Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0651643	04/25/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. 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 program as required under 493.801 for testing performed under the subspecialty of Hematology. Findings are as follows: The laboratory failed to enroll in an HHS approved proficiency testing program for Blood Cell Identification. Failure to enroll in an HHS approved proficiency program as required under 493.801 constitutes Condition level non-compliance.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory

	failed to ensure microscopic examination proficiency testing (PT) was performed consistent with the number of times the laboratory routinely tested patient samples. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. Microscopic examination PT for Gram Stain and Morphology from the API 2018 Microbiology 3rd event was completed by the GS, Testing Personnel 2, Testing Personnel 3 and a former employee as indicated on hand written result documents. 4. In an interview at 10:50 a.m. on 04/25/19, the GS confirmed the PT had been performed by multiple testing personnel prior to the submission date and patient specimens would not routinely be handled in this manner.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to retain all Hematology calibration records for at least 2 years. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. 2. A Beckman Coulter Unicel DxH 600 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Calibration verification was required every 6 months as established in the Performing Complete Blood Count with WBC Differential (and Parameters) on the Unicel DxH 600 Coulter Cellular Analysis System procedure located in the Lab Policies manual. 4. Each calibration document from the 06/12/18 was not retained and comprehensive calibration records were not retrievable from the analyzer software on date of survey. 5. In an interview at 2:10 p.m. on 04/25/19, the GS confirmed the above finding and indicated the CBC Calibration Summary Report from 06/12/18 was the only document available.
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 Hematology proficiency testing (PT) result for 1 analyte in 2017. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. 2. The laboratory performed PT through the American Proficiency Institute (API) program. 3. The laboratory received unacceptable PT result in the API 2017 Hematology/Coagulation 2nd event for the analyte listed below. Sample Test Lab result API range COU-07 Mono* 6.2 6.4-10.0 4. Investigation of unacceptable results was required as established in the Proficiency

	Testing Policy located in the Lab Policies manual. 5. An investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview on at 10:50 a.m. on 04/25/19, the GS confirmed a documented investigation of the unacceptable result was not performed. * Note Mono - Monocytes
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the actual reportable range values obtained during the performance verification of a new Chemistry analyzer were included in the procedure manual (6). Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. 2. An Abbott Architect Plus chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities and began testing patient specimens using this analyzer on 10/12/17 as indicated in laboratory records. 3. The reportable range found in the procedure for the analytes listed below did not reflect the actual reportable range values obtained by the laboratory during the PV. Analyte PV Procedure Calcium 2.3-22.4 2-24 Chloride 54.8-143.5 20-150 Potassium 1.3-9.5 1.0-10.0 CO2 0-41.8 5-50 Creatinine 0.29-34.08 0.2-37.0 4. In an interview at 2:15 p.m. on 04/25/19, the GS confirmed the above finding and indicated the laboratory had included the manufacturer's analytical measurement range as the reportable range in procedure.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. 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 activities as required for a Microbiology test system and established by the manufacturer of a Chemistry test. Findings are as follows: The laboratory performed Microbiology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. A. Microbiology 1. A BioMerieux Vitek2 analyzer was observed as present and available for use during the tour. The GS indicated microbial identification (ID) and antibiotic susceptibility testing (AST) were performed on this analyzer. 2. The manufacturer's operator's manual and quick reference guide were in use as procedure. Quality control (QC) requirements were not found during review of procedures provided by the laboratory. 3. Laboratory records indicated Vitek2 ID QC was performed upon receipt of new lots and/or shipments of ID cards and AST panel QC was performed weekly . 4. The laboratory did not establish an IQCP to reduce the amount and frequency of AST QC performance from 2 levels of control material each day of patient testing. 5. In an interview at 12:05 p.m. on 04/25/19, the GS confirmed an IQCP had not been implemented to reduce the amount and frequency of Vitek2 AST QC. The IQCP for the retired Microscan system was still in place. B. Chemistry 1. A MedTox analyzer was observed as present and available for use during the tour. The GS indicated Drugs of Abuse testing was performed on this analyzer. 2. MedTox quality control (QC) performance was required weekly as established in the manufacturer's Quick Reference Instructions. 3. QC performance was required upon receipt of new lots and/or shipments of cassette devices as indicated in the laboratory's MedTox Individualized Quality Control Plan (IQCP). The IQCP did not include weekly QC performance. 4. Laboratory records indicated MedTox QC was performed with new lots and/or shipments of cassette devices. 5. In an interview at 2:57 p.m. on 04/25/19, the GS confirmed the MedTox QC had not been performed weekly as required by the manufacturer.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a Quality Assessment Plan (QAP) for Individualized Quality Control Plans (IQCP) developed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. 2. The laboratory developed an IQCP to reduce quality control requirements for the following tests or test systems. Microbiology - Agar, BD Affirm General Immunology - Amnisure, Mononucleosis Chemistry - i-STAT, MedTox

