

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0957076	(X3) Date Survey Completed 01/28/2021
Name of Provider or Supplier Diagnostic Laboratory Science Inc	Street Address, City, State 7711 Garden Grove Blvd, Garden Grove, 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	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>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.</p> <p>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 technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the analyte in each testing event was unsatisfactory analyte performance for the PT testing event. the findings included: a. The laboratory used Beckman Coulter AU 680 to performs routine chemistry testing including, but not limited to serum glucose. b. The laboratory enrolled with American Association of Bioanalysts (AAB) PT programs to ensure the laboratory produces accurate and reliable patient test results. c. The laboratory attained a score of 60 % for serum glucose in the 1st 2021 PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed serum glucose in approximately 125 patient samples monthly. e. The laboratory technical consultant affirmed 1/28/2020 @ 12:35 PM that the laboratory attained a score of 60 % for serum glucose in the 1st 2021 PT event, which was unsatisfactory analyte performance for the testing event.</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:</p>

Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory technical consultant, it was determined that the laboratory failed that, at least twice annually, the laboratory must verify the accuracy of any test or procedure it performed that is not included in subpart I of this 42 CFR part 493. The findings included: a. The laboratory used Beckman Coulter AU 680 or Siemen Centaur XP to performs testing included in the subspecialties of general immunology, endocrinology testing including, but not limited to; C-peptide, GH, Transferrin, Vitamin B12, Folate, which are not included subpart I of 42 CFR part 493. b. The laboratory elected to enroll with American Association of Bioanalysts (AAB) PT programs to verify the accuracy of the testing systems which are not included subpart I of 42 CFR part 493. c. The laboratory attained unsatisfactory scores for the following tests as follows: Analyte Score (%) Event INR 60 Q3 2018 GH 66.6 Q1 2019 Q1 2020 Analyte Score (%) Event C-peptide 66.6 Q1 2020 Folate 0 Q3 2018 Vit B12 50 Q2 2020 Transferrin 50 Q2 2019 50 Q2 2020 PTH 0 Q2 2020 Insulin 0 Q3 2019 d. The laboratory technical consultant affirmed (1/28/2021 @ 12:20 PM) that the laboratory failed to verify and ensure the accuracy of the testing system identified above from the 3rd 2018 thru 2020 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 proficiency testing (PT) result reports, and interview with the laboratory technical consultant, it was determined that the laboratory director failed to be responsible to ensure that the proficiency testing samples were tested as required under Subpart H of this part. The findings included: a. The laboratory used Beckman Coulter AU 680 to performs routine chemistry testing including, but not limited to serum glucose. b. The laboratory enrolled with American Association of Bioanalysts (AAB) PT programs to ensure the laboratory produces accurate and reliable patient test results, see D-2087.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

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)(6) 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 proficiency testing (PT) result reports, and interview with the laboratory technical consultant, 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: a. The laboratory used Beckman Coulter AU 680 to performs routine chemistry testing including, but not limited to serum glucose. b. The laboratory enrolled with American Association of Bioanalysts (AAB) PT programs to ensure the laboratory produces accurate and reliable patient test results, see D-2087. c. The laboratory elected to enroll with American Association of Bioanalysts (AAB) PT programs to verify the accuracy of the testing systems which are not included subpart I of 42 CFR part 493, see D-5217