Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2255255	07/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Alpha Counseling And Treatment Inc	5430 Campbell Blvd, Suite 112, White Marsh, MD	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of the electronic reagent log and interview with the technical supervisor (TS), the laboratory failed to ensure that reagent logs for urine drug confirmation testing were retained for at least 2 years. Findings: 1. The laboratory started testing patient specimens on 04/27/2022. 2. The electronic reagent logs included lot numbers, preparation dates, expiration dates, and verification results for the reagents used for urine drug confirmation testing. 3. The electronic reagent logs for the working calibrators and quality control materials, hydrolysis enzyme and buffer, mobile phases A and B, sample diluent, control diluent, and needle wash started in 08/2022. 4. The TS stated that the reagent logs were kept on paper before the electronic logs were implemented in 08/2022. The paper logs for the reagents used from 04/27/2022 until documented on the electronic log in 08/2022 were not available at the time of the survey. 5. During the survey on 07/24/2023 at 2:00 PM, the TS confirmed that the paper reagent logs from 04/2022 to 08/2022 were not available.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by:

	Based on review of the validation report and interview with the technical supervisor (TS), the laboratory failed to document the procedures used and the results from additional validation studies performed on two analytes to bring them within acceptable criteria for urine drug confirmation testing. Findings: 1. Validation of the laboratory's liquid chromatography tandem mass spectrometry assay for urine drug confirmation testing was documented on the "Analytical Method Validation Report (March 2023)" (validation report) and included a study to validate ion suppression. 2. Section 5.2 "Ions Suppression" of the validation report stated "Ion suppression was deemed acceptable if the accuracy was within +/- 30 %. Precision was deemed acceptable if the %CV was less than 30. All analytes met these criteria other than the following:" then listed the analytes normorphine and sertraline. The report went on to state "ISTD [internal standard] pairing might need to be updated. Will see how PT [proficiency testing] results are graded." 3. The TS stated that normorphine and sertraline were brought back into acceptance criteria for ion suppression using updated ISTD pairing and further optimization. 4. The procedures used and the results from the additional ion suppression studies for normorphine and sertraline were not documented. 5. During the survey on 07/24/2023 at 2:00 PM, the TS confirmed that the follow-up ion suppression studies to bring normorphine and sertraline within acceptance criteria were not documented.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the procedure and calibration records and interview with the general supervisor (GS), the laboratory failed to document calibration of the dry bath with the frequency defined in the procedure. Findings: 1. The laboratory's procedure titled "DryBath MDALP" stated that "Calibration should be done every 6 months" and provided instructions for calibrating the dry bath temperature. 2. Records showed that the dry bath temperature calibration was only documented as performed in 02/2023. 3. The records did not include details of what certified thermometer or temperature sensor was used for calibration and whether the instrument temperature was within acceptable ranges or required adjustments. 4. During the survey on 07/24/2023 at 2:00 PM, the GS confirmed that calibration of the dry bath temperature was not documented as performed every six months as stated in the procedure.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for

	example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure and interview with the technical supervisor (TS), the laboratory failed to follow the procedure for verification of newly prepared quality control (QC) materials. Findings: 1. The procedure titled "New QC Material MDALP" stated that for new lot numbers of QC to "Set a parallel run date to allow enough time for 20 (minimum 5) test dates and data assessments. Established control lot is run in conjunction with new lot number controls." 2. During the survey on 07/24 /2023 at 2:00 PM, the TS confirmed that new lots of unassayed QC are only parallel tested with the established control lot on a single test run and not over a minimum of 5 test dates as stated in the procedure.
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 review of the final report and interview with the general supervisor (GS), the laboratory failed to ensure that the name of the laboratory performing the testing was found on all pages of the test report. Findings: 1. The laboratory performing the testing (Lab 1) shared the physical space, instrumentation, personnel, and laboratory information system with another laboratory (Lab 2). 2. The top left corner of the second and third pages of the test report included the logo for Lab 2. 3. The statement in the footer of the third page of the test report stated that testing was performed by Lab 2. 4. During the survey on 07/24/2023 at 2:00 PM, the GS confirmed that the second and third pages of the test report included the name of Lab 2 and not the name of Lab 1.