

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0450866	<b>(X3) Date Survey Completed</b>  11/17/2020
<b>Name of Provider or Supplier</b>  Andover Medical Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interview, the laboratory failed to attest that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. Review of the five PT events performed during 2019 and to date of survey 2020 from the provider American Proficiency Institute (API) revealed that the attestation statements: a. Did not contain the signature of the laboratory director (LD) or designee for 3 of the 5 events reviewed: 2019 Hematology/ Coagulation 1st Event, 2020 Hematology/ Coagulation 1st Event, 2020 Hematology/ Coagulation 3rd Event b. Did not contain the signatures of the testing personnel for 1 of the 5 events reviewed: 2020 Hematology/ Coagulation 2nd Event 2. Interview with the Testing Personnel #1 (TP#1) on November 17, 2020 at 9:35 a.m. confirmed, the laboratory failed to attest that proficiency testing samples were handled in the same manner as patient samples.</p>
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or</p>

baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on an absence of thermometer function check protocols, current certificates of accuracy and interview, the laboratory failed to define and perform a function check protocol for the thermometers. Findings: 1. No documentation of a function check protocol for the thermometers was available at the time of survey. 2. The presented certification of accuracy (NIST traceable) documents on 4 of 4 thermometers contained calibration due dates of 9/5/2020 for 3 thermometers and 12/29/2017 for one thermometer. 2. Interview with TP#1 on November 17, 2020 at 9:10 a.m. confirmed, the laboratory failed to define and perform a function check protocol for the thermometers.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the lack of competency documentation and interview, the technical consultant failed to evaluate and document competency on all testing personnel for 2019 and to date 2020. Findings: 1. No documentation of competency assessment for 2019 and to date 2020 on 3 of 3 testing personnel was made available at the time of survey. 2. Interview with TP#1 on November 17, 2020 at 10:10 a.m. confirmed, the technical consultant failed to evaluate and document competency on all testing personnel for 2019 and to date 2020.