

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2006536	(X3) Date Survey Completed 06/11/2025
Name of Provider or Supplier Pdp Az Dermatopathology Lab	Street Address, City, State 6320 W Union Hills Dr, Bldg A Ste 200, Glendale, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of histopathology quality control records on June 11, 2025 and interview with the facility personnel, the laboratory failed to retain stain acceptability records for the Hematoxylin & Eosin (H&E) stain from September 2024 through December 2024, and the laboratory failed to retain Immunohistochemical (IHC) stain acceptability records from 12/05/24. Findings include: 1. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 100,000. 2. The laboratory failed to provide evidence of H&E stain acceptability records from September 2024 through December 2024. The laboratory performed testing on approximately 81 days during that timeframe. 3. The facility personnel interviewed on 6/11/25 at 2:55 PM acknowledged that the laboratory could not locate the H&E stain acceptability documentation at the time of the survey for the dates indicated above. 4. The laboratory failed to provide documentation of IHC stain acceptability (for both positive and negative controls) for the following stain protocols performed on 12/05/24: SOX-10, PRAME250 and MART-1. 5. The facility personnel interviewed on 6/11/25 at 3:45 PM confirmed the laboratory failed to retain documentation of the IHC stain acceptability records from 12/05/24.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p>

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of annual and semiannual competency evaluation documentation from 2024 and 2025 and interview with the facility personnel, the technical supervisor failed to evaluate and document the competency of four out of four testing personnel who perform testing in the subspecialty of Histopathology. Findings include: 1. The CMS-209, Laboratory Personnel Form presented for review during the survey listed 4 testing personnel (TP) who perform the gross examination of pathology specimens. 2. The 2024 annual competency documentation reviewed for TP-4 and TP-5 and the 2025 annual competency documentation reviewed for TP-6 and TP-7 revealed the competency evaluations were not performed and documented by the Technical Supervisor. 3. The 2025 semiannual competency documentation reviewed for TP-6 and TP-7 revealed the competency evaluations were not performed and documented by the Technical Supervisor. 4. The facility personnel interviewed on 6/11/2025 at 1:45 PM confirmed that the competency evaluations indicated above were not performed and documented by the Technical Supervisor. 5. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 100,000.