Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1080362	06/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Assoc Ltd	236 Brodhead Rd, Suite #100, Bethlehem, PA	

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 review of Laboratory competency policy and interview with testing personnel (TP) #11, the laboratory failed to follow their competency assessment policies to assess 4 of 5 clinical consultants (CC) and 1 of 2 general supervisors (GS) for competency in 2020. Findings include: 1. The competency policy states "staff who hold CLIA supervisors positions: (general supervisor, Technical consultant, technical supervisor, or clinical consultant), will be assessed annual for their supervisor competence in addition to laboratory. 1. On the day of survey, 06/09/2020, the laboratory could not provide competency assessment performed on 4 of 5 CC and 1 of 2 GS. 3. TP #11 confirmed the findings above on 06/09/2020 around 09:30 am.
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 the review of the KOH and scabies examination procedures and interview with testing personnel (TP) #11, the laboratory failed to include quality control (QC) measures in the KOH and scabies microscopic examination procedures from 01/16 /2020 to 06/09/2020. Findings Include: 1. On the date of survey, 06/09/2020, review of the KOH and scabies microscopic examination procedures revealed, the procedures did not include QC measures. 2. The laboratory could not provide QC records for KOH and scabies microscopic examinations read from 01/16/2020 to 06/09/2020. 3. From 01/16/2020 to 06/09/2020, 3 KOH microscopic examinations were analyzed. 4. From 01/16/2020 to 06/09/2020, 32 scabies microscopic examinations were analyzed. 5. TP#11 confirmed the findings above on 06/09/2020 around 9:35 am. *****KOH = Potassium Hydroxide
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the review of Mohs Hematoxylin and Eosin (H&E) quality control (QC) records and interview with testing personnel (TP) #11, the laboratory failed to document QC each time of patient testing for Mohs microscopic examination H&E stained slides from 01/16/2020 to 06/09/2020. Findings Include: 1. On the date of survey, 06/09/2020, review of the H&E stain logs revealed, the TP reading the slides did not document QC. 2. From 01/16/2020 to 06/09/2020, 14 patients were seen for Mohs microscopic examination. 3. TP#11 confirmed the findings above on 06/09 /2020 around 9:15 am.
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 the review of patient test reports (6 of 6 sampled) and interview with testing personnel (TP) #11 the laboratory failed to include on their test reports the location where mohs, KOH and scabies microscopic examinations were analyzed from 01/16/2020 to the date of survey. Finding Include: 1. On the day of survey, 06/09/2020, a review of some test reports (6 of 6 sampled) revealed, the mohs, KOH and scabies microscopic examination test reports did not include the correct address where the slides were being analyzed. 2. Slides were read at Advanced Dermatology Associates (236 Brodhead Road, Suite 100, Bethlehem PA 18017) but Advanced Dermatology Associates (1259 S Cedar Crest Blvd #100, Allentown, PA 18103) were listed on the final reports. 3. From 01/16/2020 to 06/09/2020, 14 patients were seen for Mohs microscopic examinations. 4. From 01/16/2020 to 06/09/2020, 3 KOH microscopic examination were analyzed. 5. From 01/16/2020 to 06/09/2020, 32 scabies microscopic examination were analyzed. 6. TP#11 confirmed the findings above on 06/09/2020 around 9:45 am. ****KOH = Potassium Hydroxide