

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  51D0898048	<b>(X3) Date Survey Completed</b>  09/21/2018
<b>Name of Provider or Supplier</b>  Central Labs Inc	<b>Street Address, City, State</b>  97 Main Avenue, Pineville, WV	
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>TESTING OF PROFICIENCY TESTING SAMPLES 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 review of proficiency testing test records and interview with the Director /Technical Supervisor, the laboratory director did not attest to the routine integration of samples for some of the Chemistry and Hematology Proficiency Testing (PT) Event for 2018. Findings include: 1. The 1st Chemistry Core PT event for 2018 attestation statement documentation was not signed by the Laboratory director. 2. The 2nd Hematology PT event for 2018 attestation statement documentation was not signed by the laboratory director. 3. On September 21, 2018 at approximately 12:30PM, the Laboratory Director/Technical Consultant stated that he had missed signing the attestation documents for the 1st Event Chemistry Core and the 2nd event Hematology PT events for 2018.</p>
<b>D5423</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test</p>

results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of Chemistry records and interview with Director/Technical Consultant, the laboratory did not verify acceptable limits of calibration at least at the minimal, mid-point and maximum values to verify reportable range of the Dimension Expand Plus Chemistry system. Findings include: 1. There were no record to support the laboratory had verified reportable ranges of manufacturer's literature limits for all chemistry analytes from 2016-2018. 2. On September 21, 2018 at approximately 11:45 PM, the Laboratory Director stated that the chemistry analyte reportable ranges had not been verified in-house. The manufacturer limits were available and used as the reportable ranges.

**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 observation and interview with the Laboratory Director/Technical Consultant, the laboratory has in use thermometers which monitored freezer, refrigerator and room temperatures daily. All of the thermometers were beyond the manufacturer instructions for calibration due date. Findings include: 1. The Fisher Scientific refrigerator thermometer calibration due date was 5/28/2018. 2. The Fisher Scientific room temperature thermometer calibration due date was 2/26/2018. 3. The Fisher Scientific freezer temperature thermometer calibration due date was 4/6/2014 4. On September 21, 2018 at approximately 12:45 PM. The Laboratory Director /Technical Supervisor stated that he had not realized the thermometer calibrations were due.

**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 review of Hematology Calibration records and interview with testing personnel, it was determined that laboratory was not following policy on frequency of calibrations for 2017 and 2018. Findings include: 1. The calibration records according to policy were to be performed at least twice per year or when a preventive maintenance occurred. 2. The Calibrations records available for the Medonic Hematology analyzer for 2017 was dated 9/7/2017. It was the only calibration record available for 2017. 3. The Calibration record available for the Medionic Hematology Analyzer for 2018 was dated 5/16/2018. 4. The Preventive Maintenance records were found but no calibration data found during the 2017 timeframe. 5. The Laboratory Director and Testing personnel stated that they typically performed Hematology Analyzer calibrations 2 X per year in February and September. That data was found for 2016 but not at that frequency for 2017 and 2018.