

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D2103841	<b>(X3) Date Survey Completed</b> 01/29/2026
<b>Name of Provider or Supplier</b> Connecticut Addiction Medicine	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2003</b>	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1).</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to evaluate the accuracy of the liquid chromatography tandem mass spectrometry (LC/MS/MS) test system twice annually in the subspecialty of toxicology. Findings include: 1. Record review on 1/29/2026 of the laboratory's proficiency testing (PT) records for 2024 and 2025 revealed the following: a. Alternate PT assessments for Methylone, Ketamine, and Norketamine analytes were completed on 2/22/2024. b. Lack of documentation of biannual accuracy assessment for the analytes listed 1(a) above in 2024 and 2025. 2. Record review on 1/29/2026 of the laboratory's 'Proficiency' standard operating procedure revealed 'Alternate PT testing - If there is no PT program available for any analyte, the supervisor will prepare specimens to be tested by the testing personnel' . 3. Staff interview on 1/29/2026 at 12:55 PM with the laboratory's technical supervisor confirmed the above findings. 4. The laboratory performs 261,532 tests annually in the subspecialty of toxicology.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to follow their established policies and procedure and document monthly quality assessments (QA) reviews in the subspecialty of toxicology. Findings include: 1. Record review on 01/29/2026 of the laboratory's monthly QA review forms revealed lack of documentation of QA reviews for the following months and year. a. August, September, October, November and December of 2024. b. February, March, April, May, July, August, September and October of 2025. 2. Record review on 01/29/2026 of the laboratory's QA policies and procedure revealed 'Monthly, the laboratory will review pre-analytical, analytical and post-analytical processes in the lab to assess overall quality, efficiency, effectiveness of policies and procedures, accuracy and timeliness of test results, competency of employees and problem identification and correction'. 3. Staff interview on 01/29/2026 at 1:15 PM with the laboratory's technical supervisor confirmed the above findings. 4. The laboratory performs 261,532 tests annually in the subspecialty of toxicology.