Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1096969	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Darst Dermatology, Pc	11301 Golf Links Drive North, Suite 203, Charlotte, NC	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of 2024 and 2025 verification of accuracy records, lack of documentation, interview with laboratory director (LD) and interview with practice manager (PM) 05/14/25, the laboratory failed to verify the accuracy of the Mart 1 immunostain and the Periodic Acid-Schiff (PAS) stain at least twice annually since January of 2024; approximately 152 Mart 1 and 32 PAS stains were performed since January of 2024. Findings: Review of 2024 and 2025 verification of accuracy records revealed the laboratory sends out hematoxylin and eosin (H&E) stained slides to another pathologist for a verification of accuracy twice annually. There was no documentation the laboratory sent Mart 1 or PAS stained slides for a verification of accuracy since January of 2024. Interview with LD at approximately 11:45 a.m. confirmed the laboratory failed to verify the accuracy of the Mart 1 and PAS stains. He stated they were not aware of this requirement. Interview with PM at approximately 11:45 confirmed approximately 152 Mart 1 and 32 PAS stains were performed since January of 2024.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2024 and 2025 "Cryostat Quality Control...Equipment Quality Control" logs and interview with testing personnel (TP) #1, 05/14/25, the laboratory failed to document and/or perform established maintenance protocol of the cryostat instrument. 1. The laboratory failed to document the cryostat thermometer temperature each day of use since January of 2024. Findings: Review of laboratory procedure "Equipment Quality Control...Form 3: Cryostat and Microtome Use Protocol" revealed "8. Cryostat thermometer check is done Monthly and As Used.". Review of 2024 and 2025 "Cryostat Quality Control... Equipment Quality Control" logs revealed the laboratory was documenting the cryostat temperature check monthly and not each day of use. Interview with TP #1 at approximately 1:00 p.m. confirmed the temperature check was documented monthly and not each day of use. They stated they were just following what was previously documented on the logs when they began employment. 2. The laboratory failed to document and/or perform the defrost of the cryostat every 2 months. Findings: Review of laboratory procedure "Equipment Quality Control...Form 3: Cryostat and Microtome Use Protocol" revealed "4. Defrost of cryostat is done Every two months.". Review of 2024 and 2025 "Cryostat Quality Control...Equipment Quality Control" logs revealed the laboratory documented the defrost of the cryostat in December of 2024 and in April of 2025, a period of approximately 5 months between defrosting of the cryostat. Interview with TP #1 at approximately 1:00 p.m. confirmed there was no documentation of a defrost performed between December of 2024 and April of 2025. They stated it was performed but they must have not documented it.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based of review of laboratory procedure, review of TP #1 personnel records, lack of documentation and interview with LD 05/14/25, the technical supervisor (TS) (laboratory director) failed to perform semiannual performance assessments for TP #1 during the first year of testing patient specimens. Findings: Review of laboratory quality assessment procedure revealed "The competency of Testing Personnel...will be evaluated and documented every year by the Laboratory Director...CLIA regulations for laboratories performing Moderate and High complexity testing require semiannual performance assessments during the first year and annual assessments thereafter.". Review of TP #1 personnel records revealed TP #1 began employment in April of 2024 and a performance assessment was completed in December of 2024. There was no documentation of a second performance assessment during the first year of testing patient specimens. Interview with TS (laboratory director) at approximately 1:30 p.m. confirmed a second performance assessment was not completed for TP #1, they stated they had not hired a new employee for a long time and did not realize this was required.