Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0687071	03/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Hennepin County Public Health Clinic	525 Portland Avenue, Mc 952, Minneapolis, 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 Hennepin County Public Health 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 March 24, 2026. The following standard-level deficiencies were cited: 493.1251 Procedure manual 493.1291 Test report .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 pertinent Microbiology and Immunology reference intervals in the procedure manual in 2024 and 2025 for ten of ten Microbiology analytes, and two of two Immunology analytes reviewed on the date of survey. Findings are as follows: A. Microbiology 1. The laboratory performed an eight-analyte Vaginal Wet Prep (VWP) microscopic examination and a two-analyte Gram Stain microscopic examination as confirmed by the Technical Consultant (TC1) during a tour of the laboratory at 11:02 a.m. on 3/24/26. 2. The following items were observed as present and available for use for Microbiology testing during the tour: Three Laxco 3000 microscopes and potassium hydroxide solution used for Wet Prep testing One Laxco 4000 microscope and staining reagents used for Gram Stain testing 3. Eight of eight analyte reference intervals were not included in the Wet Prep procedure found in the Manual of Laboratory Services provided by the laboratory on the date of survey. See below: Analyte Procedure Trichomonoas -- Yeast -- Clue Cells -- White Blood Cells -- Bacteria -- pH fluid -- Lactobacillus Fluid -- Amine Fluid -- 4. Two of two reference intervals were not included in the Gram Stain procedure found in the Manual of Laboratory Services provided by the laboratory on the date of survey. See below: Analyte Procedure GNIDs* -- PMNs** -- *Gram Negative Intracellular Diplococci **Polymorphonuclear Leukocytes 5. In an interview at 2:23 p. m. on 3/24/26, TC1 confirmed the above findings. 6. The laboratory performed 826 VWP tests and 635 Gram Stain tests annually as indicated by TC2 in an email received at 12:23 p.m. on 4/1/26. B. Immunology 1. The laboratory performed qualitative Rapid HIV and Rapid Plasma Reagin (RPR) kit testing as confirmed by TC1 during the tour. 2. The following items were observed as present and available for use for Immunology testing during the tour: SureVue RPR Qualitative test kit and MacroVue Rotator used for RPR testing Insti HIV-1/HIV-2 Antibody kit test 3. A reference interval was not included in the RPR (Rapid Plasma Reagin) procedure found in the Manual of Laboratory Services provided by the laboratory on the date of survey. See below: Analyte Procedure RPR -- 4. A reference interval was not included in the Insti HIV-1/HIV-2 Antibody Test procedure found in the Manual of Laboratory Services provided by the laboratory on the date of survey. See below: Analyte Procedure HIV 1/2 -- 5. In an interview at 2:23 p.m. on 3/24/26, TC1 confirmed the above findings. 6. The laboratory performed 7082 Rapid HIV tests and 236 RPR tests annually as indicated by TC2 in an email received at 12:23 p.m. on 4/1/26. .
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 laboratory personnel, the laboratory failed to ensure eight of eight Vaginal Wet Preparation (VWP) analyte reference intervals and two of two Gram Stain reference intervals were included on patient test reports in 2024 and 2025. Findings are as follows: 1. The laboratory performed an eight-analyte Vaginal Wet Prep (VWP) microscopic examination and a two-analyte Gram Stain microscopic examination as confirmed by the Technical Consultant (TC1) during a tour of the laboratory at 11:02 a.m. on 3/24/26. 2. The following items were observed as present and available for use during the tour: Three Laxco 3000 microscopes and potassium hydroxide solution used for VWP testing One Laxco 4000 microscope and staining reagents used for Gram Stain testing 3. Eight of

	eight VWP reference intervals were not included on patient test report from 4/15/25 reviewed on the date of survey. See below. Analyte Test Report Trichomonas -- Yeast -- Clue Cells -- White Blood Cells -- Bacteria -- pH fluid -- Lactobacillus fluid -- Amine fluid -- Two of two Gram Stain reference intervals were not included on patient test report in from 12/17/24 reviewed on the date of survey. See below. Analyte Test Report GNIDs* -- PMNs** -- *Gram Negative Intracellular Diplococci **Polymorphonuclear Leukocytes Pertinent reference intervals were not defined in the Wet Prep and Gram Stain procedures found in the Manual of Laboratory Services provided by the laboratory on the date of survey. See D5403. 4. In an interview at 2: 13 p.m. on 3/24/26, TC1 confirmed the above findings. 5. The laboratory performed 826 VWP tests and 635 Gram Stain tests annually as indicated by TC2 in an email received at 12:23 p.m. on 4/1/26.