Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0312905	06/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Anne Arundel Dermatology, Pa	123 Fox Rd, Knoxville, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on direct observation, review of the Histology procedure manual and interview with the laboratory's lead Histology testing person (TP#1), determined the laboratory failed to include a procedure for preparing 95% alcohol in the Histology procedure manual. Findings: 1. Direct observation of the laboratory's Histology room at approximately 10:45 am on 06.15.2023 revealed 95% alcohol in use for tissue microtomy. 2. Review of the Histology procedure manual revealed no preparation

	instructions for 95% alcohol. 3. Interview with the laboratory's lead Histology TP#1 in the conference room at approximately 1:00 pm on 06.15.2023 confirmed the above findings.
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: Citation 1: Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and staff interview, determined the laboratory failed to document humidity for the Leica CM 1850 and Avantik QS12 cryostats for 17 of 17 months. Findings included: 1. Observation of the MOHS processing room at approximately 10:00 am on 06.15.2023 revealed 1 Leica CM 1850 and 2 Avantik QS12 cryostats in use for patient testing. 2. Review of the cryostat instruction manuals revealed the following: ~ Leica CM 1850 cryostat Instruction Manual (V 2.0 English-03/2001) stated, "Air humidity must not exceed 60% High room temperatures and excessive air humidity affect the cooling capacity of the cryostat." ~ Avantik QS12 cryostat Instruction Manual (5259000 rev2-R9) stated, "Max. 60% RH up to 35 C." 3. Review of laboratory environmental records revealed no documentation of humidity monitoring in the MOHS processing room from January 2022 through May 2023. 4. Interview with the CLIA Coordinator at approximately 3:00 pm on 06.15.2023 in the conference room confirmed the above findings. Word Key: C = degrees Celsius RH = Relative Humidity MOHS= micrographically oriented histograph surgery Citation 2: Based on direct observation, request for the laboratory's environmental records, review of manufacturer's storage requirements, and interview with the laboratory staff, determined the laboratory failed to document temperature and ensure proper storage for 3 of 3 MOHS processing reagents for 17 of 17 months. The findings include: 1. Observation of the laboratory's Biohazard/MOHS reagent storage room at approximately 10:30 am on 06.15.2023 revealed the following reagents on shelves and no device for temperature monitoring: a. Leica Hematoxylin 560 MX b. Surgipath Alcoholic Eosin Y515 c. Scott Tap Water Substitute EKI 2. Request for laboratory's Biohazard/MOHS reagent storage room environmental records from January 2022 through May 2023 revealed none were present. 3. Review of the manufacturer's storage requirements listed on the Leica Hematoxylin 560 MX, Surgipath Alcoholic Eosin Y515, and Scott Tap Water Substitute reagent bottles stated, "store at 15-30 C." 4. Interview with the CLIA Coordinator at approximately 3:00 pm on 06.15.2023 in the conference room confirmed the above findings. Word Key: C = degrees Celsius MOHS= micrographically oriented histograph surgery Citation 3: Based on direct observation, request for the laboratory's environmental records, review of manufacturer's storage requirements, and interview with the laboratory staff, determined the laboratory failed to document temperature and ensure proper storage for 4 of 4 Histology processing reagents for 17 of 17 months. The findings include: 1. Observation of the laboratory's Histology storage room at approximately 10:45 am on 06.15.2023 revealed the following reagents on shelves and no device for temperature

	monitoring: a. Surgipath Blue Buffer 8 b. Surgipath Hematoxylin 560 MX c. Surgipath Define MX-aq concentrate d. Histoplast paraffin 2. Request for laboratory's Histology storage room environmental records from January 2022 through May 2023 revealed none were present. 3. Review of the manufacturer's storage requirements listed on the Surgipath Blue Buffer 8, Surgipath Hematoxylin 560 MX, Surgipath Define MX-aq concentrate, and Histoplast paraffin reagent bottles stated, "store at 15-30 C." 4. Interview with the CLIA Coordinator at approximately 3:00 pm on 06.15.2023 in the conference room confirmed the above findings. Word Key: C = degrees Celsius
