

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2188616	(X3) Date Survey Completed 10/17/2022
Name of Provider or Supplier Regency Specialties	Street Address, City, State 14725 W Mountain View Blvd, Suite 100, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's established Quality Assessment policies, review of QA records and interview with the facility personnel, the laboratory failed to identify and correct errors found within the accuracy verification process. Findings include: 1. The laboratory performs a microscopic examination and diagnosis on tissue specimens in conjunction with Mohs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 2,400. 2. It is the practice of the laboratory to randomly select four completed Mohs cases each quarter which are reviewed by another qualified Mohs physician to verify accuracy of the testing. The review is documented on the "Quality Assurance, proficiency testing" form. 3. The laboratory's established policy titled, "Quality Assurance Program" states, "Peer review will be documented as proficiency testing is scheduled....A Corrective Action Form must be completed should any problems occur during testing process. This form must be reviewed and signed by the Laboratory Director". 4. Review of the quarterly slide review form from Jan-Feb 2022 revealed a discrepancy for case# M22-328. The reviewing physician noted slide IB as positive (P), however the final test report for this case noted 'Free of Tumor'. 5. The laboratory failed to review the results generated from the accuracy verification process to determine if any discrepancies were noted. 6. The laboratory failed document corrective action as required by laboratory policy for the discrepancy noted above, including but not limited to, whether or not an amended test report was issued or required due to the discrepancy.</p>

7. The facility personnel interviewed on 10/17/22 at 11:15am confirmed the laboratory failed to review the results of the accuracy verification process and confirmed the laboratory failed to document corrective action for noted discrepancies.