Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2172713	11/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen Lutheran Medical Center	1122 West Highway 61, Winona, 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 Gundersen Winona Campus 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 November 20, 2025. The following standard-level deficiencies were cited: 493.1251 Procedure manual 493.1253 Establishment and verificaiton of performance specifications 493.1291 Test report .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure two of seven Chemistry analyte reference intervals and two of five Urinalysis reference intervals were included in the respective procedure manuals. Findings are as follows: 1. The laboratory performed Chemistry and Urinalysis testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 10:32 a.m. on 11/19/25. 2. The following equipment was observed as present and available for patient testing during the tour: Olympus BX43 for microscopic urinalysis Abbott iStat for blood gas analysis 3. Two of seven venous blood gas (VBG) reference intervals were not defined in the "Blood Gas (CG8+) iStat, Lab-0910" procedure provided by the laboratory. Additionally, two of five urine microscopic reference intervals were not defined in the "Manual Urine Microscopy, Lab 8185" procedure provided by the laboratory. Analyte Procedure TCO2 --- Base Excess --- Component Procedure Squamous Epithelial Cells --- Calcium Oxalate Crystals --- 5. In an interview at 12:10 p.m. on 11/20/25, the TS confirmed the above findings. 6. The TS provided the following annual test volumes in an email received at 9:40 a.m. on 11/26/25: VBG in 2025: 64 UA micro 2024: 6340 UA micro 2025: 5518 .
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 one of four required performance verification (PV) activities for three of three new Chemistry analytes implemented by the laboratory in 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 10:32 a.m. on 11/19/25. 2. A Roche Integra 400+ analyzer was observed as present and available for use during the tour. The laboratory performed Albumin (ALB), Aspartate Aminotransferase (AST), and Total Protein (TP) testing on this analyzer beginning in 07/12/25. 3. The laboratory was required to verify the reference intervals of new analytes or methodologies as defined in the "Quantitative Test Method Validation" procedure provided by the laboratory on the date of survey. 4. Reference interval verification documents were not found within PV activities provided by the laboratory. The laboratory was unable to provide the missing documentation upon request. The laboratory director approved the PV activities on 07/12/25. 5. In an interview at 12.57 p.m. on 11/19/25, the TS confirmed the above findings. 6. The laboratory performed the following test volumes on patient samples between 07/12/25 and 11/24/25 as indicated in an email received from the TS at 9:40 a.m. on 11/26/25: AST: 1433 Albumin: 1045 Total Protein: 541 .
D5807	TEST REPORT CFR(s): 493.1291(d)

	(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure two of five Urinalysis reference intervals and two of seven Chemistry reference intervals were included on a patient test report from 2024 and 2025. Additionally, the laboratory failed to ensure one of seven Chemistry reference intervals were consistent between the procedure and patient test report in 2025. Findings are as follows: 1. The laboratory performed Chemistry and Urinalysis testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 10:32 a.m. on 11/19/25. 2. The following equipment was observed as present and available for patient testing during the tour: Olympus BX43 for microscopic urinalysis Abbott iStat for blood gas analysis 3. One of five venous blood gas (VBG) reference intervals defined in the "Blood Gas (CG8+) iStat, Lab-0910" procedure provided by the laboratory were not consistent with VBG reference intervals included on a patient test report from 05/15/25. Additionally, two of seven pertinent VBG reference intervals were not included on the patient report. See below: Analyte Procedure Patient Report HCO3, venous 23-28 mmol/L 22-26 mmol/L TCO2 --- --- Base Excess --- --- Reference intervals for TCO2 and Base Excess were not defined in the "Blood Gas (CG8+) iStat, Lab-0910" procedure provided by the laboratory. See D5403. 4. Two of five urine microscopic reference intervals were not included on a patient test report from 10/03/24. See below: Component Patient Report Squamous Epithelial Cells --- Calcium Oxalate Crystals --- Reference intervals for Squamous Epithelial and Calcium Oxalate Crystals were not defined in the "Manual Urine Microscopy, Lab 8185" procedure provided by the laboratory. See D5403. 5. In an interview at 11: 19 a.m. on 11/20/25, the TS confirmed the above findings. 6. The TS provided the following annual test volumes in an email received at 9:40 a.m. on 11/26/25: VBG in 2025: 64 UA micro 2024: 6340 UA micro 2025: 5518 .