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Citation 1: Based on observation of the Histology laboratory and staff interview, determined the laboratory failed to label reagents used in Histopathology tissue processing with information when transferred from the primary to secondary containers. The findings include: 1. Observation of the Histology laboratory at approximately 10:45 am on 06.15.2023 revealed three secondary containers (one labeled "formalin",one labeled "DI water", and one labeled "95% alcohol") in use for processing and staining patient tissue for Histopathology procedures that were not labeled with lot number, preparation date, and expiration date when transferred from the original containers to the secondary containers. 2. Interview with the the Histology laboratory lead testing person (TP#1) at approximately 11:00 am on 06.15.2023 in the Histology laboratory confirmed the laboratory failed to label the secondary containers of formalin, deionized water and 95% alcohol with the lot number, preparation date, and expiration date. Word Key: DI water= deionized water Citation 2: Based on observation of the Histology laboratory and staff interview, determined the laboratory failed to ensure a legible expiration date was documented on 1 of 6 tissue marking dyes used in Histopathology tissue processing for patient testing from 11.1.2022 through the survey date of 06.15.2023. The findings include: 1. Observation of the Histology laboratory at approximately 10:45 am on 06.15.2023 revealed: a. 6 Mercedes Scientific tissue marking dyes at 2 tissue processing stations in use for patient testing. b. 1 of 6 tissue marking dyes had an illegible label (black). 2. Interview with the the Histology laboratory lead testing person (TP#1) at approximately 11:00 am on 06.15.2023 in the Histology laboratory confirmed the above findings
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 of the Histology laboratory and staff interview, determined the laboratory failed to ensure expired tissue marking dyes were not used in Histopathology tissue processing for patient testing from 11.1.2022 through the survey date of 06.15.2023. The findings include: 1. Observation of the Histology laboratory at approximately 10:45 am on 06.15.2023 revealed: a. 6 Mercedes Scientific tissue marking dyes at 2 tissue processing stations in use for patient testing. b. 2 of 6 tissue marking dyes in use with 10.31.2022 (black) and 2.28.2023 (red) expiration dates. 2. Interview with the the Histology laboratory lead testing person (TP#1) at approximately 11:00 am on 06.15.2023 in the Histology laboratory confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Citation 1: Based on review of the laboratory's Hematoxylin and Eosin (H&E) stain control slide log, Histology procedure manual, and staff interview, determined the laboratory failed to define the predicted characteristics of the H&E stain in 2022 thru the survey date of 06.15.2023. The findings include: 1. Review of the laboratory's H&E stain control slide logs, revealed no documentation of the predicted characteristics of the H&E stain quality for 2022 thru the survey date of 06.15.2023. 2. Review of the laboratory's Histology procedure manual revealed no definition of predictable characteristics of the H&E stain quality. 3. Interview with the laboratory's lead Histology TP#1 at approximately 1:00 pm on 06.15.2023, in the conference room, confirmed the predicted characteristics of the H&E stain quality had not been documented and/or defined for 2022 thru the survey date of 06.15.2023. Citation 2: Based on review of the laboratory's Hematoxylin and Eosin (H&E) stain control slide log and staff interview, determined the laboratory failed to document H&E stain quality by the performing provider for 2022 thru the survey date of 06.15.2023. The findings include: 1. Review of the laboratory's H&E stain control slide logs, revealed no documentation of stain quality by the performing provider for 2022 thru the survey date of 06.15.2023. 2. Interview with the laboratory's lead Histology TP# 1 at approximately 1:00 pm on 06.15.2023, in the conference room, confirmed the H&E stain quality had not been documented by the performing provider for 2022 thru the survey date of 06.15.2023.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by:

