Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406054	06/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Centracare - Sauk Centre	425 Elm Street North, Sauk Centre, 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 2019. 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 06/2/21. 2. The laboratory performed PT using the American Proficiency Institute (API) program. 3. The laboratory received an unacceptable partial pressure of oxygen (pO2) PT result for 1 of 5 pO2 PT challenges completed in 2019. See below. API 2019 Chemistry / Core 3rd event Sample Test IB-15 pO2 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 11:45 a.m., on 06/2/21, 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 6/2/21. 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 11:45 a.m., on 6/2/21, the GS confirmed the above finding. .
D5807	TEST REPORT CFR(s): 493.1291(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 a reference interval was consistent between a Chemistry procedure and a patient test report. 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 06/2/21. 2. An Abbott i-STAT chemistry analyzer was observed as present and available for use during the tour. 3. A reference interval listed in the Blood Gas & CHEM 8+ i-STAT Test System procedure, located in the on-line policy and procedure manual, was not consistent with that included on a patient test report reviewed on date of survey, as indicated below. Patient - adult female, aged 46 yrs, tested on 5/26/21 Test: Ionized Calcium Procedure 1.12 - 1.32 mmol/L Report 0.95 - 1.31 mmol/L 4. In an interview at 2:45 p. m., on 6/2/21, the GS confirmed the above finding. .