

## VALIDATION AND CALIBRATION (DIA)

### Inspector Instructions:

 <b>READ</b>	<ul style="list-style-type: none"> <li>Sampling of validation and calibration policies and procedures</li> <li>Sampling of validation/calibration records</li> </ul>
 <b>ASK</b>	<ul style="list-style-type: none"> <li>What is your course of action if calibration is unacceptable?</li> </ul>

#### 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:

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

#### BAP.05420 Quality Control - Digital Image Analysis

**Phase II**