Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0400263	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Burnsville Family Physicians	1000 W 140th Street Suite 100, Burnsville, 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 Burnsville Family Physicians 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 June 10, 2025. 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 ensure six of six Vaginal Wet Preparation (VWP) analyte reference intervals were included in the procedure manual. Findings are as follows: 1. The laboratory performed a six analyte VWP microscopic examination as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 06/10 /25. 2. An Olympus CX31 microscope and potassium hydroxide solution were observed as present and available for use during the tour. These items were used to perform the VWP examination. 3. Six of six analyte reference intervals were not included in the Wet Prep procedure found in the Laboratory Policy and Procedure Manual. In addition, five of six VWP analyte reference intervals were not listed on the patient test report from 08/05/24 reviewed on date of survey. See D5807 Patient MRN ....124, tested on 08/05/24 Analyte Procedure Report Trichomoniasis vaginalis - - Yeast cells - - PMN* Wet Prep - - Clue cells - - Bacteria urine - - pH - 3.5-4.5 4. The laboratory performed approximately 500 VWP tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 5. In an interview at 2:00 p.m. on 06/10/25, TP1 confirmed the above finding. *Polymorphonuclear leukocytes .
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 five of six Vaginal Wet Preparation (VWP) analyte reference intervals were included on a patient test report in 2024. Findings are as follows: 1. The laboratory performed a six analyte VWP microscopic examination as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 06/10/25. 2. An Olympus CX31 microscope and potassium hydroxide solution were observed as present and available for use during the tour. These items were used to perform the VWP examination. 3. Five of six VWP analyte reference intervals were not listed on the patient test report from 08/05/24 reviewed on date of survey. In addition, six of six analyte reference intervals were not included in the Wet Prep procedure found in the Laboratory Policy and Procedure Manual. See D5403 Patient MRN ....124, tested on 08/05/24 Analyte Procedure Report Trichomoniasis vaginalis - - Yeast cells - - PMN* Wet Prep - - Clue cells - - Bacteria urine - - pH - 3.5-4.5 4. The laboratory performed approximately 500 VWP tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 5. In an interview at 2:00 p.m. on 06/10/25, TP1 confirmed the above finding. *Polymorphonuclear leukocytes .