

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1066811	(X3) Date Survey Completed 03/29/2018
Name of Provider or Supplier Dulcimer Medical Center	Street Address, City, State 1950 Center Creek Dr Ste 100, Fairmont, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>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.</p> <p>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 Urinalysis proficiency testing results. Findings are as follows: 1. The laboratory performed Urinalysis testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 3/29/18 at 11:05 a. m. 2. The laboratory performed Proficiency Testing (PT) using American Academy of Family Practice (AAFP) as the provider. 3. The laboratory received non-graded PT results from AAFP due to lack of referee consensus for the event, samples, and test listed below. Year: 2017 Survey: PT-2017 B Sample: CM-13 and CM-15 Test: Urinalysis 4. An evaluation of the non-graded PT results were not found during review of laboratory records. The laboratory was unable to provide the evaluations upon request. 5. In an interview at 12:50 p.m. on 3/29/18, the GS confirmed the above findings. .</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p>

(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) or testing methods become inoperable. Findings are as follows: 1. The laboratory performed Microbiology, Mycology / Parasitology, General Immunology, Urinalysis, Chemistry, and Hematology testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 3/29/18 at 11:05 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 Policy & Procedure Manual also did not include a procedure for handling of patient testing when testing methods are unavailable. The laboratory was unable to provide procedures for these requirements upon request. 3. In an interview on 3/29/18 at 1:30 p.m., the GS confirmed the findings noted above. .