

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0994900	(X3) Date Survey Completed 10/08/2021
Name of Provider or Supplier Ameripath Florida Llc	Street Address, City, State 1200 N Central Ave Ste 103, Kissimmee, FL	
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
D0000	A recertification survey was conducted on October 8, 2021. Ameripath Florida LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5781	<p>CORRECTIVE ACTIONS 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 record review and interview, the laboratory failed to document corrective actions when the Leica CM1850 Cryostat was not within temperature range for 6 of 150 days from 01/04/2021 to 10/07/2021. Findings: Review of the Instructions for Use manual showed the temperature range for the cryostat for "skin without fat" was "-15 - -25 degrees C." (Celsius) Review of the laboratory's 2021 Temperature Monitoring Log for the Leica CM1850 listed temperature range for the cryostat as "(-15) - (-25) degrees C." The temperature log showed the temperatures were out of range and no corrective action was documented for the following dates : 03/22/2021 temperature -13 degrees C 03/29/2021 temperature -10 degrees C 04/01/2021 temperature -13 degrees C 04/05/2021 temperature -13 degrees C 04/08/2021 temperature -14 degrees C 04/13/2021 temperature -13 degrees C Review of the "Out of Limit and Corrective Action Documentation" log for the Leica CM1850 Cryostat</p>

showed there were no corrective actions documented for the above mentioned dates. On 10/08/2021 at 9:42 AM, the Director of Laboratory Operations stated there was no documentation of corrective actions.