Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0937918	07/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Tower Nephrology Medical Group	8641 Wilshire Blvd, Ste 300, Beverly Hills, 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	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of Q2-2018 of the Medical Laboratory Evaluation (MLE) proficiency summary report, random patient sampling reports, and interview with the testing personnel; it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance. The findings included: a. Q-2-2018, MLE reported unsatisfactory proficiency score of 60% for Bacterial Identification. b. For eight (8) out of eight (8) random patient test results reviewed covering period 12/6/2017 to 5/9/2019, the laboratory analyzed and reported eight patients for bacterial identification during the period in which the laboratory received the failed proficiency score. c. The testing personnel confirmed (7/5/2019, 1430) that the laboratory received the above unsatisfactory proficiency score.
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 Q3-2018 of the American Association of Bioanalysts (AAB) proficiency summary report, random patient sampling reports, and interview with the testing 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 is

	unsatisfactory analyte performance for the testing event. The finding included: a. Q3-2018, AAB reported unsatisfactory proficiency score of 60% for Thyroid Stimulating Hormone (TSH) analyte. b. For two (2) out of eleven (11) random patient test results reviewed covering period 6/23/2017 to 6/28/2019, two (2) patients had TSH analytes that the laboratory analyzed and reported during the period that the laboratory received the unsatisfactory proficiency testing score. c. The testing personnel confirmed (7/5/2019, 1430) that the laboratory received the above unsatisfactory proficiency score.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of first quarter (Q1-2018) and (Q2-2018) of the American Association of Bioanalysts (AAB) proficiency testing reports, laboratory proficiency testing records and interview with the testing personnel, the laboratory failed to have a mechanism to review proficiency testing results that have an artificial score of 100% even though the laboratory's reported results were outside the grading range. The findings included: a. The laboratory received an artificial score of 100% for Parathyroid Hormone (PTH) for the (Q1-2018, Q2-2018). The AAB proficiency test footnote reports revealed that for results with prefix codes indicated the following statement:? = "This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus." The following proficiency samples were analyzed and reported by the laboratory: PTH Q1-2018 Specimen: Value. Mean: Grading Score: Reported Range: Spec: 1? 1.2 5.11 3.8-6.4 100% Spec: 2? 2.6 20.81 15.6-26 100% Q2-2018 Specimen: Value. Mean: Grading Score: Reported Range: Spec: 1? 6.9 17.77 13.3-22.2 100% Spec: 2? 6.3 16.13 12.1-20.2 100% Note: True scores for PTH is 0% The laboratory received an artificial score of 80% for High Density Lipoprotein (HDL)) for the (Q1-2018, Q2-2018). The AAB proficiency test footnote reports revealed that for results with prefix codes indicated the following statement: # = "This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your records." The following proficiency samples were analyzed and reported by the laboratory: HDL Q1-2018 Specimen: Value. Mean: Grading Reported Range: Spec: 1 # 64 34.8 24-45 Spec: 2 # 151 107.1 75-139 Spec: 3 # 89 46.6 33-61 Spec: 4 # 30 17.8 12-23 Q2-2018 Specimen: Value. Mean: Grading Score: Reported Range: Spec: 1 # 28 16.9 12-22 Spec: 2 # 79 43.5 30-57 Spec: 4 # 14 8.9 6-12 Spec: 5# 60 33.4 23-43 Note: True scores for HDL 0% b. For two (2) out of two (2) random patient test results reviewed for PTH and for five (5) out of five (5) random patient test results reviewed for HDL covering period from 6/23/2017-6/28 /2019, two (2) patients for PTH and for five (5) patients for HDL were analyzed and reported during the time which the laboratory received an artificial 100% scores which did not reflect the true passing scores for the laboratory's proficiency testing. c.

	The testing personnel confirmed (7/5/2019, 1430) that the laboratory received the above artificial 100% passing scores even though the reported results were outside the grading range for PTH and HDL analytes.
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 Q3-2017 and Q3-2018 of the American Association of Bioanalysts (AAB) proficiency summary reports, random patient sampling reports, and interview with the testing personnel; it was determined that the laboratory failed to 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. The findings included: a. Q-3 2017, Q-2018 AAB reported unsatisfactory proficiency score of 50% for Urine sediments. b. For nine (9) out of ten (10) random patient test results reviewed covering period 6/23/2017 to 6/28/2019, seven (7) patients had urinalysis microscopic in which results cannot be assured due to the laboratory's unsatisfactory proficiency report. c. The testing personnel confirmed (7/5/2019, 1430) that the laboratory received the above unsatisfactory proficiency 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 review of the American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE) proficiency testing performance summary reports and interview with the testing personnel; 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, D 2098, D515 and D 5217. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for competency assessments and

	interview with the testing person, for eleven (11) out of eleven (11) random patient test records reviewed from 6/23/2017 to 6/28/2019, it was determined that the laboratory director failed to perform and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The evaluations must include but are not limited to the following: The findings included: a. There was no documentation to show that the testing personnel for one (1) out of two (2) were evaluated during the first six months and annually thereafter for Routine Chemistry, Urinalysis, Endocrinology, and Hematology. The evaluation must include following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. The testing personnel confirmed (7/5 /2019, 1430) that no competency assessments were performed and documented by the laboratory director. c. Based on the laboratory's annual testing declaration submitted for 2017-2019, the laboratory analyzed and reported approximately 174, 978 Routine Chemistry, Endocrinology, Urinalysis, and Hematology