

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0664964	<b>(X3) Date Survey Completed</b>  12/09/2021
<b>Name of Provider or Supplier</b>  Elmwood Pediatric Group Llp	<b>Street Address, City, State</b>  919 Westfall Road - Bldg A, Ste 105, Rochester, NY	
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 surveyor's review of the laboratory's training &amp; competency evaluation policy, review of the testing personnel training &amp; education records and an interview with the general supervisor/testing person, the laboratory director failed to follow their establish training &amp; competency assessment policy. FINDINGS: 1. The general supervisor/testing person confirmed on December 9, 2021 at approximately 9:30 AM, the surveyor's findings that the laboratory failed to follow their written competency assessment policy, which included the six required components. a. The laboratory did perform the training, six month and annual competency for the calendar years 2019, 2020 and 2021 using a form titled "Elmwood Pediatric Group Training and Education Record" which only listed the waived and moderate complexity tests that is performed. The laboratory director performed the evaluation and recorded as a check mark along the list of tests. b. However, the form "Elmwood Pediatric Group Training and Education Record" for recording the initial training, six month and annual competency for the three new and nine testing personnel did not include the six required components. The six required components are: 1. direct observation of routine patient test performance, including preparation. specimen handling and testing; 2. monitoring the recording and reporting of test results. 3. review of intermediate results of worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. direct observation of performance of instrument maintenance and function checks; 5. assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, 6. assessment of problem solving skills.</p>