

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2134444	(X3) Date Survey Completed 10/06/2022
Name of Provider or Supplier Dermopath Service	Street Address, City, State 676 Us Highway 202/206 N Building #2, Bridgewater, 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 surveyor review of the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar years 2020 and 2021. The finding includes: 1. The BA logs did not have dates written when BA was performed. 2. There were no credentials for the physician reviewing the slides for BA. 3. The GS confirmed on 10/6/22 at 10:30 am that the laboratory did not verify the accuracy of Histopathology twice a year.</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: Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to follow all procedures written for "Microscope Equipment" from 9/19/19 to the date of the survey. The findings include: 1. There was no documented evidence the below mentioned procedure was followed:</p>

a. "Yearly Maintenance:", "1. The microscope must have yearly maintenance done by a pathologist with experience.", "2. The yearly maintenance must be documented" 2. There was no documented evidence that yearly maintenance was performed on the microscope. 3. The LD confirmed on 10/6/22 at 10:30 am that the laboratory did not follow the PM.