

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0699248	(X3) Date Survey Completed 04/11/2019
Name of Provider or Supplier C-Ton Laboratory	Street Address, City, State 3870 Del Amo Blvd, Ste 504, Torrance, 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
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the second quarter (Q2-2018) of the American Association of Bioanalysts (AAB) proficiency testing records, random patient sampling test results, and interview with the technical supervisor, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance in Bacteriology. The findings included: a. Q2-2018, AAB reported an unsatisfactory score of 60% for Bacteriology. b. For two (2) out of two (2) random patient sampling test results reviewed covering period from 2/12/2018 and 1/7/2019, the laboratory analyzed and reported Bacteriology results during the approximate period that the laboratory received an unsatisfactory proficiency test results. c. The technical supervisor confirmed (4/11/2019, 1230) that the laboratory received the above unsatisfactory proficiency test score.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the American Association of Bioanalysts (AAB) proficiency testing records, random patient test results, interview with the technical consultant, it was determined that the laboratory failed to at least twice annually, the laboratory</p>

must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. AAB reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Progesterone 50% Q1-2018 Testosterone 50% Q3-2018 b. For four (4) out of four (4) random patient test results reviewed covering period from 1/3/2017 to 10/6/2018 , the laboratory analyzed and reported Progesterone and Testosterone analytes during the period the laboratory received proficiency testing failures. c. The testing personnel confirmed (4/11/2019, 1230) that the laboratory received the above unsatisfactory proficiency testing scores.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on reviews of the American Association of Bioanalysts (AAB) proficiency testing records, random patient test results, and interview with the technical supervisor, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2020, and D 5217.