Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0602385	04/10/2024
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
D0000	A proficiency testing desk review survey was performed on April 10, 2024, the laboratory was found not in compliance with the with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
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 Certification and Survey Privider Enhanced Reporting (CASPER)-0155D and American Proficiency Institute (API) records (2023-2, 2023-3) and (2024-1), the laboratory failed to successfully participate in a proficiency testing

	program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the subspecialty of Endocrinology for the analyte Triiodothyronine (T3) resulting in subsequent unsuccessful performance. Refer to D2098.
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 desk review of Certification and Survey Privider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API evaluation reports, the laboratory failed to achieve satisfactory performance for three of three events proficiency events in 2023 and 2024 for analyte Triiodothyronine (T3). The finding include: 1. The laboratory recieved the following scores: 60% on the 2023 T3 second event 0% on the 2023 T3 third event 60% on the 2024 T3 first event 2. A review of the 2023 and 2024 proficiency testing scores from American Proficiency Institute confirmed the above findings.
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 a proficiency testing desk review of the CASPER 155 report API records for 2023-2, 203-3 and 2024-1 events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
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 a proficiency testing desk review of CASPER 155 report API records for 2023-2, 2023-3 and 2024-1 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2098.