE: Patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results.

The corrective action for tests that have an Individualized Quality Control Plan (IQCP) approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified (e.g. trending for repeat failures, etc.).

REFERENCES

**REVISED** 07/28/2015
MIC.11020 Monthly QC Review

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

NOTE: The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (e.g. trending for repeat failures, etc.).

Evidence of Compliance:
✓ Records of QC review including follow-up for outliers, trends or omissions
For nonwaived direct antigen tests on patient specimens, positive and negative controls are tested and recorded at least daily, or more frequently if specified in the manufacturer's instructions, laboratory procedure, or CAP Checklist.

NOTE: This requirement pertains to nonwaived tests with a protein, enzyme, or toxin which acts as an antigen. Examples include, but are not limited to: Group A Streptococcus antigen, C. difficile toxin, fecal lactoferrin and immunochemical occult blood tests. For panels or batteries, controls must be employed for each antigen sought in patient specimens.

If an internal quality control process (e.g. electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director to address the use of the alternative control system. Please refer to the individualized Quality Control Plan section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

For each test system that requires an antigen extraction phase, as defined by the manufacturer, the system must be checked with an appropriate positive control that will detect problems in the extraction process. If an IQCP is implemented for the test, the laboratory's quality control plan must define how the extraction phase will be monitored, as applicable, based on the risk assessment performed by the laboratory and the manufacturer's instructions.

Evidence of Compliance:
✓ Written QC procedures AND
✓ Records of QC results including external and electronic/procedural/built-in control systems AND
✓ Manufacturer product insert or manual

REFERENCES

An appropriate sample from each lot and shipment of each purchased medium is checked before or concurrent with initial use for each of the following:

1. Sterility
2. Ability to support growth by means of stock cultures or by parallel testing with previous lots and shipments
3. Biochemical reactivity, where appropriate

NOTE: The laboratory must have records showing that all media are sterile, able to support growth, and are appropriately reactive biochemically. This will ordinarily require that the laboratory maintain a stock of reference organisms and test the media before or concurrent with use.

An individualized quality control plan (IQCP), including all required elements of IQCP, may be implemented by the laboratory to allow for the acceptance of the quality control performed by the media supplier for media listed as "exempt" in the CLSI/NCCLS Standard M22-A3, Quality Control for Commercially Prepared
Microbiological Culture Media. The media supplier's records must be maintained and show that the QC performed meets the CLSI/NCCLS standard and checklist requirements. Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP. End user quality control must be performed on the following, regardless of the exempt status:

- Campylobacter agar;
- Chocolate agar;
- Media for the selective isolation of pathogenic Neisseria;
- Other media not listed on Table 2 of M22-A3 (e.g. dermatophyte test medium);
- Media used for the isolation of parasites, viruses, Mycoplasmas, Chlamydia;
- Mueller-Hinton media used for antimicrobial susceptibility tests; or
- Media commercially prepared and packaged as a unit or system consisting of two or more different substrates, primarily used for microbial identification.

Laboratories receiving media from media suppliers must have a copy of the CLSI/NCCLS Standard M22-A3 as a reference source. The media supplier must provide records showing that the quality control activities meet the CLSI/NCCLS Standard M22-A3, or are otherwise equivalent. The laboratory director may wish to have a signed contractual arrangement with his/her selected media supplier to cover all expected quality control and documentation thereof.

Laboratories using exempt media that have not implemented an IQCP or are using media that do not qualify for an IQCP must continue to test each lot and shipment of media and maintain records of such testing.

Evidence of Compliance:

- Written procedure for QC on new lot numbers or shipments of purchased medium AND
- Individualized quality control plan for the media approved by the laboratory director, as applicable AND
- Records of media quality control

REFERENCES

streamlined QC is used, but in no case for less than two years.

For user-developed identification systems, commercial systems for which a streamlined QC process has not been developed, or any commercial system whose use is altered in any way from the manufacturer's instructions, all biochemical tests in each new lot number and shipment must be evaluated with known positive and negative control organisms, to assure appropriate reactivity.

Any test (e.g. oxidase test) required for interpretation of MIS results that is not part of the MIS cannot be included in MIS streamlined QC procedures. QC requirements for such tests, including the use of positive and negative controls for each new batch, lot number and shipment are given in MIC.21624 (Reagent QC).

