

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0931212	(X3) Date Survey Completed 01/20/2022
Name of Provider or Supplier Cytokine Reference Laboratory	Street Address, City, State 13-127 Pwb, 516 Delaware St Se, Minneapolis, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from 2 identical analyzers and between automated and manual methods at least twice annually in 2020 and 2021. Findings are as follows: 1. The laboratory performed General Immunology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 01/20/22. 2. Two identical ProteinSimple Ella automated test systems were observed as present and available for use during the tour. The first system was implemented in April 2020 and the second in September 2020 as indicated by the LD. Both Ella test systems were used for Cytokine Storm 4Plex and Cytokine Inflammation 4Plex testing. The analytes included in the 4Plex panels were listed on the List of Assays provided by the laboratory. See below. Cytokine Storm 4Plex - implemented April 2020 IL-1b IL-6 IL-8 TNFa Cytokine Inflammation 4Plex - Implemented April 2020 IFNg IL-10 IL-18 IL-2ra 3. Equipment used for manual ELISA testing was also observed during the laboratory tour. The analytes tested using the manual ELISA method were listed on the List of Assays provided by the laboratory. Four of these analytes were also included in the 4Plex panels. See below. Manual ELISA tests IL-1b IL-6 TNFa IFNg 4. A twice annual process for comparison of test results obtained from multiple analyzers and/or multiple testing methods was not established in the laboratory's policies and procedures. 5. Comparison of the 4Plex test results obtained from both Ella test systems or comparison of test results obtained</p>

from the Ella and manual ELISA methods was not found during review of laboratory records from 2020 and 2021. The laboratory was unable to provide documentation of test comparisons upon request. 6. In an interview at 12:15 p.m. on 01/20/22, the Technical Supervisor confirmed the above findings. .