

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405611	(X3) Date Survey Completed 01/27/2023
Name of Provider or Supplier Ortonville Area Health Services	Street Address, City, State 450 Eastvold Avenue, Ortonville, 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, record review, and an interview with laboratory personnel, the laboratory failed to evaluate and document the relationship between two Chemistry testing methods at least twice annually in 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by General Supervisor (GS) during a tour of the laboratory at 1:45 p.m. on 01/26/2023. 2. The following Chemistry methods for Basic Metabolic Panel (BMP) testing were observed as present and available for use during the tour: Siemens Dimension EXL- primary method iSTAT Chem-8+ - back up method 3. A twice annual process for comparison of test results obtained from multiple non-waived methods was found in the laboratory's procedure: Comparison of Test Results - Ortonville, signed by the Laboratory Director 12/15/2022. 4. Comparison of test results obtained from the two Chemistry methods was not found in laboratory records for 2022. The laboratory was unable to provide documentation of test comparisons upon request. 5. In an interview at 12:01 p.m. on 01/27/23, the GS confirmed the above finding. The GS indicated it was not done due to the fact they did not test any patients on the back-up method, however it was available for use as the laboratory's back-up chemistry analyzer during the 2022 year. .</p>