

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1078763	(X3) Date Survey Completed 11/03/2022
Name of Provider or Supplier Advanced Dermatology, Pc	Street Address, City, State 570 Egg Harbor Road, Sewell, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar years 2021 and 2020. The OM confirmed on 11/3/22 at 11:00 am that BA was not performed.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), Biannual Assessment (BA) and interview with the Office Manager (OM), the laboratory failed to have a complete procedure for BA at the time of survey. The finding includes: 1. The OM stated that "BA was not performed in 2020 and 2021 due to the fact that the reference laboratory where they sent BA cases was closed due to Covid" 2. The OM confirmed they had no alterative procedure for the above mentioned situation. 3. The OM confirmed on 11/3/22 at 11:40 am the laboratory did not have a complete procedure for BA. b) Based on surveyor review of the Procedure Manual (PM), observation of</p>

Staining Station (SS) and interview with the Office Manager (OM), the laboratory failed to follow the PM for Hematoxylin-Eosin (HE) staining form 10/10/19 the date of the survey. The findings include: 1. The SS in the laboratory did not correspond with the staining procedure in the PM. 2. The observation of the staining solutions and reagents in the SS had 2 changes of Clearing agent. 2. The PM stated to have three changes of clearing agent. 3. The OM confirmed on 11/3/22 at 11:30 am that the laboratory did not follow the PM.