Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0559244	(X3) Date Survey Completed 07/20/2018
Name of Provider or Supplier Tarzana Endocrine And Medical Group Laboratory	**Street Address, City, State** 18370 Burbank Blvd Ste 300, Tarzana, 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 first quarter (Q1-2017) , third quarter (Q3-2017) of the American Proficiency Institute (API) proficiency testing records, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Ferritin, and Iron, Total analytes. The findings included: a. API, reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Ferritin 67% Q1-2017 Iron, Total 20% Q3-2017 b. For five (5) out of five (5) random patient test results for Ferritin reviewed covering period from 12/7/2016 to 7/2/2018, the laboratory analyzed and reported Ferritin analytes during the period the laboratory received the unsatisfactory score for Ferritin. c. For three (3) out of three (3) random patient test results for Iron, Total reviewed covering period from 12/7/2016 to 7/2/2018, the laboratory analyzed and reported Iron, Total analytes during the period the laboratory received the unsatisfactory score for Iron, Total. d. The technical consultant affirmed (7/20/2018, 1500) that the laboratory received the above unsatisfactory proficiency testing results.
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 first quarter (Q1-2017), of the American Proficiency Institute (API) proficiency testing records, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Progesterone analyte. The findings included: a. API, reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Progesterone 67% Q1-2017 b. Based on the Laboratory's annual testing declaration submitted for 2017-2018, the laboratory analyzed and reported 6,500 Endocrinology tests which included Progesterone analytes. c. The technical consultant affirmed (7/20 /2018, 1500) that the laboratory received the above unsatisfactory proficiency testing result.
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 second quarter (Q2-2017), third quarter (Q3-2017) of the American Proficiency Institute (API), and first quarter (Q1-2018) Medical Laboratory Evaluation (MLE) proficiency testing records, and interview with the technical consultant, it was determined that the laboratory failed to 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. The findings included: a. API reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Sed Rate 50% Q2-2017 Se Rate 50% Q3-2017 UIBC 60% Q3-2017 Apolipo protein B 0% Q1-2018 b. Based on the laboratory's annual testing declaration submitted for 2017-2018, the laboratory analyzed and reported; 99,00 Hematology tests which include Sed Rate analytes, 155, 500 Routine Chemistry tests which included UIBC and Apolipoprotein B analytes. c. The technical consultant affirmed (7/20/2018, 1500) that the laboratory received the above unsatisfactory proficiency testing results.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of random patient test results (Microbiology worksheets against patient chart result entry), and interview with the technical supervisor, it was determined that the laboratory has not established and written policy and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. The findings included: a. For one (1) out of ten (10) random patient sampling test results and chart reviews covering period from 11/14/2016 to 7/5/2018, one (1) patient urine culture and sensitivity results was not in patient charts. b. The technical supervisor affirmed (7/20 /2018, 1500) that the laboratory has not established and written policy and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems.

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 review of the API and MLE proficiency testing records, random patient sampling test results and interview with the technical consultant, 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 2087, D 2098 and D 5217.