

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 03D2159960 | (X3) Date Survey Completed 11/19/2025 |
| Name of Provider or Supplier Regency Specialties | Street Address, City, State 14725 W Mountain View Blvd, Suite 275, Surprise, AZ | |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
|---------------------------|--|
| D5437 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on lack of monthly calibration records from July 2025 through October 2025 for the Hamamatsu Nanozoomer S20 Digital Slide Scanner and interview with the Testing Personnel (TP-2) on 11/19/25 at 1:44 PM, the laboratory failed to perform and document monthly calibration procedures on the scanner as required by the manufacturer. Findings include: 1. The laboratory began using the Hamamatsu Nanozoomer S20 Digital Slide Scanner on 6/24/2025 to perform patient testing in the subspecialty of Histopathology, with a reported annual test volume of 17,000. 2. The manufacturer's instructions indicate a monthly scanner calibration must be performed using calibration slides and blank slides provided by Hamamatsu. 3. The laboratory failed to perform and document monthly scanner calibrations from July 2025, August 2025, September 2025 and October 2025. 4. TP-2 interviewed on 11/19/25 at 1:44 PM acknowledged that the laboratory failed to provide evidence of monthly scanner calibrations for the timeframe indicated above .</p> |