Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D2140296	**(X3) Date Survey Completed** 06/29/2023
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 06/29/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant, general supervisor, and testing person #2 during an exit conference performed at the conclusion of the survey.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on interview with the technical consultant/technical supervisor, the laboratory failed to provide written instructions to clients collecting and referring specimens for Urine Drug Screen testing on the Thermo Fisher MGC 240 analyzer and Urine Drug Confirmatory testing on the ABSciex LCMS 3200 analyzer. Findings include: (1) On 06/29/2023 at 10:50 am, the technical consultant/technical supervisor stated the following was performed: (a) Urine Drug Screen testing using the Thermo Fisher MCG 240 test system; (b) Urine Drug Confirmatory testing using the ABSciex LCMS 3200 analyzer; (c) Specimens were transported to the laboratory from two sister clinics. (2) Interview with the technical consultant/technical supervisor on 06/29/2023 at 11:05 am confirmed the laboratory did not provide written instructions (i.e.,client service manual) to the clients to explain the laboratory's specimen handling policies.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the laboratory humidity was maintained as required by the manufacturer of the Thermo Fisher MGC 240 analyzer for seven of 11 months reviewed. Findings include: (1) On 06/29/2023 at 10:50 am, the technical consultant stated Urine Drug Screen testing was performed using the Thermo Fisher MCG 240 test system; (2) A review of the operator's manual for the test system identified the manufacturer required the analyzer be operated at a humidity of 40-80% with no condensation; (3) A review of humidity records from July 2022 through May 2023 identified the humidity readings were less than 40% for seven of 11 months as follows: (a) October 2022 - Four of eight humidity readings were documented as less than 40%; (b) November 2022 - Four of seven humidity readings were documented as less than 40%; (c) December 2022 - Seven of nine humidity readings were documented as less than 40%; (d) January 2023 - Seven of eight humidity readings were documented as less than 40%; (e) February 2023 - Five of six humidity readings were documented as less than 40%; (f) March 2023 - Four of eight humidity readings were documented as less than 40%; (g) April 2023 - Two of four humidity readings were documented as less than 40%. (4) The records were reviewed with the technical consultant who stated on 06/29/2023 at 02:25 pm, the laboratory humidity had not been maintained as required by the manufacturer.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the general supervisor the laboratory failed to ensure three of three expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 06/29/2023 at 11:20 am, identified the following expired reagents, used for Urine Drug Screen testing on the Thermo Fisher MGC 240 analyzer, that appeared to be available for use: (a) Two bottles of Thermo Fisher Acid Wash Solution - lot #74240348 with an expiration date of 03/2023; (b) One bottle of Cedia DAU Negative Calibrator - lot #74497741 with an open bottle stability of 60 days; was opened and in-use on 03/15/2023, and was beyond the open bottle stability date. (2) Interview with the general supervisor on 06/29/2023 at 11:20 a.m. confirmed the Thermo Fisher Acid Wash Solution and Cedia DAU Negative Calibrator were available for use.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records, Thermo Fisher Assay data sheet, and interview with the technical consultant, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 06/29/2023 at 10:50 am, the technical consultant stated Urine Drug Screen testing was performed using the Thermo Fisher MCG 240 test system; (2) A review of the Thermo Fisher test assay data sheet stated, "The assay provides only a preliminary atypical test result. A more specific alternative chemical method must be used in order to obtain confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used." (3) A review of one patient report with Urine Drug Screen test results reported on 05/19 /2023 identified the report did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the technical consultant who stated on 06/19/2023 at 1:15 pm, the patient report did not include the disclaimer.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person performing testing from February 2022 through the current date. Findings include: (1) On 06/29/2023 a review of personnel records for one person performing moderate complexity testing identified the following for one of one person: (a) Testing Person #1 - The initial training was complete on 02/17/2022. There was no evidence a semiannual competency evaluation had been performed between 02/17/22 through 02/17/23. (2) The records were reviewed with the technical consultant who stated on 06/29/2023 at 11:20 am, a semiannual competency evaluation had not been performed.