

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0986679	<b>(X3) Date Survey Completed</b>  04/08/2021
<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>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 review of the laboratory procedure manuals and interview with the regulatory compliance specialist, the general supervisor (GS), testing personnel (TP) #1 and #2, the laboratory failed to establish a complete competency assessment procedure to assess the competency for 2 of 2 TP performing salivary amylase and cortisol tests on the Biotech ELX-808 plate reader in 2020. Findings include: 1. On the day of survey, 04/08/2021, the laboratory failed to provide a complete written competency assessment procedure, to evaluate the competency for 2 of 2 TP performing salivary amylase and cortisol tests on the Biotech ELX-808 at least semiannually during the first year the individual tests patient specimens and the assessment of CLIA 6 points of competency in 2020. 2. The laboratory could not provide 6 month competency assessment records for TP #1 and #2. 3. Competency assessment evaluations performed in 2020 did not include the following: - Evaluation of direct observations of routine test performance, specimen handling, processing and testing. - Evaluation of direct observations of performance of instrument maintenance and function checks. 4. The regulatory compliance specialist and GS confirmed the findings above on 04/08/2021 around 09:00 am.</p>