

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0405398	<b>(X3) Date Survey Completed</b>  12/19/2024
<b>Name of Provider or Supplier</b>  Centracare-Willmar Lakeland Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Centracare-Willmar Lakeland Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on December 19, 2024. The following standard-level deficiencies were cited: 493.1251 Procedure Manual .
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to include accurate Urinalysis reference ranges in the procedure</p>

for four of four microscopic elements in 2023 and 2024. Findings are as follows: 1. The laboratory performed Urinalysis testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:07 AM on 12/19/2024. 2. An Olympus BX43 microscope was observed as present and available for use during the tour of the laboratory. The laboratory used this microscope for urine microscopic analysis. 3. Reference ranges for two of four urine microscopic elements on the patient test report were discrepant with the Urinalysis procedure found in the PolicyStat software. Reference ranges for the remaining two urine microscopic elements were absent from the Urinalysis procedure. See below: Patient report from 04/27/2023 Element Procedure Report RBC 0-4 None seen, 1-2 WBC 0-4 None seen, 1-5 Bacteria Absent None seen, few Epithelial cells Absent None seen, 1-5 4. In an interview at 3:20 PM on 12/19/2024, the LD confirmed the above findings. .