

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2285030	(X3) Date Survey Completed 01/16/2024
Name of Provider or Supplier Mankato Clinic Dermatology	Street Address, City, State 1400 Madison Ave Suite 400a, Mankato, 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
D0000	The Mankato Clinic Dermatology laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the initial certification survey performed on January 16, 2024. The following standard-level deficiencies were cited: 493.1251 Procedure Manual 493.1282 Corrective Actions .
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to approve each and every policy and procedure currently in use by the laboratory. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery testing, which falls under the specialty of Histopathology, as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:10 a.m., on January 16, 2024. 2. The following manual was observed as present and available for use on date of survey: --MOHS Lab Procedure and Forms Manual (black three-ringed binder). 3. Laboratory Director approval of the manual, and the policies and procedures contained therein, was not found during review on date of survey. 4. In an interview at 12:40 p.m. on January 16, 2024, the GS confirmed the above finding. 5. The Laboratory Director assumed the role on July 5, 2023 as indicated in the Federal database records. .</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

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.

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 an equipment operating temperature fell outside the established parameters 16 of 123 testing days, 07/01/2023 through 01/16/2024 Findings are as follows: 1. The laboratory performed Mohs micrographic surgery testing which falls under the specialty of Histopathology, as confirmed by the General Supervisor (GS) during the entrance interview at 10:05 a. m., on January 16, 2024. 2. A Leica model CM-1860 Cryostat was observed as present and available for use during a tour of the laboratory. 3. A requirement that maintenance will be performed if the temperature falls outside the acceptable range on the Cryostat (-20 to -30 degrees Celsius) was established in the Procedure: "Cryostat Temperature Monitor Log" . 4. The cryostat temperature was outside the established temperature range for 16 of 123 days on which Mohs surgery was performed during the time period reviewed, July 1, 2023 through January 16, 2024. Dates of service above -20 degrees Celsius: August 2, 2023 September 6, 2023 August 7, 2023 September 20, 2023 August 16, 2023 September 27, 2023 August 18, 2023 October 17, 2023 August 29, 2023 October 18, 2023 August 30, 2023 December 5, 2023 August 31, 2023 December 12, 2023 September 5, 2023 December 18, 2023 No corrective action or maintenance performed was found documented for the 16 days the Cryostat was found to be outside the acceptable parameters. 5. In an interview at 12:40 p.m. on January 16, 2024, the GS confirmed the above finding.