

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0986772	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Anne Arundel Dermatology Pa	Street Address, City, State 133 Associates Blvd, Alcoa, TN	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, direct observation, and interview with the practice manager, determined the laboratory failed to follow its' policy for specimen labeling in 2022 and 2023. The findings include: 1. Review of the laboratory policy titled "Histopathology Mohs Micrographic Surgery" revealed that "Slides are labeled with a handwritten label including case number, full patient name and date, site and stage of Mohs". 2. Direct observation on 06.21.2023 at 11:45 a.m. of slides from four Mohs cases revealed the following: - Mohs Case RGA22-155 containing three slides from surgery date 04.25.2022: slides were not labeled with full patient name, date, and site. - Mohs Case RGA22-348 containing four slides from surgery date 08.22.2022: slides were not labeled with full patient name and site. - Mohs Case RGA23-52 containing seven slides from surgery date 02.06.2023: slides were not labeled with full patient name and site. - Mohs Case RGA23-189 containing nine slides from surgery date 05.15.2023: slides were not labeled with full patient name and site. 3. Interview on 06.21.2023 at approximately 11:50 a.m. with the practice manager confirmed the laboratory failed to follow its' policy for labeling patient slides from Mohs procedures in 2022 and 2023. Word Key: Mohs=micrographically oriented histography surgery</p>
D5401	PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and interview with the practice manager, determined that the laboratory failed to follow its' own written policy for reviewing the procedure manual annually in 2022. The findings include: 1. Review of the laboratory's procedure manual under the section titled, "Review of Policy" revealed the following statement, "This manual is reviewed annually by the lab director". 2. Review of the procedure manual under the section titled, "Review by Laboratory Director" revealed no documented laboratory director signature for 2022. 3. Interview with the practice manager on 06.21.2023 at 12:30 p.m. confirmed the laboratory failed to follow its' own written policy for reviewing the procedure manual annually in 2022.

D5413

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

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. (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 of the laboratory, manufacturer manual review, request of environmental monitoring records and interview with the practice manager, the laboratory failed to monitor temperature and humidity environmental conditions where two Leica cryostats and a Linistat automated stainer were in use for patient tissue processing in 2022 and 2023. The findings include: 1. Observation of the laboratory on 06.21.2023 at 9:05 a.m. revealed a Leica CM1850 cryostat (serial number 2705/02.2002), a Leica CM1860 cryostat (serial number 2022/09.2015), and a Thermo Scientific Linistat automated stainer (serial number B100302238) in use for processing patient tissue samples removed during Mohs surgical procedures. 2. Review of the manufacturer manuals revealed the following: - Leica CM1850 operating temperature range 18C to 35C and air humidity lower than 60%. - Leica CM1860 operating temperature range 18C to 35C and relative humidity not more than 60%. - Linistat automated stainer environmental operating conditions require +5C to 40C and maximum relative humidity 80%. 3. Request of environmental monitoring records revealed no room temperature monitoring records available for surveyor review for 2022 and no room humidity monitoring records available for surveyor review for January 2022 through June 15, 2023. 4. Interview on 06.21.2023 at 12:15 p.m. with the practice manager confirmed the laboratory failed to monitor room

temperature in 2022 and room humidity from January 2022 through June 15, 2023 where the Leica cryostats and Linistat automated stainer were in use in 2022 and 2023. Word Key: C = degrees Celsius

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 review of the laboratory's procedure manual, review of laboratory records, and interview with the practice manager, the laboratory failed to follow the procedure for quality control assessment in 2022 and 2023. The findings include: 1. Review of the laboratory's procedure titled "Quality Assurance Program" revealed that, "The Mohs surgeon will review the technicians QC logs. These include daily records of cryostat temperature, control slide log, staining records, and preventative maintenance records". 2. Review of the laboratory's cryostat temperature logs from January 2022 through May 2023 revealed no documentation of Mohs surgeon review. 3. Interview with the practice manager on 06.21.2023 at 10:30 a.m. confirmed the Mohs surgeon which is the lab director failed to follow the procedure for quality control assessment in 2022 and 2023. Word Key: Mohs=micrographically oriented histography surgery QC=quality control

D5793

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

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment plan, laboratory records, and interview with the practice manager, the laboratory's quality assessment process was ineffective when it failed to detect and correct problems in 2023. The findings include: 1. Review of the laboratory's quality assessment plan revealed the laboratory's quality assurance program "assists in identifying and quickly correcting problems". 2. Review of laboratory room temperature records revealed laboratory room temperatures recorded were outside the stated acceptable range for 6 of 20 days when patient testing occurred from January 9, 2023 through June 19, 2023 with no documented corrective action. 3. Interview with the practice manager on 06.21.2023 at 12:30 p.m., confirmed the laboratory's quality assessment process was ineffective when it failed to detect and correct problems when unacceptable laboratory room temperatures were recorded with no documented corrective action for 6 of 20 days in 2023.