

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0947884	(X3) Date Survey Completed 03/02/2023
Name of Provider or Supplier Sanford Worthington Clinic	Street Address, City, State 1680 Diagonal Road, Worthington, 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 two identical Microbiology analyzers at least twice annually in 2021 and 2022. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor during a tour of the laboratory at 10:30 a.m. on March 2, 2023. 2. Two identical Cepheid GeneXpert test systems were observed as present and available for use during the tour. Both test systems were used for Group A Strep, Influenza A & B, RSV and SARS CoV-2 testing. Serial # 815592 and #815585. 3. A twice annual comparison requirement for test results obtained from multiple instruments was established in the laboratory's Sample Comparison procedure, approved by the Laboratory Director on February 13, 2023. 4. Comparison of the test results obtained from both Cepheid GeneXpert test systems was not found during review of laboratory records for the period reviewed; May 2021 through January 2023. The laboratory was unable to provide documentation of the comparisons upon request. 5. In an interview at 1:50 p.m. on March 2, 2023, the General Supervisor confirmed the above findings. .</p>