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" section 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.

ANP.23009 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:

READ	• Sampling of QC policies and procedures • Sampling of QC records
ASK	• How do you determine when QC is unacceptable and corrective actions are needed?
DISCOVER	• Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

ANP.23018 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