

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2048182	(X3) Date Survey Completed 07/20/2022
Name of Provider or Supplier Alliant Dermatology Pa	Street Address, City, State 8620a E Cr 466, The Villages, 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	A Recertification survey was conducted on July 20, 2022. Alliant Dermatology PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, observation, and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and identify problems. Findings: Cross Reference D5413. Based on observation, record review and interview, the laboratory failed to record the temperature for 1 out of 2 Leica CM1850 Cryostats from 10/22/2020 to 07/20/2022. This is a repeat deficiency for the Recertification survey on 09/10/2020.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.</p>

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to record the temperature for one of two Leica CM1850 Cryostats from 10/22/2020 to 07/20/2022. This is a repeat deficiency for the Recertification survey on 09/10/2020. Findings: A tour of the laboratory on 07/20/2022 at 10:17 AM revealed both Leica 1850 Cryostats were turned on. Review of the laboratory's "Temperature / Humidity / Microscope / AC / H&E" log showed there was only one column with one temperature recorded for the two cryostats. Review of the Statement of Deficiencies and Plan of Correction (CMS-2567) signed and dated by the Laboratory Director on 10/22/2020 for the Recertification survey on 09/10/2020, read, "The Daily mohs logbook was updated to show measurements for two cryostats." According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 07/20/2022, the laboratory had an estimated annual test volume of 42,500 histopathology tests per year. On 07/20/2022 at 12:30 PM, the Mohs Technician stated they used one cryostat for keeping the tissue frozen and the other cryostat for cutting the tissue. On 07/20/2022 at 12:33 PM, the Mohs Technician stated they were recording the temperature of only one of the cryostats.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to ensure the Scott's Tap Water Substitute used in their Hematoxylin and Eosin Staining (H&E) was not expired prior to patient testing from 01/09/2022 to 07/20/2022. Findings: Observations made during a tour of the laboratory on 07/20/2022 at 10:17 AM, showed an opened bottle of Scott's Tap Water Substitute lot number 2036410 expired on 01/08/2022. The laboratory used the Scott's Tap Water Substitute as a bluing reagent for their H&E stained slides for their Mohs surgical procedures. Review of the laboratory's "H&E Stainer Mohs Maintenance Log" showed the Scott's Tap Water Substitute lot number 2036410 was first used in 03/2022. Review of the "H&E Stainer Mohs Maintenance Log" from 03/01/2022 to 07/20/2022 showed no other bluing reagent was listed in the logs. On 07/20/2022 at 10:20 AM, the Mohs Technician acknowledge the Scott's Tap Water Substitute was expired.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory Quality Assurance (QA) failed to monitor, access and correct problems in the analytic system from 10/22/2020 to 07/20/2022. Findings: 1. Cross Reference D5413. The laboratory failed to record the temperature for 1 of 2 Leica CM1850 Cryostats from 10/22/2020 to 07/20/2022. Review of the "Monthly Quality Assurance Checklist" from 10/2020 to 6/2022, signed by the Laboratory Director, showed a check mark that indicated "All required temperatures were taken and recorded." On 07/20/2022 at 12:33 PM, the Mohs Technician stated they were recording the temperature of only one the cryostats. 2. Cross Reference D5417. The laboratory failed to ensure the Scott's Tap Water Substitute used in their Hematoxylin and Eosin Staining (H&E) was not expired prior to patient testing from 01/09/2022 to 07/20/2022. Review of the "Monthly Quality Assurance Checklist" from 01/2022 to 6/2022, signed by the Laboratory Director, showed a check mark that indicated "All reagents, controls, kits, etc. that exceeded their expiration date were discarded." On 07/20/2022 at 10:20 AM, the Mohs Technician acknowledge the Scott's Tap Water Substitute was expired. On 07/20/2022 at 11:37 AM, the Laboratory Consultant acknowledge the QA failed.