Evidence of Compliance:
✓ Written procedure for QC on new lot numbers or shipments of reagents for each MIS
AND
✓ Individualized quality control plan for the MIS approved by the laboratory director, as applicable
AND
✓ Records of MIS quality control

REFERENCES

**REVISED** 07/28/2015
MIC.21910 Susceptibility Test QC Frequency Phase II

For antimicrobial susceptibility testing by either disk or gradient diffusion strips or broth dilution (MIC) methods, quality control organisms are tested with each new lot number or shipment of antimicrobials or media, and each day the test is performed thereafter.

NOTE: The frequency of QC testing may be reduced to weekly (including the testing of new lots or batches of antimicrobials or media) if the laboratory director approves the use of an individualized quality control plan (IQCP), including all required elements of IQCP, and the laboratory has records of satisfactory performance with daily QC tests as suggested by CLSI Standards. Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP. For this purpose, satisfactory performance is defined as follows:

1. There are records that all QC organisms were tested for 20 or 30 consecutive test days, and
2. For each drug/microorganism combination, no more than 1 of 20 or 3 of the 30 values (zone diameter or MICs) may be outside the accepted QC ranges. These accepted QC ranges may be those defined in the current CLSI guidelines or commercial device instructions or may be established by the laboratory

Or

1. There are records that all QC organisms were tested in triplicate (using separate inoculum suspensions) for 5 consecutive test days
2. For each drug/microorganism combination, no more than 1 of the 15
values (zone diameter or MICs) may be outside the accepted QC range

3. If 2 or 3 values are outside the accepted QC range during testing of 15 replicates, daily QC testing must be continued and performed in triplicate (using separate inoculum suspensions) for another 5 consecutive test days

4. For each drug/microorganism combination, no more than 4 of the 30 values (zone diameter or MICs) may be outside the accepted QC range

When a result is outside the accepted QC range during weekly QC testing, refer to the most recent CLSI Standards for the required corrective action.

If the laboratory performs QC on antimicrobial screening tests as defined by the CLSI Standard and manufacturer instructions do not require QC on each day the test is performed, the laboratory must have an IQCP that meets all requirements defined in the All Common Checklist.

Evidence of Compliance:
✓ Records of susceptibility QC results at defined frequency and meeting defined acceptability criteria

REFERENCES


MYCOBACTERIOLOGY

MIC.31380 Media QC - Purchased

An appropriate sample from each lot and shipment of each purchased medium is checked before or concurrent with initial use for each of the following:

1. Sterility
2. Ability to support growth by means of stock cultures or by parallel testing with previous lots and shipments
3. Biochemical reactivity, where appropriate

NOTE: The laboratory must have records showing that all media are sterile, able to support growth, and are appropriately reactive biochemically. This will ordinarily require that the laboratory maintain a stock of reference organisms and test the media before or concurrent with use. End user quality control must be performed on media not listed on Table 2 of M22-A3 (e.g. dermatophyte test medium), regardless of the exempt status.

This checklist requirement does not apply to commercially prepared additives that are reconstituted when added to mycobacterial media.

An individualized quality control plan (IQCP), including all required elements of IQCP, may be implemented by the laboratory to allow for the acceptance of the quality control performed by the media supplier for media listed as “exempt” in the CLSI/NCCLS Standard M22-A3, Quality Control for Commercially Prepared...
Microbiological Culture Media. The media supplier's records must be maintained and show that the QC performed meets the CLSI/NCCLS standard and checklist requirements. Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP.

Laboratories receiving media from media suppliers must have a copy of the CLSI/NCCLS Standard M22-A3 as a reference source. The media supplier must provide records showing that the quality control activities meet the CLSI/NCCLS Standard M22-A3, or are otherwise equivalent. The laboratory director may wish to have a signed contractual arrangement with his/her selected media supplier to cover all expected quality control and documentation thereof.

Laboratories using exempt media that have not implemented an IQCP or are using media that do not qualify for an IQCP must continue to test each lot and shipment of media and maintain records of such testing.

