Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0602385	04/15/2019
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports and records, and interview with the laboratory personnel, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events was unsuccessful performance. The findings included: See D-2107
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 proficiency testing (PT) 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 performed endocrinology testing including but are not limited to Free T3, TSH , b. The laboratory attained a score of 0% for TSH in the 3rd 2017 PT event. c. The laboratory performed TSH in approximately 20 patient samples monthly. d. The laboratory personnel affirmed (04/15/2019 @2:15 PM) that the laboratory failed to attained at least 80 % of responses for TSH was unsatisfactory analyte performance for the testing event.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports and records, and interview with the laboratory personnel, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events was unsuccessful performance. The findings included: a. The laboratory performed endocrinology testing including but are not limited to Free T3. b. The laboratory elected to enroll its evaluation of PT performance with API (American Proficiency Institute) to compline with CLIA regulations. c. The laboratory attained scores of 60 % and 40% for analyte Free T3 in the 3rd 2018 and the 1st 2019 PT, respectively events. d. The laboratory failed to achieve satisfactory performance for Free T3 in two consecutive testing events was unsuccessful performance. e. The laboratory performed Free T3 in approximately 20 patient samples monthly f. The laboratory personnel affirmed (04/15/2019 @ 2:20 PM) that the laboratory failed to achieve satisfactory performance for Free T3 in two consecutive testing events was unsuccessful performance.
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 proficiency testing (PT) result reports and records, and interview with the laboratory personnel, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of any test or procedure it performs that is not included in subpart I of 42 CFR Part 493. The findings included:

	a. The laboratory performed serum phosphors (iP), 25-OH Vitamin D, Estradiol (E2), urine Microalbumin (uAbu) (semi-quant), Urine Creatinine (uCr) (semi-quant), and E2 which are not listed in the subpart I of 42 CFR Part 493. b. In order to compline with CLIA regulations to ensure the laboratory verify, at least twice annually, the accuracy of the testing systems which are not listed in the subpart I of 42 CFR Part 493. The laboratory elected to enroll the analyte mentioned (a) above with API (American Proficiency Institute PT programs. c. The laboratory attained scores of 0%, 20% and 20% for analyte iP, respectively in the 2nd 2018, the 3rd 2018 and the 1st 2019 PT events. d. The laboratory attained scores of 67% for analyte of uAbu and uCr, respectively in the 2nd 2017 PT event. e. The laboratory attained scores of 67% for analyte of E2 in the 2nd 2018 PT event. f. The laboratory attained scores of 67% for analyte of 25-OH Vit D (Vit D) in the 1st 2017 PT event. g. The laboratory performed iP, uCr, uAbu, E2, and Vit D for approximately 6, 1,846, 10, 54, and 66 patient samples, respectively in a monthly. h. The laboratory personnel affirmed (10 /15/2019 @ 2:15 PM) that the laboratory failed to attained, for the listed analyte above (c - f), at least 80 % of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. i. The laboratory failed to verify, at least twice annually, the accuracy of any test or procedure it performs that is not included in subpart I of 42 CFR Part 493.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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--When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's documents and records, and interview with the laboratory personnel, it was determined that the laboratory failed to use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. The findings included: a. The laboratory used Shimadzu LC /MS/MS to perform urine drugs confirmation testing and provided urine concentration for the drug confirmed. b. The laboratory purchased its drug analyte from one source manufacture with same lot number to prepare for working calibrator and quality control materials. c. The laboratory must use different lot number to prepare for calibrators and quality control materials and documented all procedures performed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports and records,

	and interview with the laboratory personnel, it was determined that the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. The findings included: See D-6016
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 proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of 42 CFR Part 493. The findings included: See D-2098, D-2107,
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: See D-5467