

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0189114	<b>(X3) Date Survey Completed</b> 06/08/2021
<b>Name of Provider or Supplier</b> Dr Jessica Pagana-Defazio Fpc	<b>Street Address, City, State</b> 1072 Market Street, Sunbury, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director (LD), the laboratory failed to document maintenance for 1 of 1 refrigerator thermometer in 2021. Findings include: 1. On the day of survey, 05/26/2021, Observation of laboratory revealed, a Fisher Brand Traceable thermometer's on the laboratory refrigerator was due for service on April 17, 2021. 2. The laboratory could not provide documentation of service performed on the thermometer from April 17, 2021 to June 8, 2021. 2. The LD confirmed the finding above at the summation on 06/08/2021 around 2:10 pm.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT)</p>

records and interview with the laboratory director (LD), the LD failed to ensure that all proficiency testing reports identify any problems that require corrective actions in 2020. Findings include: 1. On the day of survey, 06/08/2021, review of the API PT revealed, on the 2020 event #3 for red blood cell count, the laboratory received a score of 60%. 2. The laboratory did not document a complete corrective action for the unsuccessful PT score. 3. The LD confirmed the finding above at the summation on 06/08/2021 around 2:10 pm.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel (TP) competency assessment records, proficiency testing (PT) records and interview with the laboratory director, the Technical Consultant (Laboratory director) failed to assess the competency of 1 of 2 TP through internal blind testing samples or external PT samples in 2020. Findings Include: 1. On the day of survey, review of TP competency assessment records, and PT records revealed, 1 of 2 TP (TP#2) was not assessed for their test performance through internal blind testing samples or external PT samples on the Abbott Cell Dyn Emerald hematology analyzer in 2020. 2. The LD confirmed the finding above at the summation on 06/08/2021 around 2:10 pm.