Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2004723	01/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Nj Pc	700 Paramus Park, Paramus, NJ	

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 the lack of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform a CA on one out of one testing personnel for the calendar years 2019 and 2018. The OM confirmed on 1/22/20 at 10: 30 am that the CA was not performed as stated above.
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 surveyor review of the Procedure Manual (PM), observation of the Manual Staining Station (MSS) and interview with the Office Manager (OM), the laboratory failed to follow Mohs Staining Procedure from 1/31/18 to the date of the survey. The findings include: 1. The MSS in the laboratory did not correspond with the staining procedure in the PM. a) The PM stated Staining Container (SC) # 5 was for 95% Alcohol but the MSS had water. 2. Approximately 300 patients were stained. 3. The OM confirmed on 1/22/20 at 10:00 am that laboratory failed to follow the PM.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Cryostat Maintenance Log (CML) and interview with the Office Manager (OM), the laboratory failed to take and document Corrective Action (CA) when the Cryostat Temperature (CT) was out of range on 8/14/19. The finding includes: 1. A review of the CML revealed that CT was outside the established range on 8/14/19. 2. There was no documented evidence of corrective action taken. 3. Approximately 12 patient samples were prepared in the Cryostat. 4. The OM confirmed on 1/22/20 at 10:45 am the laboratory did not document corrective action.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL) Mohs Maps (MM) and interview with the Office Manager (OM), the laboratory failed to maintain an accurate information system for Mohs tests from 11/6/19 to the date of the survey. The findings include: 1. Review of five AL entries revealed: a. Two patients had a testing date of 11/6/19 but the AL had 11/16/19 b. One patient had a testing date of 12/2/19 but he AL had 12/4/19 2. The OM confirmed on 1/22/20 at 11:25 am that the laboratory did not maintain an accurate information system.