

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0995034	(X3) Date Survey Completed 01/18/2022
Name of Provider or Supplier Elizabeth M Spiers Md Llc	Street Address, City, State 1456 Ferry Road, Doylestown, PA	
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 peer review records and interview with the Laboratory Director (LD), the laboratory failed to asses at least biannually verification accuracy of histology slides read on site in 2020. Findings include: 1. On the day of survey, 01/18/2022 at 11:30 a. m The laboratory director could not provide peer review records from 1/1/ 2020 to 12 /31/2020. 2. The LD confirmed the finding above on 01/18/2022 at 12:00 p.m.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Assurance (QA) documentation and interview with the Laboratory Director (LD), the Laboratory Director (LD) failed to ensure a QA program, was established and maintained to ensure the quality of services provided by the laboratory in 2020 and 2021. Findings include: 1. On the day of survey 1/18/2022 at 11:44 a.m., The LD could not provide a QA documentation that reviews the pre-analytical, analytical, and post analytical phases of the laboratory in 2020 and 2021. 2. The LD confirmed there were no QA records on 01/18/2022 at 12:00 p.m.</p>