Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405611	02/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ortonville Area Health Services	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
D0000	The Ortonville Area Health Services laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey completed on February 6, 2025. The following standard-level deficiencies were cited: 493.1253 Establishment and verification of performance specifications .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete required performance verification (PV) activities for 1 of 45 analytes implemented in the laboratory in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant 1 (TC1) during a tour of the laboratory at 1:07 PM on 2/5/25. 2. An Ortho Vitros 7600XT Chemistry analyzer was observed as present and available for use during the tour. The laboratory performed Procalcitonin (PCT) testing using this analyzer beginning on 9/19/2023. 3. PV documentation for Chemistry testing on the Ortho Vitros 7600XT analyzer found in the System Verification manual included accuracy, precision, and reportable range verification for PCT. Reference range verification documentation for PCT was not found. The laboratory was unable to provide the missing documentation upon request. The Laboratory Director approved PV activities

	on 9/18/2023. 4. The laboratory was required to verify reference ranges for new analytes during PV activities as established in the New Test Requirements procedure found in the Lab Standard Operating Procedures and Policies manual. 5. In an interview at 9:31 AM on 2/6/2025, TC1 confirmed the above findings. 6. In an email received at 8:32 AM on 2/13/2025, TC1 indicated 389 PCT tests were performed on patient samples since 9/19/2023. .