

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2140296	(X3) Date Survey Completed 06/05/2025
Name of Provider or Supplier Elite Pain & Health Pc	Street Address, City, State 13100 N Western Ave, Ste 303, Oklahoma City, OK	
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
D0000	The recertification survey was performed on 06/04/2025 through 06/05/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the clinical consultant, technical supervisor, and general supervisor at the conclusion of the survey.
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 review of written policies and procedures and interview with the technical supervisor, the written policy did not define the frequency of the assessments for the clinical consultant, technical consultant, technical supervisor, and general supervisor based on the position responsibilities for one of one clinical consultant, one of one technical consultant, one of one technical supervisor, and one of one general supervisor. Findings include: (1) A review of the competency assessment policy titled, "Job Descriptions" identified it did not define the frequency of the assessments; (2) Interview with the technical supervisor on 06/04/2025 at 11:23 am confirmed that although the competencies based on the position responsibilities of the clinical consultant, technical consultant, technical supervisor, and general supervisor had been performed annually, the policy did not define the frequency of assessments.</p>
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>

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical supervisor, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the AB Sciex 3200 analyzer during the review period of July 2024 and May 2025. Findings include: (1) On 06/04/2025 at 09:52 am, the general supervisor stated the laboratory performed urine drug testing (6-Acetylmorphine, Alprazolam, Amphetamine, Buprenorphine, Carisoprodol, Benzoyllecgonine, Codeine, Diazepam, EDDP, Fentanyl, Hydrocodone, Hydromorphone, MDA, MDMA, Meperidine, Meprobamate, Methadone, Methamphetamine, Morphine, Norbuprenorphine, Nordiazepam, Norfentanyl, O-Desmethyl-cis-Tramadol, Oxycodone, Oxymorphone, Tapentadol, TCH-COOH, Tramadol) using the AB Sciex 3200 analyzer; (2) A review of the operator's manual titled "Sciex 3200 Systems - System User Guide" under section 7 "Service and Maintenance Information - Mass Spectrometer" showed the following required maintenance procedures: (a) Daily: (i) Clean curtain plate (b) Weekly: (i) Inspect the level of roughing pump oil (c) Every 6 months: (i) Replace card cage air filter (3) A review of maintenance records from July 2024 through May 2025 identified daily, weekly, and 6-month maintenance had not been documented as performed as follows: (a) Daily: (i) Between 07/01/2024 and 05/31/2025 (b) Weekly: (i) Between 7/01/2024 and 05/31/2025 (c) Every 6 Months: (i) Between 7/01/2024 and 05/31/2025 (4) Interview with the technical supervisor on 06/04/2025 at 03:20 pm confirmed the maintenance procedures had not been documented as performed as stated above.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of three proficiency testing events reviewed in 2024 and 2025. Findings include: (1) On 06/04/2025, a review of 2024 and 2025 proficiency testing events identified an attestation statement had not been signed before the graded evaluation was completed by the proficiency testing program for one of three events reviewed: (a) First Chemistry Miscellaneous Event 2025 - The graded evaluation was completed on 05/27/2025 and the attestation statement had not been signed by the laboratory director. (2) The records were reviewed with the technical consultant who stated on 06/04/2025 at 01:10 pm the attestation statement had not been signed as stated above.