

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2063474	(X3) Date Survey Completed 12/07/2023
Name of Provider or Supplier Advanced Dermatology And Skin Surgery, Pa	Street Address, City, State 35 Mann Drive, Asheville, NC	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based upon the absence of 2022 and 2023 quality control documentation and interview with TP (Testing Personnel) #1 on 12/7/23, the laboratory failed to check its H&E (hematoxylin and eosin) stain each day of use to ensure its intended staining characteristics. Findings: During survey, the absence of 2022 and 2023 "H&E Stain Control" logs was observed. In interview at approximately 11:35 a.m., TP #1 confirmed that she does not utilize the "H&E Stain Control" log when she reviews slides at this location.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by:</p>

Based upon the absence of 2022 and 2023 competency records and interview with TP (Testing Personnel) #1 on 12/7/23, the Laboratory Director failed to assess the competency of 1 of 1 testing personnel in the laboratory. Findings: During survey, the absence of 2022 and 2023 competency records for TP #1 was observed. In interview at approximately 11:35 a.m., TP #1 confirmed the Laboratory Director does not assess her competency for testing she performs at this location.