	Scan, hCG* 3. A QAP to monitor and assess the the effectiveness of the IQCP's was not found in laboratory records. The laboratory was unable to provide documentation of IQCP quality assessment in 2017 and 2018 upon request. 4. In an interview at 4:45 p.m. on 04/25/19, the GS confirmed the above finding. *hCG - Human Chorionic Gonadotropin
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to evaluate 7 of 7 testing personnel in 2018 for competency in a moderate complexity test procedure. Findings are as follows: 1. The laboratory performed KOH* microscopic examinations as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m on 04/25/19. 2. Review of personnel records indicated 7 of 7 testing personnel were not evaluated for KOH microscopic examination competency in 2018. The Laboratory Competency Assessment - Lab Tech form and the Laboratory Training Assessment - Lab Tech form did not include the KOH microscopic examination. The laboratory was unable to provide additional competency assessment documents upon request. 3. In an interview at 9:10 a.m. on 04 /25/19, the GS confirmed KOH microscopic examination competency assessment had not been performed in 2018.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical supervisor (TS) failed to ensure 2018 annual competency assessments for 3 of 3 experienced testing personnel included assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry, Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. 2. Proficiency testing (PT) results for each of the following testing specialties/subspecialties were being used to evaluate testing personnel competency as indicated by the GS at 9:15 on 04/25 /19. Specialty Instrument/test Microbiology - Vitek2, Gram Stain, BD Affirm, KOH, Hematology - DXH600, Sedimat 15, Blood Cell ID (BCID), Post-vasectomy Coagulation - CA-1500 Immunology - Amnisure Chemistry - i-STAT Urinalysis - MedTox, Urine sediment (US) Endocrinology - Serum hCG Immunohematology (BB) - Type, Antibody Screen, Crossmatch 3. The laboratory's competency assessment procedure located in the Lab Policies manual included a requirement to evaluate test

	performance using blind samples or proficiency testing results during annual competency assessments. 4. The 2018 PT samples were not distributed in a manner to ensure 3 of 3 experienced testing personnel performed PT across all specialties /subspecialties as indicated in the American Proficiency Institute Attestation Statements. The laboratory was unable to provide additional documented evaluations of blind sample test performance upon request. See below where "0" indicates proficiency testing was not performed in 2018. Testing Personnel GS 1 2 Vitek2 0 0 Gram Stain 0 BD Affirm 0 0 KOH 0 DXH 600 0 0 Sedimat 15 0 0 BCID* 0 0 0 Post-vas 0 CA-1500 0 0 Amnisure 0 0 0 i-STAT 0 MedTox 0 US 0 hCG 0 0 BB 0 0 5. In an interview at 9:55 a.m. on 04/25/19, the GS confirmed the 2018 PT samples were not distributed in manner to ensure each testing personnel performed PT across all specialties/subspecialties. * Proficiency testing for BCID was not performed. See D2000.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to perform a documented evaluation of problem solving skills during 2018 annual competency assessments for 3 of 3 experienced testing personnel. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry, Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/25 /19. 2. The laboratory's competency assessment procedure located in the Lab Policies manual included a requirement to evaluate problem solving skills during annual competency assessments. 3. The Laboratory Competency Assessment - Lab Tech form did not include assessment of problem solving skills. The laboratory was unable to provide evidence that problem solving skills were evaluated for 3 of 3 experienced testing personnel during annual competency assessments in 2018. 4. In an interview at 9:15 a.m. on 04/25/19, the GS confirmed the above finding and indicated a verbal evaluation of problem solving skills was performed but not documented during annual competency assessments.