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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D0189114 | <b>(X3) Date Survey Completed</b><br>06/13/2023 |
| <b>Name of Provider or Supplier</b><br>Dr Jessica Pagana-Defazio Fpc   | <b>Street Address, City, State</b><br>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>  |
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| <b>D2009</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's procedure manual, American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory director (LD), the LD/designee and testing personnel (TP) failed to sign 11 of 18 API PT attestation statement documents for chemistry, hematology, and microbiology testing performed in 2021 and 2022. Findings Include: 1. The Office Lab Proficiency procedure states, "When surveys are received: Laboratory Director/Designee must sign the survey form." 2. On the day of the survey, 06/13/2023 at 10:15 am, the following 11 of 18 API PT attestation statements reviewed were not signed by the LD or designee in 2021 and 2022. - Miscellaneous Chemistry: - 2021 Event #2 - 2022 Event #1 - 2022 Event # 2 -Chemistry Core: - 2021 Event # 3 - 2022 Event # 2 - Microbiology: - 2022 Event # 1 - 2022 Event #2 - 2022 Event # 3 - Hematology /Coagulation - 2021 Event # 3 - 2022 Event # 1 - 2022 Event #2 3. The following 2 of 18 API PT attestations reviewed were not signed by TP that performed the testing: - Chemistry Core - 2021 Event # 3 - 2022 Event # 2 4. The LD confirmed the findings above on 06/13/2023 around 11:00 am.</p> |
| <b>D6048</b>              | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413(b)(8)(ii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.</p>   |

This STANDARD is not met as evidenced by:

Based on review of competency assessment records, and interview with the laboratory director (LD), the technical consultant (TC) failed to provide documentation for the monitoring of recording and reporting of test results for 1 of 4 testing personnel (TP) that performed complete blood cell counts (CBC) from 07/09/2022 to the date of survey. Findings include: 1. On the day of the survey, 06/13/2023 at 09:00 am, the competency assessment records revealed that the TC failed to document the monitoring of the recording and reporting of test results for 1 of 4 TP (CMS 209 TP #1) that performed CBC testing on the Cell-Dyn Emerald hematology analyzer from 07/09/2022 to 06/13/2023. 2. The LD confirmed the findings above on 06/13/2023 around 11:00 am.