

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450866	(X3) Date Survey Completed 10/21/2024
Name of Provider or Supplier Andover Medical Clinic	Street Address, City, State 308 East Central, Andover, KS	
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 a review of proficiency testing (PT) records from American Proficiency Institute (API) and interview with technical consultant (TC) #1, the laboratory failed to evaluate its proficiency testing results that were not scored by the PT program for two of six events in 2023 and 2024. Findings: Review of PT results from API for 2023 and 2024 revealed: 1. 2023 3rd event Hematology/Coagulation PT performance evaluation included one ungraded response for specimen VA-03 Vaginal Wet Preparation. No evaluation for the ungraded results was provided at the time of survey. 2. 2024 2nd event Hematology/Coagulation PT performance evaluation included one ungraded response for specimen VA-02 Vaginal Wet Preparation. No evaluation for the ungraded results was provided at the time of survey. 3. Interview with TC #1 on 10/21/24 at 11:50 a.m. confirmed the laboratory failed to evaluate its proficiency testing results that were not scored by the PT program for two of six events in 2023 and 2024.</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</p>

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 the review of the procedure " Routine Urinalysis" and interview with TC #1, the laboratory failed to include the reference intervals (normal values) for urinalysis microscopic elements in the procedure. Findings: 1. Review of the Routine Urinalysis procedure revealed the procedure did not include the reference intervals for UA Mucous, UA Epithelial, UA WBC, UA Bacteria and UA RBC. 2. Interview with the TC on 10/21/24 at 12:15 p.m. confirmed, the laboratory failed to include the reference intervals (normal values) for urinalysis microscopic elements in the procedure.

D5805

TEST REPORT
CFR(s): 493.1291(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 review of patient test reports and interview with TC #1, the laboratory failed to include the performing laboratory's address on the patient test report. Findings: 1. Review of a selected patient test reports for urine culture revealed the performing laboratory's address was not on the report. 2. Interview with TC #1 on 10/21/24 at 12: 10 p.m. confirmed, the laboratory failed to include the performing laboratory's address on the patient test report.