Evidence of Compliance:
✓ Written procedure for QC on new lot numbers or shipments of purchased medium AND
✓ Individualized quality control plan for the media approved by the laboratory director, as applicable AND
✓ Records of media quality control

REFERENCES

MYCOLOGY

**REVISED** 07/28/2015
MIC.41200 Media QC - Purchased Phase II

An appropriate sample from each lot and shipment of each purchased medium is checked before or concurrent with initial use for each of the following:

1. Sterility
2. Ability to support growth by means of stock cultures or by parallel testing with previous lots and shipments
3. Biochemical reactivity, where appropriate

NOTE: The laboratory must have records showing that all media used are sterile, able to support growth, and are appropriately reactive biochemically. This will ordinarily require that the laboratory maintain a stock of reference organisms and test the media before or concurrent with use. End user quality control must be performed on media not listed on Table 2 of M22-A3 (e.g. dermatophyte test medium), regardless of the exempt status.

An individualized quality control plan (IQCP), including all required elements of IQCP, may be implemented by the laboratory to allow for the acceptance of the quality control performed by the media supplier for media listed as "exempt" in the CLSI/NCCLS Standard M22-A3, Quality Control for Commercially Prepared Microbiological Culture Media. The media supplier's records must be maintained and show that the QC performed meets the CLSI/NCCLS standard and checklist requirements. Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP.

Laboratories receiving media from media suppliers must have a copy of the
CLSI/NCCLS Standard M22-A3 as a reference source. The media supplier must provide records showing that the quality control activities meet the CLSI/NCCLS Standard M22-A3, or are otherwise equivalent. The laboratory director may wish to have a signed contractual arrangement with his/her selected media supplier to cover all expected quality control and documentation thereof.

Laboratories using exempt media that have not implemented an IQCP or are using media that do not qualify for an IQCP must continue to test each lot and shipment of media and maintain records of such testing.

Evidence of Compliance:
✓ Written procedure for QC on new lot numbers and shipments of medium **AND**
✓ Records of media QC **AND**
✓ Individualized quality control plan for the media approved by the laboratory director, as applicable

REFERENCES


**NEW** 07/28/2015

Susceptibility Testing QC Frequency Phase II

For antifungal susceptibility testing by either disk, strip or MIC methods, quality control organisms are tested with each new lot number and/or shipment and each day the test is performed thereafter.

NOTE: The frequency of QC testing may be reduced to weekly (and whenever any reagent component of the test is changed) if the laboratory director approves the use of an individualized quality control plan (IQCP), including all required elements of IQCP, and the laboratory has records of satisfactory performance with daily QC tests as suggested by CLSI Standards and Guidelines (M27, M44, and M38). Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP.

Evidence of Compliance:
✓ Records of susceptibility QC results recorded at defined frequency and meeting defined acceptability criteria

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services, Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24):[42CFR493.1263(b)(2)].


MOLECULAR MICROBIOLOGY

Daily QC - Molecular-based Testing Phase II

Controls are run at least daily, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, for molecular-based
quantitative and qualitative tests.

NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed.

Controls must be run prior to reporting patient results, after a change of analytically critical reagents, major preventive maintenance, or change of a critical instrument component.

Daily quality control must be run as follows:
- Quantitative tests - three controls at least daily, including a negative control, a low-positive control and a high-positive control, except where a specific exception is given in this checklist
- Qualitative tests - a positive and negative control at least daily

Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical or analytical criteria.

If an internal quality control process (e.g. electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director to address the use of the alternative control system. Please refer to the Individualized Quality Control Plan section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

Controls must assess adequacy of extraction and amplification, e.g. positive and negative controls that go through the entire testing process.
- Laboratories performing tests using an IQCP approved by the laboratory director may define their own quality control procedures to monitor the extraction and amplification phases based on the risk assessment performed by the laboratory and the manufacturer’s instructions.
- If an IQCP is not in place that monitors the extraction and amplification processes, the following must be followed:
  1. An extraction control must be used for each run (positive controls fulfill this requirement).
  2. If the samples from an extraction batch are tested over multiple amplification runs, each amplification run (as defined by the laboratory) must have its own amplification control. A single extraction control need only be tested in one of the amplification runs.
  3. If samples from multiple extraction batches are tested in a single amplification run, each extraction batch needs an extraction control. All extraction controls must be tested in a single amplification run. A single amplification control is sufficient.

Evidence of Compliance:
✓ Written QC procedures
✓ Records of QC results including external and electronic/procedural/built-in control systems AND
✓ Manufacturer product insert or manual

REFERENCES