Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0602385	04/18/2023
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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's API (American Proficiency Institute) proficiency testing (PT) test result reports, and interview with the laboratory personnel, it was determined that 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 testing event. The findings included: a. The laboratory attained a score of 20% for Sodium (Na) in Q3 2021 API PT event which was unsatisfactory analyte performance for the PT testing event. b. The laboratory performed Na in approximately 955 patient samples per month. c. The laboratory personnel affirmed (4 /18/2023 @ 11:45 am) that the laboratory attained a score of 20% for Na in Q3 2021 API PT event which was unsatisfactory analyte performance for the testing event.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's API (American Proficiency Institute) proficiency testing (PT) test result reports, and interview with the laboratory personnel, it was determined that 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 testing event. The findings included: a. The laboratory attained a score of 40% for TSH in Q2 2022 PT event which was unsatisfactory analyte performance for the API PT testing event. b. The laboratory performed TSH in approximately 200 patient samples per month. c. The laboratory personnel affirmed (4 /18/2023 @ 11:45 am) that the laboratory attained a score of 40% for TSH in Q2 2022 PT event which was unsatisfactory analyte performance for the API PT testing event.
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 API (American Proficiency Institute) proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to ensure and to verify, at least twice annually, the accuracy of any test or procedure it performed those are not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed routine chemistry, general immunology and endocrinology tests including, but are not limited to Phos, CRP (hs), Free T3 (FT3) and Estradiol (E2), which are NOT listed in the subpart I of 42 CFR part 493. b. The laboratory elected to enroll the API PT programs and failed to ensure and to verify, at least twice annually, the accuracy of Phos, CRP (hs), FT3 and E2 as follows. Score in %; Vol = estimated monthly test volume PT event Analyte Score Vol Q3 2021 Phos 40 955 Q3 2021 CRP (hs) 0% 78 Q1 2022 FT3 60 % 72 Q3 2022 E2 50% 56 c. The laboratory personnel affirmed (4/18/2023 @ 11. 50 AM) that the laboratory failed to ensure and to verify, at least twice annually, the accuracy of Phos, CRP (hs), FT3, and E2 API PT events.
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 API (American Proficiency Institute) proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to be responsible for the overall operation and failed to ensure that the proficiency testing samples were tested as required. The findings included: a. The laboratory director failed to be responsible for the overall operation and failed to ensure and to verify that the accuracy of the API PT testing samples was tested as required. b. The laboratory performed routine chemistry, endocrinology tests including but not limited to Sodium (Na) and TSH which are listed in the subpart I of 42 CFR part 493 and attained scores of 20% and 40% for Na and TSH in Q3 2021 and Q2 2022 PT, respectively, were unsatisfactory performance, see D-2087 and D-2098. c. The laboratory performed routine chemistry, general

	immunology and endocrinology tests including, but not limited to Phos, CRP (hs), E2, and FT3 which are NOT listed in the subpart I of 42 CFR part 493 and failed to attain, at least twice annually, scores of at least 80% in PT events, see D-5217