

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2087838	(X3) Date Survey Completed 06/18/2019
Name of Provider or Supplier Champlain Toxicology Lab	Street Address, City, State 32 Veterans Lane, Suite 2, Plattsburgh, NY	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the College of American Pathologists (CAP) Proficiency Testing (PT) reports and confirmed in an interview with the laboratory Supervisor, the Laboratory Director failed to review the proficiency test results performed in March of 2019. Findings: 1. At approximately 11:30AM on June 18, 2019, the laboratory Supervisor confirmed that there was no documented review of the March 2019 PT results. 2. CAP DAI-A March 2019 Toxicology Adulterant PT was not signed off even though an extensive remediation was done on the failure of 2 out of 3 Creatinine results. 3. CAP DMPM-A March 2019 Drugs of Abuse PT had no documented review of PT scores. 4. CAP ETB-A March 2019 ETG PT had no documented review of PT scores.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records from the</p>

College of American Pathologists (CAP) and confirmed in an interview with the Laboratory Supervisor, the laboratory failed to evaluate and verify the accuracy of the PT results for the analytes that were not scored by the PT program. Findings: 1. At approximately 11:00 AM on June 18, 2019, the laboratory Supervisor confirmed that for CAP PT event DMPM-A in March of 2019 proficiency tests results had no review or evaluation for educational challenge (code 26) and results outside the method instrument reportable range (code 22). 2. CAP March 19, 2019 ETB-A proficiency tests results had no review or evaluation for results listed as outside the method instrument reportable range (code 22).

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on a lack laboratory's proficiency testing (PT) records or twice year verification records and confirmed in an interview with the laboratory Supervisor, the laboratory failed to evaluate and verify the accuracy of the of 44 toxicology analytes and 4 adulterants tested in the year 2018. Findings: At approximately 11:00 AM on June 18, 2019 the laboratory Supervisor confirmed that the laboratory failed to perform PT or twice year verification for the year 2018.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:
Based on a review of the procedure manual and an interview with the laboratory Supervisor the laboratory failed to have a complete procedure for quality control (QC), calibration and manual integration. Findings: It was confirmed in an interview with the laboratory supervisor at approximately 10:30AM on June 18, 2019 that items had been left out of the current procedure manual. 1. The laboratory did not have

acceptance criteria for quality control values for 42 of 44 toxicology analytes tested on the LCMSMS analyzer. 2. The laboratory did not have a detailed acceptance and rejection criteria for calibration data performed on the LCMSMS. 3. The laboratory did not have a description of when manual integration should be performed on the LCMSMS.