

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2117418	(X3) Date Survey Completed 09/30/2025
Name of Provider or Supplier Wayzata Childrens Clinic-Maple Grove	Street Address, City, State 9325 Upland Lane Suite 111, Maple Grove, 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
D0000	. The Wayzata Childrens Clinic -Maple Grove 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 validation survey performed on September 30, 2025. The following standard-level deficiencies were cited: 493.1291 Test report .
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure pertinent reference intervals were included on patient test reports for three of three microscopic tests reviewed from 2024 and 2025. Findings are as follows: 1. The laboratory performed microscopic testing under the Microbiology specialty and Urinalysis subspecialty as confirmed by Testing Personnel 2 (TP2) during the tour of the laboratory at 11:11 a.m. on 09/30/35. 2. A LW Scientific Revelation III microscope was observed as present and available use for the following microscopic tests: Vaginal Wet Mount (VWP)/Potassium hydroxide (KOH) Preparation Urinary Sediment Microscopic Exam (UA Micro) Pinworm Preparation 3. Three of three VWP reference intervals were not listed on a patient test report from 05/23/2024. Six of eight UA Micro reference intervals were not listed on a patient test report from 09/12/2025. One of one Pinworm Preparation reference intervals were not listed on a patient test report from 06/18/2024. All test reports were reviewed on the date of survey. See below. VWP from 05/23/2024: Analyte Test Report Procedure Clue cells - Negative Yeast - Negative Trichomonas - Negative UA Micro from 09/12/2025: Analyte Test Report Procedure WBCs 2-5/hpf 2-5/hpf RBCs</p>

0-2/hpf 0-2/hpf Crystals -- trace Casts -- 0-2 or none Epithelial Cells -- squamous only
Bacteria -- none-trace Yeast -- none Mucous -- none-light Pinworm Preparation from
06/18/2024: Analyte Test Report Procedure Pinworm -- Negative 4. The laboratory
performed 2 VWP tests in 2024 and 0 tests in 2025. The laboratory performed 4
Pinworm Preparation tests in 2024 and 0 tests in 2025. The laboratory performed 101
UA Micro tests in 2024 and 83 tests in 2025. 5. In an interview at 1:12 p.m. on 09/30
/25, TP2 confirmed the above findings. .