

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2299363	(X3) Date Survey Completed 10/24/2024
Name of Provider or Supplier Arsenault Dermatology	Street Address, City, State 5807 21st Avenue West Suite B, Bradenton, 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	An announced CLIA initial survey was conducted at Arsenault Dermatology on 10/18/2024 - 10/24/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure quality control (QC) results for Periodic Acid Schiff (special stain for histology) were documented by the Laboratory Director before sending 67 patient slides to the laboratory that performed the professional component from 07/04/2024 - 10/17/2024. Findings Included: Review of the "Path Worksheet Log Report" logs from 07/03/2024 - 09/30/2024 revealed 60 patients had Periodic Acid Schiff stains. On 10/18/2024 at 12:45 PM, a white board posted in the laboratory documented an additional 7 patients had Periodic Acid Schiff stains that were not noted on the Log Reports, 1 on 09/18/2024, 1 on 09/19/2024, 1 on 09/20/2024, 2 on 10/15/2024, and 2 on 10/17/2024. Review of the laboratory's procedure titled Quality Control Testing revealed quality control results should be documented daily to detect changes from the usual performance of the test system. Record review of the Periodic Acid Schiff stain records revealed there was no documentation of the Periodic Acid Schiff QC. During an interview on 10/18/2024 at 2:10 PM, the outside consultant confirmed she had not documented the QC result for the Periodic Acid Schiff QC slide.</p>