

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2134444	(X3) Date Survey Completed 09/19/2019
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 Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the LD failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar year 2018. The LD confirmed on 9/19/19 at 10:10 am that the laboratory did not verify the accuracy of Histopathology testing twice annually in 2018.</p>
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on lack of a Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to have an approved PM for the professional component of Histopathology testing from 5/17/18 to the date of the survey. The LD confirmed on 9/19/19 at 10:00 am that the LD did not ensure an approved PM was available.</p>