

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2172414	(X3) Date Survey Completed 06/10/2025
Name of Provider or Supplier Pain Evaluation And Management Center	Street Address, City, State 1550 Yankee Park Place, Dayton, OH	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's expiration date and an interview with the General Supervisor (GS), the laboratory failed to perform the Traceable brand thermometer maintenance as defined by the manufacturer. This deficient practice had the potential to affect 917 out of 917 patients tested in the subspecialty of Toxicology from 05/15/2025 through 06/10/2025. Findings Include: 1. Direct observation of a Traceable brand thermometer, serial number 230332385, used to monitor the laboratory room temperature where the Sciex 4500 instrument is used for Toxicology tests, revealed a calibration expiration date of 05/15/2025. 2. Review of the Sciex 4500 manufacturer's performance specifications found an operating temperature of 15 C to 30 C (59 F to 86 F), and a relative humidity of 20% to 80%. 3. The GS confirmed the Traceable brand thermometer had exceeded its calibration date and the laboratory did not perform instrument maintenance as required by the manufacturer. The interview occurred on 06/10/2025 at 11:15 AM. C; Celsius F: Fahrenheit</p>
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and an interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to perform the direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing, in person, for the evaluation of the competency of one out of four testing personnel (TP) who conducted high complexity Toxicology testing procedures. This deficient practice had the potential to affect all patients tested by TP#2 from 12/12/2024 through 06/10/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 05/13/2025, revealed four out of four individuals listed as TP to perform high complexity Toxicology testing procedures. 2. Review of the laboratory's policy and procedure titled "Performance/Competency Testing" approved via signature and date by the Laboratory Director on 07/31/2023 and provided on the date of the inspection found the following statement: "II. ASSESSMENT METHODS Direct Observation of routine test performance ...Assessment of Test Performance" 3. Review of the "December 2024 Annual Training/Competency Assessment" form for TP#2 found an electronic signature and date of 12/12/2024 for the TS and a hand-written signature and date of 12/12/2024 for TP#2. 4. The GS stated the 2024 competency assessment for TP#2 had been conducted remotely and the TS was not onsite for the direct observation. The interview occurred on 06/10/2025 at 10:00 AM.

D6124

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iv)

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:
Based on record review and an interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to perform the direct observation of instrument maintenance and performance checks, in person, for the evaluation of the competency of one out of four testing personnel (TP) who conducted high complexity Toxicology testing procedures. This deficient practice had the potential to affect all patients tested by TP#2 from 12/12/2024 through 06/10/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 05/13/2025, revealed four out of four individuals listed as TP to perform high complexity Toxicology testing procedures. 2. Review of the laboratory's policy and procedure titled "Performance/Competency Testing" approved via signature and date by the Laboratory Director on 07/31/2023 and provided on the date of the inspection found the following statement: "II. ASSESSMENT METHODS Direct Observation of routine test performance ...Preventative Maintenance records" 3. Review of the "December 2024 Annual Training/Competency Assessment" form for TP#2 found an electronic signature and date of 12/12/2024 for the TS and a hand-written signature and date of 12/12/2024 for TP#2. 4. The GS stated the 2024 competency assessment for TP#2 had been conducted remotely and the TS was not onsite for the direct observation. The interview occurred on 06/10/2025 at 10:00 AM.