Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1044372	04/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine Group Pllc (The)	2996 Kate Bond Road Suite #405, Bartlett, TN	

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
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 laboratory observation, a review of the laboratory's procedure manual, patient test result worksheets, review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interviews, the laboratory procedure failed to include required procedure elements for wet prep testing with approximately 100 patient wet prep analyses performed per year. The findings included: 1. Laboratory observation on 4/2/26, at 10: 05 a.m. revealed a microscope used for patient wet prep testing. 2. A review of the

	laboratory's procedure titled "Wet Preparation for Trichomonas Vaginalis" revealed the following: The procedure stated that normal saline solution stored in a dropper bottle was "good for several months." The procedure did not include a specific expiration date, criteria for determining if the saline was acceptable for use, or instructions for discarding expired or unacceptable saline. The procedure did not include labeling requirements (lot number and corrected expiration date) for saline that had been poured from original container and stored in a secondary container. The procedure stated swabs should be submitted "in a small amount of saline or on Culturette to prevent drying of the organism." The procedure did not define a specific volume for "a small amount." The procedure did not include requirements for specimen stability after collection or specimen rejection criteria. The procedure noted to "immerse swab in saline" and "several drops are needed." The procedure did not specify the specific volume to be used. The procedure did not include the microscope objective power to be used or number of fields to be examined. The procedure did not include reporting of elements other than "observance of motile Trichomonas vaginalis." The procedure did not define criteria for grading or reporting of results. The procedure lacked the process of reporting patient results into the patient's electronic record. 3. A review of patient wet prep result worksheets revealed the following: The worksheets did not include a field for the patient identifier. A secondary patient identifier was not recorded on one of four patient worksheets reviewed (Patient #3). The worksheet included recording of elements not included in the procedure. The worksheet included fields for reporting bacteria, clue cells, epithelial cells, red blood cells, white blood cells, pH, and yeast. 4. A review of patient Wet Prep worksheets revealed the laboratory used inconsistent descriptions when recording patient results for four of four patients. (Patient #1, performed on 10 /11/24, Red Blood Cells (RBC) were recorded as 1-2 Present, White blood Cells (WBC) were recorded as 1-2 Present. Patient #2 performed on 1/28/2025, epithelial cells were recorded as "numerous." Patient #3 performed on 2/6/2025, epithelial cells were recorded as "bunch." Patient #4 performed on 3/7/2025, epithelial cells were reported as "a lot") 5. A review of Form CMS-116 revealed the laboratory performed approximately 100 wet prep analyses annually. 6. The Lab Director and testing person one confirmed the survey findings during interviews on 4/2/2026 at 2:30 p.m.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports, review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interviews, the laboratory report failed to include the unit of measure for test results for wet prep testing and inconsistently reported patient results for four of four patients reviewed from 2024 and 2025, with approximately 100 patient wet prep analyses performed per year. The findings included: 1. A review of

	final patient test reports revealed the laboratory failed to include units of measurement (magnification per field) for four of four patients. (Patient #1, reported on 10/11/2024, Patient #2, reported on 1/28/2025, Patient #3, reported on 2/6/2025, Patient #4, reported on 3/7/2025) 2. A review of final patient test reports revealed the normal range was defined as "Yes - No." 3. A review of patient test results revealed inconsistencies in reporting as follows: Patient #1, reported on 10/11/2024: Bacteria, Clue Cells, Epithelial Cells, Trichomonas, and Yeast were reported as "NO." RBC and WBC were reported as 1-2 cells present. Patient #2, reported on 1/28/2025: Bacteria, Clue Cells, Trichomonas, and Yeast were reported as "NO." Epithelial Cells were reported as "Numerous." RBC and WBC fields were not listed on the final patient report. Patient #3, reported on 2/6/2025: Bacteria, Clue Cells, Trichomonas, and Yeast were reported as "NO," Epithelial Cells were reported as "bunch." pH was noted as "NI." pH, RBC, and WBC fields were included on the final patient report, but no results were reported. Patient #4, reported on 3/7/2025: Bacteria, Clue Cells, Trichomonas, and Yeast were reported as "NO." Epithelial Cells were reported as "a lot." pH was reported as "NI." RBC and WBC are listed on the report, but no results were reported. 4. A review of Form CMS-116 revealed the laboratory performed approximately 100 wet prep analyses annually. 5. The Lab Director and testing person 1 confirmed the survey findings during interviews on 4/2/2026 at 2:30 p.m.