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| <p>Statement of Deficiencies</p> | <p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>39D0986679</p> | <p>(X3) Date Survey Completed</p> <p>06/04/2025</p> |
| <p>Name of Provider or Supplier</p> <p>Salimetrics Llc</p> | <p>Street Address, City, State</p> <p>101 Innovation Boulevard Suite 302, State College, PA</p> | |
| <p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p> | | |

| <p>(X4) ID Prefix Tag</p> | <p>Summary Statement of Deficiencies</p> |
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| <p>D5209</p> | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview with the General Supervisor (GS), the laboratory failed to follow established procedures to assess the competency of 2 of 2 General Supervisor (GS) for their supervisory responsibilities in 2023 and 2024. Findings Include: 1. The laboratory's Clinical Laboratory Quality System Regulations Manual states: " The Laboratory Director will annually evaluate the competency of the General Supervisor on form CL-001-F02." 2. On the day of survey, 06/04/2025 at 09:45 am, the laboratory could not provide the annual competency assessment for 2 of 2 GS (CMS 209 personnel #2 and #3) for their supervisory responsibilities in 2023 and 2024. 3. The GS confirmed the finding above on 06/04/2025 at 10:00 am. *** Repeat deficiency ***</p> |
| <p>D6128</p> | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on review of the Laboratory Personnel Report (CMS-209), competency assessment (CA) records and interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to evaluate the annual competency of 1 of 5 testing personnel (TP) that performed Enzyme-linked immunoabsorbant assay (ELISA) testing in 2024. Findings include: 1. On the day of survey, 06/04/2025 at 9:45 am, review of the laboratory's CA records revealed the TS failed to perform the annual competency assessment for 1 of 5 TP (CMS 209 TP# 1) that performed ELISA testing in 2024. 2. The laboratory reported an annual volume of 2600 ELISA tests (CMS 116 estimated annual volumen for 2024). 3. The GS confirmed the findings above on 06/04/2025 at 9:45 am.