



VALIDATION AND CALIBRATION (DIA)

Inspector Instructions:

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|---|--|
|  | <ul style="list-style-type: none"> • Sampling of validation and calibration policies and procedures • Sampling of validation/calibration records |
|  | <ul style="list-style-type: none"> • 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:

| | |
|---|---|
|  | <ul style="list-style-type: none"> • Sampling of QC policies and procedures • Sampling of QC records |
|  | <ul style="list-style-type: none"> • How do you determine when QC is unacceptable and corrective actions are needed? |

BAP.05420 Quality Control - Digital Image Analysis

Phase II