# VALIDATION AND CALIBRATION (DIA)

## Inspector Instructions:

| | |
|---|---|
|  | • Sampling of validation and calibration policies and procedures<br>• Sampling of validation/calibration records |
|  | • What is your course of action if calibration is unacceptable? |

**BAP.05410 Preanalytic Testing Phase Validation** **Phase II**

**There are records showing that the preanalytic phase of the test system has been validated for each assay, including fixation and processing.**

*NOTE: Applicable requirements under the "Test Method Validation and Verification-Nonwaived Tests" of the All Common Checklist must be followed.*

REFERENCES

1) Hipp J, Bauer TW, Bui MM, et al. *CAP Pathology Resource Guide: Digital Pathology.* Version 7.0(2). Northfield, IL: College of American Pathologists; 2017.

**BAP.05415 Calibration** **Phase II**

**Each instrument is calibrated in accordance with the specifications of the instrument.**

REFERENCES

1) Hipp J, Bauer TW, Bui MM, et al. *CAP Pathology Resource Guide: Digital Pathology.* Version 7.0(2). Northfield, IL: College of American Pathologists; 2017.

# QUALITY CONTROL

## Inspector Instructions:

| | |
|---|---|
|  | • Sampling of QC policies and procedures<br>• Sampling of QC records |
|  | • How do you determine when QC is unacceptable and corrective actions are needed? |

**BAP.05420 Quality Control - Digital Image Analysis** **Phase II**

**Control materials are run concurrently with patient specimens to ensure appropriate functionality of the digital image system.**

*NOTE: Controls are samples that act as surrogates for patient/client specimens. They are periodically processed like a patient/client sample to monitor the ongoing performance of the analytic process. Controls should check test performance at relevant decision points for the digital image analysis system.*

*For qualitative tests, a positive and a negative control may be sufficient. For quantitative or semiquantitative tests, controls at more than one level should be used.*

**Evidence of Compliance:**

✓ Records of QC results

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 2003(Jan 24):5232 [42CFR493.1256(d)(3)(i)]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

## BAP.05425 QC Handling — Phase II

**The biorepository tests control specimens in the same manner and by the same personnel as patient/client samples.**

*NOTE: Personnel who routinely perform patient/client testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.*

**Evidence of Compliance:**

✓ Records reflecting that QC is run by the same personnel performing patient testing

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):7166 [42CFR493.1256(d)(8)]; 2) *ibid*, 2003(Jan 24):3708[42CFR493.1256(d)(7-8)

## BAP.05430 QC Confirmation of Acceptability — Phase II

**Personnel review control results for acceptability before reporting results.**

*NOTE: Control results must be reviewed before reporting patient/client results.*

**Evidence of Compliance:**

✓ Records of control result approval

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):7166 [42CFR493.1256(f)]
2) 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):3708 [42CFR493.1256(d)(6)]

## BAP.05435 Monthly QC Review — Phase II

**The biorepository director or designee reviews and assesses quality control data at least monthly.**

*NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.*

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