

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0651643	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier Centracare - Long Prairie	Street Address, City, State 50 Centracare Drive, Long Prairie, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program as required under 493.801 for Chemistry testing performed in 2021. Findings are as follows: 1. The laboratory performed C-Reactive Protein (CRP) Chemistry testing in 2021 as indicated in the laboratory test menu provided by the Technical Supervisor (TS) prior to survey and confirmed by the TS during a tour of the laboratory at 8:10 a.m. on 04/26/23. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The CRP analyte was not included in API documentation for the three 2021 Chemistry PT events reviewed on date of survey. 4. In an interview at 11:20 a.m. on 04/26/23, the TS confirmed the above finding. .</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of one of one manual Endocrinology test performed in the laboratory at least twice annually in 2021. Findings are as follows: 1. The laboratory performed serum hCG testing using the Sekisui OSOM hCG Combo Test as as indicated by the laboratory test menu provided by the Technical Supervisor (TS) prior to survey and confirmed by the TS during a tour of the laboratory at 8:10 a.m. on 04/26/23. 2. The Laboratory performed proficiency testing using the American Proficiency Institute (API) proficiency testing provider in 2021. 3. Twice annual serum hCG accuracy verifications documentation for the Sekisui OSOM hCG Combo Test was not found for 2021 during review of API documents and laboratory records. The laboratory was unable to provide the missing accuracy verification documentation upon request. 4. In an interview at 4:00 p.m. on 04/26/23, the TS confirmed the above finding.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to follow their proficiency testing (PT) written procedure in 2023. Findings are as follows: 1. The laboratory performed serum hCG testing using the Abbott Architect ci4100 analyzer and the Sekisui OSOM hCG Combo Test as as indicated in the laboratory test menu provided by the Technical Supervisor (TS) prior to survey and confirmed by the TS during a tour of the laboratory at 8:10 a.m. on 04/26/23. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. The laboratory was enrolled in serum hCG PT on the Architect ci4100 in the Chemistry Core package and used the serum hCG Verification package for the OSOM hCG Combo Test in 2023 3. The Proficiency Testing Policy found in the electronic procedure software PolicyStat indicated the laboratory must follow all PT instructions. 4. The API instructions for the 2023 Chemistry - Core 1st event directed the laboratory to wait until after the Chemistry Core event submission deadline on 02/01/23 had passed before testing the serum hCG verification samples. 5. Architect ci4100 printed results dated 01/19/23 for serum hCG Chemistry - Core 1st event PT samples HCG-01 through HCG-05 were found in the API 3 ring binder. 6. The API Serum HCG Quantitative result form included the serum hCG results obtained on the Architect ci4100 handwritten in the designated text boxes. 7. Electronic medical record system HCG Serum QU labels generated on 01/19/23 for serum hCG verification samples HCG-01 through HCG-05 were found at the bottom of the API Serum HCG Quantitative result form. Each EMR label had a handwritten result of positive or negative. 8. In an interview at 10:55 a.m. on 04/26/23, the TS confirmed the above finding.