

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405983	(X3) Date Survey Completed 08/27/2026
Name of Provider or Supplier Centracare Melrose	Street Address, City, State 525 Main St W, Melrose, 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 CentraCare Melrose 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 performed on August 26, 2026 and August 27, 2026.. The following standard-level deficiency was 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 all required Performance Verification (PV) activities prior to reporting patient test results for 11 of 14 analytes implemented in 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 11:10 a.m. on 08/26 /26. 2. An Abbott Alinity chemistry analyzer and an Abbott i-STAT blood analyzer were observed as present and available for use during the tour. 3. The laboratory implemented the following Chemistry tests in 2025 as indicated below: Test Implementation date i-STAT CG4+ blood gas cartridge 03/11/25 -Analytes: pH, partial pressure of carbon dioxide, partial pressure of oxygen, bicarbonate, base excess, and oxygen saturation Alinity Albumin2 03/14/25 Alinity high-sensitivity Troponin I 03/18/25 Alinity Creatinine2 serum 04/01/25 Alinity Creatinine2 urine 04

/01/25 Alinity Total Bilirubin 04/01/25 4. PV documentation for the above tests found in the New Testing/Validations manual and the Sigma Strong manual included accuracy, precision, reportable range verification, and laboratory director approval. Reference range verification documentation was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 5. Reference range verification was required for new non-waived tests as established in the electronic Performance Verification - West Region procedure found in the laboratory's document management program PolicyStat. 6. 30,664 patient test reports were released without verified reference ranges after test implementation through 08/26/26, as indicated by the Technical Supervisor and listed below. Test Patient results i-STAT CG4 blood gas cartridge 135 Alinity Albumin2 5494 Alinity high-sensitivity Troponin I 1603 Alinity Creatinine2 serum 18000 Alinity Creatinine2 urine 301 Alinity Total Bilirubin 5131 7. In an interview at 3:40 p.m. on 08/26/26, the GS confirmed the above finding. .