	Based on review of employee personnel records and laboratory staff interview, determined the laboratory's technical supervisor failed to perform direct observation of routine patient test performance for assessing personnel competency for 3 of 4 testing personnel (TP) in 2022. The findings include: 1-Review of MOHS testing personnel (TP#4) 2022 competency assessments stated, "This evaluation has been performed during the time period of July 2019 thru June 2020. During this time frame the Histotechnician has been observed by the evaluator performing all required job skills. Job Description: ~Processes, embeds, cuts and stains quality frozen tissue specimens. ~Performs and documents tests in compliance with written quality control procedures, established parameters and standards. ~Maintains histology equipment in good working order and troubleshoots equipment problems. ~Works with the Mohs surgeon to resolve quality control, patient, or procedural problems. ~Consistently follows all policies, procedures and protocols set by Federal, state and local agencies. ~Maintains an extremely high level of confidentiality and follows HIPPA guidelines. ~Responsible for delivering a high level of customer service in all interactions with patients, providers, employees, vendors, and guests. ~Performs other duties as assigned." 2-Review of Histology testing personnel (TP#1 and TP#2) 2022 competency assessments revealed the laboratory's technical supervisor failed to include direct observation of routine patient test performance on the competency assessment. 3-Interview with the CLIA Coodinator at approximately 3:00 pm on 06.15.2023 in the conference room, confirmed the above findings. Word Key: MOHS= micrographically oriented histograph surgery
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of employee personnel records and laboratory staff interview, determined the laboratory's technical supervisor failed to perform direct observation of performance of instrument maintenance and function checks for assessing personnel competency for 3 of 4 testing personnel (TP) in 2022. The findings include: 1-Review of MOHS testing personnel 2022 (TP#4) competency assessments stated, "This evaluation has been performed during the time period of July 2019 thru June 2020. During this time frame the Histotechnician has been observed by the evaluator performing all required job skills. Job Description: ~Processes, embeds, cute and stains quality frozen tissue specimens. ~Performs and documents tests in compliance with written quality control procedures, established parameters and standards. ~Maintains histology equipment in good working order and troubleshoots equipment problems. ~Works with the Mohs surgeon to resolve quality control, patient, or procedural problems. ~Consistently follows all policies, procedures and protocols set by Federal, state and local agencies. ~Maintains an extremely high level of confidentiality and follows HIPPA guidelines. ~Responsible for delivering a high level of customer service in all interactions with patients, providers, employees, vendors, and guests. ~Performs other duties as assigned." 2-Review of Histology testing personnel (TP#1 and TP#2) 2022 competency assessments revealed the laboratory's technical supervisor failed to document direct observation of performance of instrument maintenance and function checks on the competency assessment. 3-Interview with the CLIA Coordinator at approximately 3:00 pm on 06.15.2023 in the

	conference room, confirmed the above findings. Word Key: MOHS= micrographically oriented histograph surgery
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of employee personnel records and laboratory staff interview, determined the laboratory's technical supervisor failed to perform assessment of problem solving skills for assessing personnel competency for 3 of 4 testing personnel (TP) in 2022. The findings include: 1-Review of MOHs testing personnel (TP#4) 2022 competency assessments stated, "This evaluation has been performed during the time period of July 2019 thru June 2020. During this time frame the Histotechnician has been observed by the evaluator performing all required job skills. Job Description: ~Processes, embeds, cute and stains quality frozen tissue specimens. ~Performs and documents tests in compliance with written quality control procedures, established parameters and standards. ~Maintains histology equipment in good working order and troubleshoots equipment problems. ~Works with the Mohs surgeon to resolve quality control, patient, or procedural problems. ~Consistently follows all policies, procedures and protocols set by Federal, state and local agencies. ~Maintains an extremely high level of confidentiality and follows HIPPA guidelines. ~Responsible for delivering a high level of customer service in all interactions with patients, providers, employees, vendors, and guests. ~Performs other duties as assigned." 2-Review of Histology testing personnel (TP#1 and TP#2) 2022 competency assessments revealed the laboratory's technical supervisor failed to perform assessment of problem solving skills on the competency assessment. 3-Interview with the CLIA Coordinator at approximately 3:00 pm on 06.15.2023 in the conference room, confirmed the above findings. Word Key: MOHS= micrographically oriented histograph surgery