Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405820	03/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Centracare Laboratory Services - Albany	30 Railroad Ave, Albany, 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 Laboratory Services - Albany 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 March 18, 2026. The following standard-level deficiency was cited: 493.1253 Establishment and verification of performance specification 493.1256 Control procedures 493.1407 Laboratory director responsibilities .
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 one of one Chemistry analytes implemented in 2026. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 during a tour of the laboratory at 11:05 a.m. on 03/18/26. 2. An Abbott i-STAT blood analyzer was observed as present and available for use during the tour. The laboratory implemented high-sensitivity Troponin I (hs-TnI) testing using the i-STAT on 03/02/26. 3. High Sensitive Troponin Test PV documentation approved by the laboratory director on 03/05/26 included accuracy, reference range, and linearity verification data completed in February and March 2026. Precision verification documentation was not found. 4. Precision verification

	was required for new non-waived tests as established in the Method Performance Specifications procedure provided by the laboratory on date of survey. 5. The Technical Consultant (TC) indicated 14 patients received hs-TnI testing on the i-STAT analyzer since test implementation to 03/18/26. 6. In an interview at 1:20 p.m. on 03/18/26, the TC confirmed the above finding. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform minimum quality control (QC) activities required for a Chemistry analyte in 2026. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by General Supervisor 1 during a tour of the laboratory at 11:05 a.m. on 03/18/26. 2. An Abbott i-STAT blood analyzer was observed as present and available for use during the tour. The laboratory implemented high-sensitivity Troponin I (hs-TnI) testing using the i-STAT on 03/02/26. 3. QC testing with 2 levels of material was required for new hs-TnI lots and shipments and every 30 days as established in the i-STAT hs-TnI procedure found in the iSTAT FIB, HCG, Mono, Strep, Flu, POC INR manual. The QC documentation log indicated hs-TnI QC was performed on 02/12/26 and 03/12/26. 4. An i-STAT hs-TnI Individualized Quality Control Plan (IQCP) to reduce the frequency of QC testing was not found during review of laboratory records. The laboratory was unable to provide an hs-TnI IQCP upon request. 5. 14 patients received hs-TnI test results from implementation to 03/18/26 as indicated by the Technical Consultant (TC). 6. In an interview at 3:20 p.m. on 03/18/26, the TC confirmed the above finding. .
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director (LD) failed to perform a site visit in 2025. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology,

	Immunology, Chemistry, and Hematology testing as indicated by General Supervisor 1 during a tour of the laboratory at 11:05 a.m. on 03/18/26. 2. The following analyzers, devices, and test kits were observed as present and available for use during the tour: Quidel Sofia infectious disease analyzer Abbott Architect c4000 chemistry analyzer Abbott i-STAT blood analyzer MEDTOXScan drugs of abuse test system DxH hematology analyzer Alcor miniiSED ESR analyzer Sysmex CA600 coagulation analyzer Cardinal Health hCG Combo test kit Nikon Eclipse microscope for manual differential and urine sediment examinations 3. Documentation of an LD site visit was not found during review of 2025 laboratory records and documents. 4. Twice annual laboratory director site visits were required as established in the Medical Director Responsibility procedure provided by the laboratory on data of survey. 5. In an interview at 2:35 p.m. on 03/18/26, the Technical Consultant confirmed the above finding and indicated the LD had not performed a site visit in 2025. .