

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2299034	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Sutton Dermatology, Pllc	Street Address, City, State 1114 Highway 59 S Suite 1, Detroit Lakes, 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 Sutton Dermatology, PLLC 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 survey performed on September 18, 2024. The following standard-level deficiency was cited: 493.1253 Establishment and verification of performance specifications .
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate 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 complete required performance verification (PV) activities for one of one Histopathology test implemented by the laboratory in 2024. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery with tissue gross and slide interpretation as confirmed by Histotechnician 1 during a tour of the laboratory at 1:00 p.m. on 09/18/24. 2. The following equipment was observed as present and available for use during the tour: Epredia HM 525 Nx cryostat Epredia linistat autostainer Epredia Hyperclean Truair fume hood Olympus BX43 microscope 3. The laboratory established a PV protocol consisting of 20 slides using various tissue types in the Validation of the Staining Protocol procedure located in the Mohs Procedure Manual. 4. PV documentation for the Mohs process was not found in laboratory records. The laboratory was unable to provide the missing documentation</p>

upon request. 5. In an interview at 2:44 p.m. on 09/18/24, the Laboratory Director confirmed the above finding. .