Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406017	10/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Centracare Paynesville	200 1st Street W, Paynesville, 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
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 establish a system to evaluate and define the relationship between test results obtained from different analyzers or methodologies at least twice annually. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 10/04/18 at 8:05 a. m. 2. An Abbott Architect Chemistry Analyzer and Alere Triage Meter were observed as present and available for use during the tour of the laboratory. 3. TC1 indicated that the Abbott Architect Chemistry Analyzer was the primary testing method for Troponin, and that the Alere Triage Meter was available as a back-up testing method. 4. The laboratory's procedure manuals did not include a system to define and evaluate the relationship between test results obtained from different test methodologies or analyzers at least twice annually. Documentation of such an evaluation for Troponin was not found during review of laboratory records. 5. In an interview on 10/04/18 at 12:15 p.m., TC1 confirmed the above findings. .
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 reference intervals were consistent between Chemistry & Hematology procedures, and patient final test reports. Findings are as follows: A. Chemistry 1. The laboratory performed Chemistry testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 10/04/18 at 8:05 a.m. 2. An Abbott i-Stat chemistry analyzer was observed as present and available for use during the tour. 3. The reference intervals listed in the i-Stat Test System procedure, located in the on-line procedure manual, were not consistent with those included on a patient test report (Female - 63 years, Date performed = 5/3/18) reviewed on date of survey. See below. Analyte Procedure Report pO2* 75 - 85 80 - 105 HCO3* 20 - 26 22 - 26 Total CO2 21 - 27 24 - 30 Base Excess 0 - 2 0 - 3 4. In an interview on 10/4/18 at 3:10 p.m., TC1 confirmed the above findings. * pO2 = Partial Pressure of Oxygen * HCO3 = Bicarbonate B. Hematology 1. The laboratory performed Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 10/04 /18 at 8:05 a.m. 2. A Nikon Eclipse SO1 microscope was observed as present and available for use during the tour. 3. The reference values intervals listed in the Hematology Normal Values table, located in the on-line procedure manual, were not consistent with those included on a patient test report (Female - 76 years, Date performed = 2/23/17) reviewed on date of survey. See below. Analyte Table Report % Neutrophils 48 - 76 43 - 80 (Segs*) 0 - 6 (Bands*) % Lymphocytes 20 - 48 16 - 49 Absolute Neutrophils 1.7 - 8.4 1.8 - 9.2 Absolute Lymphocytes 0.8 - 5.3 1.2 - 3.9 4. In an interview on 10/4/18 at 3:10 p.m., TC1 confirmed the above findings. * Segs = Segmented Neutrophils *Bands = Non-segmented Neutrophils .