Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0602385	09/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Equaltox, Llc	550 N Golden Circle, Ste B, Santa Ana, CA	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, the laboratory API (American Proficiency Institute) proficiency testing (PT) results reports, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to, at least twice annually, verify the accuracy of the tests the laboratory performed which are not listed in the subpart I of 42 CFR part 493. The findings included: a. The laboratory performed routine chemistry, endocrinology, and virology and reported the test results included but are not limited to the followings: Inorganic Phosphorus (Phs), Free T3 (FT3), UIBC, Vitamin B-12 (Vit 12), and SARS-CoV-2 (COV). b. The laboratory elected to enroll with API to verify the accuracy of the tests not listed in the subpart I of 42 CFR part 493 for evaluation of proficiency testing performance listed above (a). c the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each PT testing event was unsatisfactory analyte performance for the PT testing event as follows: Event = PT event; Test = analyte; Re (%) = Result in %; TV = estimated test volume monthly. Event Test Re (%) TV 2019 Q1 FT3 40 103 2019 Q1 Phs 20 193 2019 Q3 Phs 40 193 2019 Q3 UIBC 0 163 2020 Q3 UIBC 60 163 2021 Q1 FT3 60 103 2021 Q2 Vit B 60 144 2021 Q2 COV 0 4,066 c. The laboratory TP affirmed (9/7/2021 @ 1:30 PM) that the laboratory failed to attain a score of at least 80% of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the PT testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on touring the laboratory facility, observed digital thermometers (DT) for monitoring the storage equipment's, and interview with the laboratory personnel (TP), it was determined that the laboratory failed to follow the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system. The findings included: a. The laboratory failed to follow the manufactuer's instruction how to use the DT device. b. The laboratory used DT device for monitoring the temperature of the storage equipment to assure and maintain the quality of the laboratory supplies, quality control or standard materials, and the patient samples in the storage equipment. c. See D-5413
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 touring the laboratory facility, observed digital thermometers (DT) for monitoring the storage equipment, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to be consistent with the manufacturer's instructions for the DT device used. The DT must be monitored and documented. The findings included: a. The laboratory used DT device for monitoring the temperature of the storage equipment to assure and maintain the quality of the laboratory's supplies, quality control or standard materials, and the patient samples in the storage equipment. b. The DT features a "Mode" to indicate Min/Max for the temperature when reached in the past, and Low/High for the setting of the acceptable temperature range to trigger an Alarm system (On/Off), if out of the acceptable temperature setting, so the laboratory could take remedial actions immediately, to assure and to maintain the good quality of the materials stored inside of the storage equipment. c. The laboratory defined an acceptable temperatures range for the refrigerator is between 2 to 8 oC. d. A DT for a refrigerator was found to have set the Low/High acceptable range between 10 and 30 oC and the Alarm was set to "Off". e. When one switched the Alarm to "On" position, this DT's ring alarmed to indicated that temperature was out of the acceptable range sometime in the past. f. Interview of the TP at the time of survey (9/7/21 @ 11:35 am) that the laboratory was not aware the DT setting for that refrigerator and did not notice the acceptable temperature setting was not for a refrigerator (2 to 8 oC).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on touring the laboratory facility, observed the Levy Jennings (LJ) chart from the instrument monitor, review the laboratory records, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to monitor over time the accuracy and precision of test performance including review of the LJ charts for trend and shift that may be influenced by changes in test system performance, environmental conditions, and variance in operator performance. The laboratory failed to document remedial actions taken, if identified. The findings included: a. The laboratory used Horiba hematology analyzer to perform Complete Blood Cell Count (CBC) and reported WBC, with cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). b. Observed the CBC LJ chart on 5/4/21 thru 7/2/21 from the instrument monitor, there were numbers of the daily QCs, High, Norm and Low, noted and indentified that they were out of +/- 3SD including WBC, RBC, Hct, Plt. c. The laboratory failed to document the corrective actions taken when a daily control out of the laboratory's established quality control acceptable ranges.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on touring the laboratory facility, observing the instrument operations, review the laboratory quality control (QC) records, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to document all corrective actions taken, including actions taken when outside of established operating parameters. The findings included: a. The laboratory used Horiba hematology analyzer to perform Complete Blood Cell Count (CBC) and reported WBC, with cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). b. The laboratory failed to document all the corrective actions taken when the daily

	control results were out of +/- 3SD. c. The laboratory TP affirmed (9/7/2021 @ 12:35 PM) that the laboratory failed to document all corrective actions for its CBC daily QC testing when the QC outside of established operating parameters. d. See D-5441
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on touring the laboratory facility, observing the digital thermometers (DT) devices and the hematology analyzer, review the laboratory temperature records, and interview with the laboratory personnel (TP), it was determined that the laboratory failed to follow the manufacturer's instructions to use DT device, failed to document the remedial actions when any daily control test result out of the laboratory's established specification, and to assure providing quality laboratory operations. The findings included: a. The laboratory failed to follow the manufacturer's instructions to properly use a DT device for monitoring the temperature of the storage equipment and to assure and maintain the quality of the laboratory supplies, quality control or standard materials, and the patient samples in the storage equipment, See D-5413 b. The laboratory failed to document the remedial actions taken when any of the CBC daily QC test results out of the laboratory established specifications, see D-5441 and D-5781
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's records, the laboratory proficiency testing (PT) results reports, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as the analytes were in the list of subpart I of 42 CFR part 493. The findings included: a. The laboratory performed routine chemistry, endocrinology, and virology, and reported the test results included but are not limited to the followings: Inorganic Phosphorus (Phs), Free T3 (FT3), UIBC, Vitamin B-12 (Vit 12), and SARS-CoV-2 (COV) which are not in the listed of subpart I of 42 CFR part 493. b. The laboratory elected to enroll with API (American Proficiency Institute) to verify annually the accuracy of the tests for the evaluation of proficiency testing performance listed above (a). c the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the PT testing event, see D-5217

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on touring the laboratory facility, observed the Levy Jennings (LJ) chart from the instrument monitor, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided b. The laboratory failed to follow the manufacturer's instruction to properly used DT device to assure the quality of the laboratory's supplies, quality control materials, standard materials or patient samples in the storage equipment. c. See D-5413 d. The laboratory used Horiba hematology analyzer to perform Complete Blood Cell Count (CBC) and reported WBC, with cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). e. The laboratory failed to document corrective actions taken when any daily QC result out of 2+/-3SD,. f. See D-5441, D-5781.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on touring the laboratory facility, observed the Levy Jennings (LJ) quality control charts from the instrument monitor, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance specifications were identified. The findings included: a. The laboratory used Horiba hematology analyzer to perform Complete Blood Cell Count (CBC) and reported WBC, with cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). b. The laboratory failed to document all necessary remedial actions were taken and whenever significant deviations from the laboratory's established performance specifications identified. c. See D-5441, D-5781
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on touring the laboratory facility, observed digital thermometers (DT) device for monitoring the storage equipment, and interview with the laboratory personnel (TP), it was determined that the laboratory technical consultant (TC) failed to be responsible for the technical and scientific oversight of the laboratory. The findings included: a. The technical consultant (TC) had failed to be responsible for the technical and scientific oversight of the laboratory. b. See D-5413, D-5441, and D-5781