

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2140296	(X3) Date Survey Completed 06/28/2021
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 06/28/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and testing person at the conclusion of the survey.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person, the laboratory failed to retain temperature and humidity logs for at least 2 years. Findings include: (1) On 06/28/2021 at 10:00 am, the testing person stated to the surveyor urine drug screen testing for Amphetamine, Barbiturates, Buprenorphine, Cocaine Metabolite, Ethanol, Methadone, PCP (Phencyclidine), Opiates, Oxycodone, and THC (Tetrahydrocannabinol) was performed using the Medica EasyRA analyzer; (2) The surveyor reviewed the manufacturer's requirements in the operator's manual. The manufacturer required the analyzer be operated at a temperature of 15-30 degrees C (Centigrade) and less than 85% humidity. In addition, the laboratory stored urine samples in the refrigerator at 2-8 degrees C up to 3 days prior to testing; (3) The surveyor requested room temperature, humidity, and refrigerator records from 06/01/2020 through the day of the survey. The technical consultant provided the surveyor with logs beginning 08/25/2020 and stated on 06/28/2021 at 11:30 am, temperature and humidity records prior to 08/25/2020 could not be located; (4) Therefore, since the temperature records had not been maintained for at least 2 years, the surveyor could not determine if the refrigerator, room temperature, and humidity had been monitored and were acceptable from 06/01/2020 through 08/24/2020.</p>

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant and testing person, the laboratory failed to perform calibration verification procedures at least once every 6 months for urine drug screen testing for 2 of 12 months. Findings include: (1) On 06/28/2021 at 10:00 am, the testing person stated to the surveyor urine drug screen testing for Amphetamine, Barbiturates, Buprenorphine, Cocaine Metabolite, Ethanol, Methadone, PCP (Phencyclidine), Opiates, Oxycodone, and THC (Tetrahydrocannabinol) was performed using the Medica EasyRA analyzer; (2) The surveyor reviewed 2021 calibration records and identified calibration procedures had been performed with one level of calibrator. Since the calibration procedures included only one level, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) The surveyor reviewed calibration verification records from January 2020 through the day of the survey and identified calibration verification had not been performed between 04/10/2020 and 02/12/2021; (4) The surveyor then reviewed the records with the technical consultant, who stated calibration verification procedures had not been performed as shown above.