

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2006536	(X3) Date Survey Completed 06/18/2021
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of histopathology stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Hematoxylin, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides in conjunction with dermatopathology testing, with an approximate annual test volume of 29,000 tests. 2. During the survey conducted on June 18, 2021, direct inspection of the Hematoxylin reagent, lot #060319, indicated an expiration date of 06/03/21. 3. The total number of patients tested using the expired reagent could not be determined at the time of the survey. 4. The facility personnel confirmed that the expired reagent indicated above was still in use on the day of the survey.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of the (A) Hematoxylin & Eosin (H & E) staining materials and (B) Periodic acid-Schiff (PAS) staining materials used for patient testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology, with an approximate annual test volume of 29,000. 2. The dermatopathology test report for patient D20-10952, reported by the laboratory on 09/08/2020, was reviewed during the survey conducted on June 18, 2021. The laboratory performed the H & E and PAS stain on the patient's specimen in order to render the pathological diagnosis. A3. No documentation of the H & E stain acceptability was presented for review for testing that occurred on 09/08/2020 or for any other testing date during the month of September 2020. A4. Approximately 2,214 patient specimens were tested by the laboratory with the H & E stain during September 2020. B5. No documentation of the PAS stain acceptability was presented for review for testing that occurred on 09/08/2020 or for any other testing date during the month of September 2020. B6. Approximately 82 patient specimens were tested by the laboratory with the PAS stain during September 2020. 7. The facility personnel confirmed that the laboratory failed to document the H & E and PAS stain acceptability during September 2020.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory's QA processes failed to monitor and identify errors found in the analytic portion of histopathology testing which is performed by the laboratory. Findings include: 1. The laboratory processes and interprets dermatopathology slides from patient specimens. The laboratory's approximate annual test volume is 29,000. 2. The laboratory's established procedure for QA processes includes a monthly QA checklist to monitor the analytic portion of the testing, including but not limited to, QC performance. 3. No QA documentation was presented for review during the survey to indicate the laboratory identified and corrected issues found with the laboratory's failure to perform and document the H & E Stain and PAS stain acceptability during September 2020, see D5473 for findings. 4. No QA documentation was presented for review during the survey to indicate the laboratory established QA processes to monitor the expiration date of the stains used for patient testing. See D5417 for findings. 5. The facility personnel confirmed that the laboratory failed to monitor and identify errors found with a lack of QC performance and acknowledged that the laboratory's QA processes failed to monitor and identify errors found with expired reagents.