

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0889367	(X3) Date Survey Completed 05/30/2018
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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
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. (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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the procedure manual and an interview the laboratory manager, the laboratory failed to have a quality control (QC) criteria procedure in place for the hematology, chemistry, endocrinology and hemoglobin A1C. Findings Include: 1. It was confirmed with the laboratory manager on May 30, 2018 about 12:30 pm that the laboratory failed to have a QC criteria procedure in place. 2. The procedure failed to include the acceptance for two of three controls tested, lot to lot verification and a calibration schedule procedure for tests performed on the Horibas Micros 60, Ace Alera, Beckman Coulter Unicel DXI 600 and the Bio Rad D-10.</p>

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of calibration records and confirmed in an interview with the laboratory manager, the laboratory failed to calibrate the Horiba Micros 60 hematology analyzer every six months. Findings Include: 1) It was confirmed with the laboratory manager at approximately 12:30 pm that the laboratory failed to follow the manufacturers and CLIA regulations to calibrate the Micros 60 every six months. 2) Calibration was last performed on October 25, 2017 and has not been performed since. Calibration was due to be performed on April 25, 2018. 3) Approximately 98 patient specimens were tested and results released during that time.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of calibration verification records and an interview with the laboratory manager, the laboratory failed to perform calibration verification. Findings Include: It was confirmed with the laboratory manager on May 30, 2018 at

approximately 2:00 pm that the laboratory failed to perform calibration verification on the Ace Alere Chemistry Analyzer when it was due on October 26, 2018. The laboratory was out of calibration from October 27, 2018 through November 28, 2018. Approximately 254 patient specimens were tested and results released during this time.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based in a review of calibration and calibration verification records for the Horiba Micros 60 hematology analyzer and Alere ACE chemistry analyzer and an interview with the laboratory manager, the laboratory director failed to ensure that the quality control program for hematology chemistry testing was maintained to assure quality laboratory services. Refer to D5437 and D5439