

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2193225	(X3) Date Survey Completed 02/14/2023
Name of Provider or Supplier Monarch Addiction Recovery Clinics, Sc	Street Address, City, State 521 E Washington Ave, Madison, WI	
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
D2009	<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 surveyor review of proficiency testing (PT) records from 2021 and 2022 and interview with the general supervisor, testing personnel and the laboratory director did not attest to the routine integration of the PT samples into the patient workload. The director did not sign the attestation statements for three of three events, testing personnel did not sign the statements for two of three events. Findings include: 1. Review of the three proficiency testing events from CAP (College of American Pathologists) since the last survey showed no evidence the director attested to the routine integration of the samples into the patient workload and showed testing personnel did not attest to using the laboratory's routine methods for two of three events. Review of the attestation statement forms showed: Event 2021-B: No signatures Event 2022-A: No signatures Event 2022-B: No director signature, two testing personnel signatures 2. Interview with the general supervisor on February 14, 2023 at 10:50 AM confirmed signatures were missing from the attestation statements for the three events and confirmed the director and / or testing personnel did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for each of the last three PT events.</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</p>

(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).

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing (PT) records from events in 2021 and 2022, laboratory procedures, and interview with the general supervisor, the laboratory did not document review of results that the PT provider did not score in three of the last three events. Findings include: 1. Review of CAP (College of American Pathologists) PT records for the second event in 2021 and two events (A and B) in 2022 showed no documented review of test results the PT provider did not score. The CAP 'Original Evaluation' forms for the DMPM (Drug Monitoring for Pain Management) events included exception codes for results the PT provider did not score due to insufficient peer group data, when the result was outside the method /instrument reportable range, and when the result was qualified with a greater than or less than sign. The records for the three events reviewed (2021-B, 2022-A, and 2022-B) showed no documented review of the unscored results the PT provider identified with exception codes. 2. Review of the 'External Proficiency Test Procedure' showed section V, Ungraded PT Challenges, included the statement, "Any challenge that was not graded because the result was linked to a non-graded exception code will be reviewed". 3. Interview with the general supervisor on February 14, 2023 at 11:00 AM confirmed personnel did not document the review of unscored PT results for any of the last three events.

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 surveyor review of laboratory records and interview with the general supervisor, the laboratory did not evaluate accuracy of the qualitative ethyl glucuronide immunoassay test system twice annually in two of the last two years. Findings include: 1. Review of proficiency testing records from the CAP (College of American Pathologists) showed no evidence of accuracy evaluation of qualitative ethyl glucuronide testing in 2021 or 2022. 2. Review of other laboratory records showed no evidence the laboratory evaluated the accuracy of the qualitative ethyl glucuronide immunoassay performed on the Pictus 700 analyzer. 3. Interview with the general supervisor on February 14, 2023 at 12:15 PM confirmed the laboratory had not evaluated the accuracy of the qualitative ethyl glucuronide immunoassay test system twice annually in 2021 or 2022.