

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2103841	(X3) Date Survey Completed 09/29/2022
Name of Provider or Supplier Connecticut Addiction Medicine	Street Address, City, State 330 Main St, Hartford, CT	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of the laboratory general supervisor(GS). Findings include: 1. Review of the laboratory's personnel competency records on 9/29/22 revealed the following: a. The laboratory did not have policy in place to assess the competency of the GS. b. Lack of competency assessment documentation for the GS. 2. Staff interview with the technical supervisor on 9/29/22 at 10:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the GS and they were not assessed. 3. The laboratory performs 689,378 tests in the sub-specialty of toxicology.</p>
D5217	<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 staff interview, the laboratory failed to assess the accuracy of its test system twice annually for the non-regulated analytes in the subspecialty of toxicology. Findings include: 1. Record review on 09/29/2022 of the "Alternative Proficiency Testing Results Review Form" for the year of 2021 revealed</p>

only one event of alternative proficiency testing for methylone, ketamine and norketamine analytes was performed. 2. Staff interview on 09/29/2022 at 1:45 PM with the technical supervisor (TS) confirmed the above findings. The TS further commented that he/she was aware that the laboratory failed to conduct alternate proficiency testing twice a year on the analytes listed above. 3. The laboratory performs 689,378 tests annually in the subspecialty of toxicology.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to discontinue the use of expired standards to conduct preventative maintenance prior to patient testing in the subspecialty of toxicology. Findings include: 1. Surveyor observation on 09/29/2022 at 11:44 AM of the laboratory refrigerator revealed the current standards in use are as follows: a. PPG positive standard with a lot number of M006024 and an expiration date of 07/23/2021. b. PPG negative standard with a lot number of M008075 and an expiration date of 07/22/2021. 2. Record review on 09/29/2022 of the '4000-QTRAP MS/MS Detector Preventative Maintenance & Calibration Form' revealed the following: a. Use of expired PPG positive standard with a lot number of M006024 and an expiration date of 07/23/2021. b. Use of expired PPG negative standard with a lot number of M008075 and an expiration date of 07/22/2021. c. PM start date of 12/29/2021 and a finish date of 12/30/2021. d. PM acceptance sign-off that was reviewed and approved by the technical supervisor. 3. Staff interview on 09/29/2022 at 12:19 PM with the technical supervisor (TS) and a telephone interview with the service engineer from 'mSPEC group' confirmed the above findings. The TS further commented that he/she was unaware that the PPG positive and negative standards had expired. 4. The laboratory performs 689,378 tests annually in the subspecialty of toxicology.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on surveyor observation and staff interview, the laboratory failed to perform function checks to ensure the accuracy of the device used for measuring precise volumes of liquids prior to patient testing in the subspecialty of toxicology. Findings include: 1. Surveyor observation on 09/29/2022 at 10:33 AM of the laboratory pre-analytical work bench area revealed the use of the following pipettes: a. 20 l volume

pipette with a calibration expiration date of 11/2021. b. 20 - 200 l volume pipette with a calibration expiration date of 11/2021. c. Repeater pipette with a calibration expiration date of 12/2021. 2. Staff interview on 09/29/2022 at 10:40 AM with the technical supervisor (TS) confirmed the above findings. The TS further commented that the pipette calibration should be done every 6 months. 3. The laboratory performs 689,378 tests annually in the subspecialty of toxicology.

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 record review and staff interview the laboratory failed to ensure corrective action(s) taken to resolve instrument (Olympus AU 640e) carryover problems are effectively communicated to its testing personnel (TP) to prevent recurrence if the subspecialty of toxicology. Findings include: 1. Record review of the laboratory's toxicology "Edited Report Form" for quality assurance on 9/29/22 revealed: a. For specimen ID# 176635 dated 8/26/21 a corrected report was issued due to carryover problem for the analyte Buprenorphine. b. For specimen ID# 168984 and 169135 dated 6/17/21 corrected reports were issued due to "Tech failure to review results for carryover" for the analyte Suboxone. c. Documentation for corrective action stated "retraining for all TP". d. Lack of retraining documentation for the testing personnel (TP) in identifying carryover problems. 2. Records review of the laboratory's step by step procedure manual (SOP) on 9/29/22 revealed the lack of policies and procedures for identifying carryover problems in the subspecialty of toxicology. 3. Staff interview with the technical supervisor (TS) on 9/29/22 at 1:00 PM confirmed the lack of a policy/procedure to detect carryover problems in the specialty of toxicology. The TS further stated the SOP is incomplete and needs to be updated to identify carryover problems. 3. The laboratory performs 689,378 toxicology tests annually.