Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0995625	(X3) Date Survey Completed 10/27/2025
Name of Provider or Supplier Wickersham Health Campus	**Street Address, City, State** 1421 Premier Dr, Mankato, 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 Wickersham Health Campus 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 October 23, 2025. The following condition-level deficiency was cited: 493.1403 Laboratories performing moderate complexity testing; laboratory director. The following standard-level deficiencies were cited: 493.1291 Test report. 493.1407 Laboratory director responsibilities. .
D5807	TEST REPORT CFR(s): 493.1291(d) (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 the laboratory personnel, the laboratory failed to ensure four of fifteen Urinalysis reference intervals were available to the authorized person responsible for using the test results. Findings are as follows: 1. The laboratory performed urinalysis testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 11:06 a.m. on 10/23/24. 2. A Nikon Eclipse E2000 microscope was observed as present and available for use for urine microscopic examination during the tour. 3. Four urine microscopic examination reference intervals established in the Urine Procedure: Macroscopic and Microscopic found in the Procedures binder were not included on a patient test report from 2/28/25 reviewed during the survey. See below: Analyte Patient Report Procedure White blood cells --- 0-5/hpf Red blood cells --- 0-3/hpf Epithelial Cells --- Negative Bacteria --- 0-3/hpf 4. In an interview at 1:47 p.m., the TC confirmed the

	above findings. The laboratory performed approximately 843 urinalysis exams annually as indicated on the Form CMS-2567 provided by the laboratory on the date of survey. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to ensure successful participation in proficiency testing in 2023 and 2024. Findings are as follows: 1. The laboratory director failed to ensure the laboratory was enrolled in in an HHS approved proficiency testing (PT) program as required under 493.831 for Virology testing performed in 2023 and 2024. See D6015. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for moderate-complexity Virology testing in 2023 and 2024. Findings are as follows: 1. The laboratory performed moderate-complexity RSV (respiratory syncytial virus) testing on patients 7-19 years old under the Virology subspecialty as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 11:06 a.m. on 10/23/25. 2. A Quidel Sofia was observed as present and available for use for RSV testing during the tour. 3. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) provider. 4. PT documentation for RSV was not found during review of the laboratory's 2023 and 3034 API PT records. The laboratory was unable to provide PT documentation or alternative verification of accuracy documentation for RSV testing completed in 2023 and 2024 upon request. 5. The laboratory was enrolled in and successfully performed PT for RSV testing in 2025 as verified by the laboratory's 2025 API PT records reviewed during the survey. 6. In an interview at 2:00 p.m. on 10 /23/25, the TC confirmed the above findings. In an email received at 11:27 a.m. on 10 /27/25, the TC indicated the laboratory performed 13 moderate-complexity RSV tests in 2023 and 10 moderate-complexity RSV tests in 2024. .