Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0953618	01/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
M Health Fairview Clinic - Woodwinds	1825 Woodwinds Drive, Woodbury, 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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded Parasitology, Urinalysis and Microbiology proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Parasitology, Urinalysis, and Microbiology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 1/17/18 at 8:05 a.m. 2. The laboratory performed PT using the American Academy of Family Physicians (AAFP) as its PT provider. 3. The laboratory received non-graded PT results from AAFP due to lack of consensus or excessive variability in data for the events and tests listed below. The Data Summaries from AAFP with the expected results for these tests were not included in the laboratory's records. Event 2016 - B Sample ID CM-15 Test Vaginal Wet Prep Code Lack of consensus Event 2017 - B Sample ID CM-12 Test Urine Sediment Code Lack of consensus Event 2017 - B Sample ID CM-13 Test Urine Sediment Code Lack of consensus Event 2017 - B Sample ID CM-15 Test Vaginal Wet Prep Code Lack of consensus Event 2017 - B Sample ID UA-2 Test Urine Urobilinogen Code Excessive variability in data Event 2017 - C Sample ID RS-11 Test Strep A Rapid Antigen Detection Code Excessive variability in data 4. The Proficiency Testing Policy and the Proficiency Test Report Summary Form, both located in the Laboratory Policies & Procedures Manual, established a requirement to evaluate non-graded PT results. 5. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide the evaluations upon request. 6. In an interview on 1/17/18 at 11:30 a.m., TC1 confirmed the findings noted above. .

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 document review and interview with laboratory personnel, the laboratory failed to ensure the procedure manual included a description of the course of action to take if the laboratory information system (LIS) becomes inoperable. Findings are as follows: 1. The laboratory performed Microbiology, Mycology / Parasitology, General Immunology, Urinalysis, Chemistry, and Hematology testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 01/17/18 at 8:05 a.m. 2. The Laboratory Policy & Procedure Manual did not include a procedure for communicating patient results when the LIS system is inoperable. The laboratory was unable to provide a procedure for this requirement upon request. 3. In an interview on 01/17/18 at 11:30 a.m., TC1 confirmed the findings noted above. .