Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2050521	04/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Associated Plastic Surgeons Of Western New York Pc	5604 Main Street,, Williamsville, NY	

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: Based on surveyor's review of the competency assessment policies and two histotechnicans personnel records, the laboratory failed to follow the laboratory's written competency assessment policies and perform a six months competency evaluation for the new histotech and an annual competency evaluation for part time histotech. FINDINGS: The surveyor's findings on April 9, 2019 at approximately 10: 00 AM found that the laboratory failed to follow the their established written competency assessment policies, that requires assessment at six months after training for new hire and annually thereafter. a. a six month competency evaluation for the new histotech hired on November 2, 2017 and training completed on May 2018 was not performed. b. an annual competency evaluation for the part time histotech was not performed in the 2018.
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 surveyor's review of the laboratory's Mohs' procedures and lack of twice

	year verification records for Mohs slides, the laboratory failed to verify the accuracy of the Mohs slides in the calendar year 2018. Approximately 402 patient Mohs slides were interpreted and results reported for Mohs' surgery.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory's Quality Assessment (QA) policies and the lack of QA records for the calendar year 2018, the laboratory failed to follow their established QA policy and perform an annual QA review in the calendar year 2018. FINDINGS: The surveyor's findings on April 9, 2019 at approximately 10:30 AM found that the laboratory's QA policy states, "that an annual QA review is performed and review is documented for the following laboratory systems: 1. patient test management 2. complaint investigation and communication 3. personnel competency 4. comparison of test results 5. procedure manual 6. quality control 7. test reports and test requisition
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor's review of the current test requisition in use for Mohs' surgery, the laboratory failed to include the new address, when the laboratory moved to their current location on May 11, 2017. FINDINGS: The surveyor's findings on April 9, 2019 at approximately 10:00 AM found that the current test requisition in use has the histopathology processing laboratory's address at 5611 Main St., Williamsville NY 14221, which closed on May 11, 2017. The Mohs' laboratory was moved to the current address at 5604 Main St., Williamsville, NY 14221.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	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. This CONDITION is not met as evidenced by: Based on surveyor's review of laboratory records, the laboratory failed to ensure that the: 1. current laboratory director sign and date the Dermatology/Mohs Procedure manual, refer to D5407; 2. laboratory follow the manufacturer's temperature requirements for the Lecia Cryostat CM 1850, refer to D5413; 3. containers used for staining Mohs slides were labeled, refer to D5415; 4. laboratory follow the established cryostat and microscope maintenance policy, refer D5429; 5. laboratory failed to identify and take corrective action for the mislabeled Mohs slides, refer to D5779.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor's review of the Dermatology/Mohs Procedure manual, at the time of this survey, the current laboratory director failed to approve, sign and date of review for the Dermatology/Mohs Procedure manual. FINDINGS: 1. The surveyor's findings on April 9, 2019 at approximately 10:00 AM confirmed that the current laboratory director failed to approve, sign and date the Dermatology/Mohs Procedure manual. 2. The laboratory had two staining procedures for the Mohs slides, both refer to a automatic strainer, the surveyor could not verify which staining procedure in the Mohs manual is currently used for staining the Mohs slides.
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 surveyor's review of the Lecia Cryostat temperature logs, the laboratory failed to record the temperature for the cryostat from 5/11/2017 through 12/31/2017. Approximately 38 patient samples were processed during this time-period. FINDINGS: The surveyor's findings on April 9, 2019 at approximately 11:00 AM found that the laboratory failed to record the temperature for the cryostat from 5/11

	/2017 through 12/31/2017. Approximately 38 patient samples were processed during this time-period.
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: Based on surveyor's review of the laboratory's staining procedure, observation of the staining containers, the laboratory failed to label the containers used for staining the Mohs slides. FINDINGS: The surveyor's findings on April 9, 2019 at approximately 11:00 AM found that the containers used for staining the Mohs' slides were not labeled to identify the concentration, stains Hematoxylin & Eosin (H & E), alcohol and solutions.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor's review of the Lecia CM 1850 cryostat and microscope maintenance procedures and lack of preventative maintenance(PM) records, the laboratory failed to perform an annual preventative maintenance for the calendar years 2017 and 2018. FINDINGS: 1. The surveyor's findings on April 9, 2019 at approximately 11:30 AM found that the laboratory did not implement the plan of correction from the survey conducted on April 27, 2017 and perform and annual PM for the cryostat and microscope in the calendar years 2017 and 2018. 2. No documentation was available for PM and/or services for the cryostat and microscope when the equipment was moved to 5406 Main St. on 5/11/2017. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED APRIL 27, 2017.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor's review of the Mohs' accession log book, Mohs slides and Mohs map and patient's chart, the laboratory failed to identify the mislabeling of the Mohs

	slides and Mohs map reports for three cases on 12/13/18. FINDINGS: 1. The surveyor's findings on April 9, 2019 at approximately 11:00 AM found that the Mohs accession log book with the patient's Mohs slides, Mohs' map report did not correlate with the patient's information for the following cases: a. Case M18-47 patient name in the accession log did not correlate with the name and accession number on the Mohs slide and Mohs map report b. Case M18-48 patient name in the accession log did not correlate with the name and accession number on the Mohs slide and Mohs map report b. Case M18-49 patient name in the accession log did not correlate with the name and accession number on the Mohs slide and Mohs map report 2. The laboratory failed to identify and take corrective action for the difference between patient and specimen information.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor's random review of 25 patient's Mohs test reports from May 25, 2017 through April 4, 2019, the laboratory failed to include the current address of the Mohs laboratory location. FINDINGS: The surveyor's findings on April 9, 2019 at approximately 11:30 AM found that the laboratory failed to include the current address of the Mohs laboratory location. a. The Mohs' laboratory was moved to the current address at 5604 Main St., Williamsville, NY 14221 on May 11, 2017 from 5611 Main St. Williamsville, NY 14221 b. Surveyor performed a random review of 25 Mohs reports from May 25, 2017 through April 4, 2019 and found all 25 charts had the old address.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's review of laboratory records and findings and an interview with the pathologist/laboratory director, the laboratory director failed to fulfill his responsibilities and provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. current laboratory director sign and date the Dermatology/Mohs Procedure manual, refer to D6087; 2. laboratory follow the established and written QA policy to include, refer to D6094; 3. laboratory personnel perform all testing procedures to provide accurate and reliable test results, refer to D6102.

D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Mohs procedure manuals, the laboratory director failed to ensure that the laboratory was performing testing according to the laboratory's procedure manual. Refer to D5407, D5413 and D5415.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a surveyor review of the QA program, laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to: D5413, D5217, D5291, D5305, D5407, D5413, D5429, D5779 and D5805.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 surveyor's review of the histotech personnel records and review of Mohs patient charts for 12/13/2018, the laboratory director failed to ensure that the histotech could perform all testing operation for Mohs surgery and provide accurate results. Refer to D5413, D5415 and D5779.