

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0686823	<b>(X3) Date Survey Completed</b>  12/05/2023
<b>Name of Provider or Supplier</b>  Dermatology Assoc Of Western Pa	<b>Street Address, City, State</b>  500 Cherrington Parkway, Suite 410, Coraopolis, PA	
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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature and humidity records and interview with the Business Manager (BM), the laboratory failed to provide documentation of the corrective actions taken when relative humidity readings were recorded below the acceptable humidity range of 40 - 60 % for 160 of 223 days when Histopathology testing was performed from 02/14/2022 through the date of survey. Findings include: 1. On the day of survey 12/05/23 at 10:03 am, review of the laboratory's temperature and humidity records revealed relative humidity levels below 40% were recorded for: - 72 of 97 days in 2022 (February - May, July, September - December) - 88 of 126 days in 2023 (January - June, August - December) 2. The laboratory could not provide documentation of corrective actions taken when relative humidity was out of range. 3. Interview with BM on 12/05/2023 at 10:40 am confirmed the laboratory did not document the corrective action taken.</p>