Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405398	12/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Centracare-Willmar Lakeland Clinic	502 2nd St Sw, Willmar, 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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. 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 non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Urinalysis, Parasitology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/05/18 at 8:05 a.m. 2. The laboratory performed PT using the American Academy of Family Physicians (AAFP) as PT provider. 3. The laboratory received non-graded results from AAFP due to no consensus in Urinalysis, Parasitology and Chemistry for the events and tests listed below. Event = AAFP PT 2017 - B Sample ID = CM-12 & CM-13 Test = Urine Sediment Exam Event = AAFP PT 2017 - B Sample ID = CM-15 Test = Wet Prep Event = AAFP PT 2018 - C Sample ID = CH-11N, CH-12N, CH-13N, CH-14N, CH-15N Test = Cholesterol, LDL* 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 12/5/18 at 10:30 a. m., the GS confirmed the above findings. * LDL = Low Density Lipoprotein .
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 include accurate reference and critical value ranges in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/05/18 at 8:05 a.m. 2. A Medonic M series Hematology Analyzer was observed as present and available for use during the tour of the laboratory. 3. The reference ranges in the Rice Laboratory Reference Intervals - Adult, Sex, Pediatric table, located in the General Lab Policies manual, did not reflect the reference range of values shown on a patient report (Female - 4 yrs, Date performed = 12/25/2017) on the day of the survey. See below. Analyte: % Granulocytes Table: 23 - 45 % (2 - 4 years of age) Patient Report: 40 - 75 % 4. In an interview on 12/5/18 at 11:00 a.m., the GS confirmed the above findings. .