

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2006536	<b>(X3) Date Survey Completed</b>  12/06/2023
<b>Name of Provider or Supplier</b>  Pdp Az Dermatopathology Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5475</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of positive and negative Quality Control (QC) documentation for Immunohistochemical (IHC) stains from 01/01/2022 through the date of the survey on 10/17/2023 and interview with the facility personnel, the laboratory failed to check immunohistochemical stains for positive and negative reactivity each time of use. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 63,000. 2. The laboratory performs IHC stains on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 3. The laboratory failed to document positive and negative reactivity each time of use for each IHC stain performed by the laboratory from 01/01/2022 through 10/17/2023. 4. The number of patient specimens tested with IHC stains during the timeframe indicated above could not be determined at the time of the survey. 5. The facility personnel interviewed on 12/06/2023 at 2:15 PM confirmed the laboratory failed to check each IHC stain for positive and negative reactivity each time of use during the timeframe indicated above.</p>