Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0651643	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Centracare - Long Prairie	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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Chemistry proficiency testing (PT) result for 1 analyte in 2021. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 05/12/21. 2. The laboratory performed PT using the American Proficiency Institute (API) program. 3. The laboratory received an unacceptable total carbon dioxide (tco2) PT result for 1 of 5 tco2 PT challenges completed in 2021. See below. API 2021 Chemistry / Core 1st event Sample Test IB-04 tco2 4. Investigation of unacceptable PT results was required as established in the Proficiency Testing Policy located in the on-line policy and procedure manual. 5. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 12:45 p.m., on 05/12/21, the GS confirmed the above finding. .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2019 proficiency testing (PT) result when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 05/12/21. 2. The laboratory performed PT using the American Proficiency Institute (API) program. 3. One urine culture minimum inhibitory concentration (MIC), for a total of 16 antibiotics, from the third 2019 Microbiology PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte UR-11 Urine culture MIC 4. Investigation of non-graded PT results was required as established in the Proficiency Testing Policy located in the on-line policy and procedure manual. 5. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above analyte was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. 6. In an interview at 12:45 p.m., on 05/12/21, the GS confirmed the above finding. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from the Hematology analyzer and a manual testing method at least twice annually. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 05/12/21. 2. A Beckman Coulter DxH hematology analyzer was observed as present and available for use during the tour. The GS indicated the laboratory performed and reported automated and manual White Blood Cell differential testing. 3. The Beckman Coulter DxH procedure located in the on-line policy and procedure manual did not include a requirement to compare automated and manual differential testing twice annually. Twice annual comparisons of these test methods was not found in laboratory records. The laboratory was unable to provide comparison records upon request. 4. In an interview at 09:15 a.m., on 05/13/21, the GS confirmed the above finding. .