

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1055175	(X3) Date Survey Completed 08/31/2018
Name of Provider or Supplier Center For Dermatology	Street Address, City, State 20520 Keokuk Ave Suite 104, Lakeville, MN	
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
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 observation, document review and interview with laboratory personnel, the laboratory failed to ensure corrective actions were taken when the cryostat operating temperature fell outside the established parameters. Findings are as follows: 1. The laboratory performed histopathology (Mohs dermatographic surgery) testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 08/31/18 at 9:05 a.m. 2. A Leica CM 1510 S cryostat was observed as present and available for use during the tour of the laboratory. 3. The operating temperature range for the Leica CM 1510 S cryostat was defined in the Cryostat Maintenance procedure as -25 degrees +/- 3 degrees Celsius. The cryostat temperature log used in 2017 and 2018 defined the temperature range as -25 degrees +/- 3 degrees Celsius. 4. The cryostat temperature was outside the defined operating temperature on 30 of 92 days in 2017, and 40 of 68 days from January, 2018 through date of survey, 08/31/18. See below: Frequency Percentage 2017 30 / 92 33% 2018 40 / 68 59% Total 70 / 160 44% 5. Documentation of corrective actions for the out of specification temperature events</p>

could not be located during the survey. The laboratory was unable to provide the corrective action records upon request. 6. In an interview on 08/31/18 at 11:35 a.m., the LD confirmed the above findings. .