

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0661133	<b>(X3) Date Survey Completed</b> 07/12/2018
<b>Name of Provider or Supplier</b> Division Of Consolidated Laboratory Services	<b>Street Address, City, State</b> 600 North 5th Street, Richmond, VA	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of the creatinine-corrected results obtained in the biomonitoring program testing. Findings include: 1. During interviews at 10:45 am and 3:00 pm on 7/12/2018, TS#2 and TS#3 explained that the urine metals and perchlorate participant results are corrected based on the participants' urine creatinine values using a spreadsheet entitled Biomonitoring Creatinine Data Entry Form (Qualtrax ID#19289). 2. Record review showed that that the Biomonitoring Creatinine Data Entry Form spreadsheet is programmed to perform a calculation using the measurements of the target analyte and creatinine to adjust for participant hydration status. 3. During interview at 3:00 pm on 7/12/2018 TS#3 stated that results reported to the proficiency testing programs for biomonitoring analytes are not corrected for creatinine.</p>
<b>D5403</b>	<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)</p>

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 record review and interview, the laboratory chemical terrorism and biomonitoring standard operating procedures (SOP) did not include a description of the laboratory's system for reporting patient results and alert values. Findings include: 1. During interview at 3:00 pm on 7/12/2018, TS#2 stated that the laboratory would consider a biomonitoring result that falls within the 95th or higher percentile to be an alert value. TS#2 confirmed that this was not stated in the SOP. 2. Record review of chemical terrorism SOP 7931 showed that there was no description of the lab's system for reporting results to an entity other than Centers for Disease Control. 3. During interview at 10:45 am on 7/12/2018, TS#2 stated that the laboratory would send the certificate of analysis through the laboratory information system but this was not described in the SOP.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform maintenance on the Bio Plex 200 instrument with the frequency required by the manufacturer. Findings include: 1. The Bio Plex 200 System Instrument Manual designated as external document A-05 received on 12/10/2015 stated on page 28, "Replace the syringe plunger's seal every 6 months." 2. The year 2017 Bio Plex Maintenance Log dated 9/29/2017 through 12/15/2017 showed that the 6-month maintenance had been performed on 11/1/2017. The year 2018 Bio Plex Maintenance Log did not show that the 6 month maintenance had been performed as of the date of the survey, 7/10/2018. 3. TS#4 and TS#5 confirmed during interview at 3:35pm on 7/10/2018 that there was no record of the 6-month maintenance having been performed since 11/1/2017.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of facility Corrective and Preventive Action (CAPA) report, centrifuge maintenance worksheets, centrifuge training documentation, a Laboratory Information Management System (LIMS) report and interview with staff, it was determined the Microbial Reference Group within the laboratory failed to include a revision of pertinent policy and procedures testing personnel were to follow to prevent the recurrence of a self-reported problem, involving a faulty centrifuge (rpm/g) indicator light, that potentially affected 454 TB cultures/smear results from February 23 through April 25, 2018 and were reported out as "No TB Detected/Negative for TB" ending on June 25, 2018. Findings include: 1. The surveyor reviewed facility CAPA Report ID #24084 initiated on April 25, 2018 at approximately 3:42pm. In this CAPA, it was reported that Sorvall #1 centrifuge, having s/n 41057115, was found to be set to 3000 rpm versus 3000 xG (this is equivalent to approximately 1962 xG) as required by sample processing for Mycobacterium specimens. 2. Centrifuge maintenance worksheets for Sorvall #1 indicated the last time it was found to be at the correct setting of 3000 xG was on February 23, 2018. 3. In the CAPA report, the Mycobacterium section staff investigating the problem determined the indicator light on the Sorvall #1 centrifuge indicating that the centrifuge was set to "xG" was not functioning properly. This CAPA report indicated that the Root Cause for the problem was due to a lack of a process to verify use of the correct centrifuge speed setting (in 3000 xG) prior to testing personnel processing patient samples. 4. The surveyor reviewed a CAPA ID 24084 related Centrifuge Training document conducted on May 4, 2018 and noted that while the training for staff working in the TB section of Microbial Reference included: (1) to check the settings on the centrifuge before use and the display should read '3000' and the units should read 'xG' not 'rpm', there was no indication that the TB Section staff were informed of any revisions to policies and procedures that would prevent the recurrence of the problem discovered on April 25, 2018. 5. During an interview with the technical supervisors of the TB Section at approximately 1:40pm, there was an admission, the facility did not revise any policy and procedures to prevent the recurrence of the problem. 6. TB=Mycobacterium tuberculosis; rpm-revolutions per minute; xG (RCF) = Relative Centrifugal Force.