Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0312905	09/10/2026
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: CITATION ONE Based on a review of the submitted Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report Form CMS-209 (FORM CMS-209), a review of the laboratory's procedure manual, a review of personnel records, and staff interview, the histopathology laboratory failed to establish a written policy for competency assessment of testing personnel and failed to have competency assessments that included the six criteria required in Subpart M of the State Operations Manual (SOM) Appendix C for two of two testing personnel in 2025 and 2026. The findings include: 1. A review of the FORM CMS-209 listed two testing personnel (TP), TP3 and TP4, for high complexity testing, who performed gross examination of surgical pathology specimens. 2. A review of the histopathology laboratory's policy and procedure manual revealed no written policies and procedures for employee competency assessment. 3. A review of laboratory personnel records revealed the following testing personnel competency assessments that failed to include the six CLIA criteria: 1.) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing, 2.) Monitoring the recording and reporting of test results, 3.) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records, 4.) Direct observation of performance of instrument maintenance and function checks, 5.) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples, and 6.) Assessment of problem-solving skills, as required in Subpart M of the SOM Appendix C: -TP 3: competency

	assessments dated 07.15.2025 and 08.04.2026 -TP 4: competency assessment dated 04.07.2026 4. An interview with the histopathology laboratory supervisor on 09.10.2026 at 11:30 a.m. confirmed the above survey findings. CITATION TWO Based on a review of the submitted Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report Form CMS-209 (FORM CMS-209), laboratory's policy, personnel records, and staff interview, revealed that the micrographically oriented histographic surgery (MOHS) laboratory failed to follow the established policy for competency assessment for one of two testing personnel (TP) who performed slide interpretation of tissue removed during MOHS procedures in 2025. The findings included: 1. A review of the submitted FORM CMS-209 form listed two TP, TP1 and TP2, for high complexity testing who performed slide interpretation of tissue removed during MOHS procedures. 2. A review of the MOHS laboratory's "Quality Assurance Program" policy revealed, "New laboratory personnel are evaluated with in the first 6 months, at the 1 year and then annually." 3. A review of laboratory personnel records revealed no documented annual competency assessment in 2025 for TP2 as listed on the FORM CMS-209. 4. An interview with the histopathology laboratory supervisor on 09.10.2026 at 11:30 a.m. confirmed the above survey findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: CITATION ONE Based on laboratory observations, a review of the laboratory's procedure manual, a review of micrographically oriented histographic surgery (MOHS) patient specimen slides, and staff interviews, the laboratory failed to follow the slide-labeling procedure for eight of eight cases, totaling 53 slides reviewed in 2025 and 2026. The findings include: 1. Observation of the MOHS laboratory on 09.10.2026 at 8:30 a.m. revealed equipment, glass slides, tissue marking dyes, and stains used to process tissue removed during MOHS procedures. 2. A review of the laboratory's procedure, "Histopathology MOHS Micrographic Surgery," revealed that "Slides are labeled either with a hand written label including case number, full patient name and date, site and stage of MOHS or the same information is written directly on the slide." 3. A review of eight MOHS cases revealed the following MOHS cases with specimen slides that failed to include the patient's full name: -MOHS Case: K-370, date of service(dos): 04.02.2025, 3 slides -MOHS Case: RGW25-501, dos: 04.03.2025, 8 slides -MOHS Case: K-1040, dos: 08.26.2025, 7 slides -MOHS Case: RGW25-1470, dos: 08.07.2025, 12 slides -MOHS Case: K-21, dos: 01.06.2026, 3 slides -MOHS Case: RGW26-58, dos: 01.15.2026, 6 slides -MOHS Case: K-1001, dos: 07.07.2026, 10 slides -MOHS Case: RGW26-963, dos: 07.28.2026, 4 slides 4. An interview with the histopathology laboratory supervisor and the MOHS lab processing technician on 09.10.2026 at 10:00 a.m. confirmed the above survey findings. CITATIONTWO Based on a review of the submitted Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report Form CMS-209 (FORM CMS-209), review of the laboratory's policies and procedures, records review, and a staff interview, the laboratory failed to follow its policy for biannual physician proficiency testing for one of two testing personnel (TP) in 2025. The findings

	include: 1. A review of the submitted FORM CMS-209 form listed two TP, TP1 and TP2, for high complexity testing who performed slide interpretation of tissue removed during micrographically oriented histographic surgery (MOHS) procedures. 2. A review of the laboratory's policy titled "Physician Proficiency Testing" revealed the following statement "A review of the test results on each MOHS provider is performed bi-annually. This review is to insure the accuracy of each test result and quality of slides the laboratory is producing. One set of random patient slides are sent on each MOHS provider and checked by a Dermatopathologist or a different MOHS provider." 3. A review of the laboratory's records revealed no documentation that the laboratory performed "physician proficiency testing" biannually for TP2 in 2025. 4. An interview with the histopathology laboratory supervisor on 09.10.2026 at 11:30 a. m. confirmed the above survey findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on a review of the submitted Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report Form CMS-209 (FORM CMS-209), lack of records, staff interview, and electronic mail communication, the laboratory director failed to ensure testing personnel four (TP4) had received the appropriate training and demonstrated accuracy before performing gross examination of patient tissue removed during histopathology procedures, with approximately 7000 cases grossed since TP4 began testing patient testing on 10.27.2025 until the date of the survey on 09.10.2026. The findings include: 1. A review of the FORM CMS-209 listed two testing personnel (TP), TP3 and TP4, for high complexity testing, who performed gross examination of surgical pathology specimens. 2. A review of training documentation revealed no record of documented training or demonstration of accuracy of test performance for grossing of patient tissue samples removed during histopathology procedures for TP4 by the laboratory director before patient testing began on 10.27.2025. 3. An interview with the histopathology laboratory supervisor on 09.10.2026 at 11:30 a.m. confirmed the above survey findings. 4. Electronic mail communication on 09.15.2026 at 9:00 a. m. with the histopathology laboratory supervisor confirmed that TP4 started patient testing on 10.27.2025 with approximately 7000 cases grossed from 10.27.2025 through the date of the survey, 09.10.2026.