

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0986679	<b>(X3) Date Survey Completed</b>  04/17/2023
<b>Name of Provider or Supplier</b>  Salimetrics Llc	<b>Street Address, City, State</b>  101 Innovation Boulevard Suite 302, State College, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 and interview with the General Supervisor (GS), the laboratory failed to perform the annual competency assessment of 1 of 1 General Supervisor (GS) for their supervisory responsibilities in 2021 and 2022. Findings Include: 1. On the day of survey 04/17/2023 at 11:55 am, the laboratory could not provide the annual competency assessment for 1 of 1 GS (CMS 209 personnel #2) for their supervisory responsibilities in 2021 and 2022. 2. The TS confirmed the finding above on 04/17/2023 at 01:30 pm.</p>
<b>D5221</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with General Supervisor (GS), the laboratory failed to document the evaluation and verification activities for 8 of 8 PT testing performed in chemistry in 2022 and 2023 . Findings Include: 1. On the day of the survey, 04/17/2023 at 12:25 pm, a review of PT records revealed that the laboratory did not document the Laboratory Director (LD) review for the following PT testing: - 4 of 4 PT results for Melatonin in 2022 - 2 of 2 PT results</p>

for Cortisol in 2022 (Q3, Q4) - 1 of 1 PT results for Melatonin in 2023 -1 of 1 PT results for Cortisol in 2023. 2. The laboratory did not document corrective action for the melatonin out of range result Q3 2022. 3. The laboratory annual test volume is 2335 for chemistry (CMS 116) 4. GS confirmed the findings above on 04/17/2023 at 01:30 pm.