Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405820	01/25/2018
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
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 reportable range of a new Hematology analyzer was included in the procedure manual. In addition, the laboratory failed to ensure the reportable range for a new Chemistry analyzer was accurate in the procedure manual. Findings are as follows: The laboratory performed Hematology and Chemistry testing as confirmed by the Testing Personnel 5 (TP5) during a tour of the laboratory on 01/25 /18 at 9:05 a.m. A. Hematology 1. A Beckman Coulter AcT 5diff CP hematology analyzer was observed as present and available for use during the tour. The laboratory

	completed performance verification activities and began testing patient specimens using this analyzer in April 2016 as indicated in laboratory records. 2. Reportable ranges for analytes tested on the hematology analyzer were not found in the Beckman Act5 Hematology Analyzer procedure located in the Hematology Coagulation manual. 3. In an interview on 01/25/18 at 4:17 p.m., TP5 confirmed the reportable ranges for the analytes tested on the analyzer were not included in the procedure. B. Chemistry 1. An Abbott Architect c4000 chemistry analyzer was observed as present and available for use during the tour. The laboratory completed performance verification (PV) activities and began testing patient specimens using this analyzer June 2016 as indicated in laboratory records. 2. The laboratory used the manufacturer's package inserts as procedure for each analyte tested on the analyzer. The manufacturer's Analytical Measurement Range (AMR), found in the package inserts, was adopted as the laboratory's reportable range for each analyte. 3. The reportable range values the laboratory obtained during the PV did not reach all outside limits of the manufacturer's AMR. See below. Analyte PV AMR A1C 5.6-21.5 4.0-14.0 Alb 0.0-9.73 0.4-10.5 AlkP 9.7-4099.3 5-4555 Alt 9.2-3839.6 6-4113 AST 6.9-3868.2 3-4202 BilD 0.0-13.73 0.1-15 BiliT 0.0-21.03 0.1-25 CaC 0.0-22.6 2-24 Chol 0.2-654.3 7-705 Cl 56.7-140.8 50-150 CO2 0.6-46.8 5-50 Crea 0.0-34.127 0.2-37 CreaCu 0.293-421.463 5-740 Glu 0.0-758.9 5-800 K 1.10-9.50 1-10 LDH 26.9-4326.9 30-4500 Mg 0.0-8.53 0.7-9.5 Na 107.9-190.5 100-200 TP 0.0-12.2 0.8-18.4 Trig 0.6-1332.6 7-1420 mAlb 0.0-493.0 5-500 HDL 0.0-175.6 5-180 BUN 0.1-118.3 2-125 Lipase 9.8-1212.5 4-1200 4. In an interview on 01/25/18 at 4:24 p.m., TP5 confirmed the above finding.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 demonstrate a new Hematology analyzer could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Testing Personnel 5 (TP5) during a tour of the laboratory on 01/25/18 at 9:05 a.m. 2. A Beckman Coulter AcT 5diff CP hematology analyzer was observed as present and available for use during the tour. The laboratory completed performance verification (PV) activities and began testing patient specimens using this analyzer on 04/05/16 as indicated in laboratory records. 3. Verification of Hematocrit (HCT) reportable range was not found during review of the Performance Verification Data Manual. The laboratory was unable to provide HCT reportable range verification data upon request. 4. In an interview on 01/25/18 at 4:11 p.m., TP5 confirmed HCT reportable range had not been verified prior to implementation of the new analyzer.
D5435	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a function check procedure and perform functions checks on all ancillary laboratory equipment. Findings are as follows: 1. Alcohol thermometers and digital timers were observed as present and available for use during a tour the laboratory on 01/25/18 at 9:05 a.m. 2. A function check procedure for the thermometers and timers was not found in the laboratory's established procedure manuals. Documentation of function checks for this equipment was not found in laboratory records. The laboratory was unable to provide a function check procedure or function check records for the above equipment upon request. 3. In an interview on 01/25/18, at 4:28 p.m., Testing Personnel 5 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 Testing Personnel 5 (TP5) during a tour of the laboratory at 9:05 a.m. on 01/25/18. 2. A Beckman Coulter AcT 5diff CP hematology analyzer was observed as present and available for use during the tour. TP5 indicated the laboratory performed and reported automated and manual White Blood Cell differential testing. 3. The Beckman Act5 Hematology Analyzer procedure located in the Hematology coagulation 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 on 01/25/18 at 4:08 p.m., TP5 confirmed twice annual comparisons of the automated and manual White Blood Cell differential testing had not been performed.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi)

	The procedures for evaluation of the competency of the staff must include, but are not limited 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 consultant (TC) failed to ensure competency assessments included an evaluation of problem solving skills for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry and Hematology testing as confirmed by the Testing Personnel 5 (TP5) during a tour of the laboratory at 9:05 a.m. on 01/25/18. 2. The laboratory established problem solving skill evaluation requirements in the competency assessment policy located in the Lab Test Manual. 3. The Laboratory Personnel Competency Assessment form did not include assessment of problem solving skills for the tests listed below. Microscopic Examinations (parasites, fungus, bacteria and semen) MedToxScan Drugs of Abuse Serum hCG An evaluation of problem solving skills for these tests was not found in laboratory records for 5 of 5 testing personnel. The laboratory was unable to provide problem solving skill evaluations for the above tests upon request. 4. In an interview on 01/25/18 at 11:15 a.m., TP5 confirmed 5 of 5 testing personnel had not received problem solving skill evaluations for the above tests.