Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2025598	02/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kos Laboratory	18300 Yorba Linda Blvd, Ste 105, Yorba Linda, 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 of the laboratory proficiency testing (PT) results reports, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to attained a score of at least 80 % acceptable responses for each analytic each testing event was unsatisfactory analyze performance for the testing event. The findings included: a. The laboratory performed and reported an analyte, total iron binding co (TIBC) in its routine chemistry panels. b. In order to ensure and verify the accuracy of the routine chemistry and meet the compliance with CLIA requirements annually, the laboratory enrolled its PT program with API. b. The laboratory attained a score of 0 % for analyze of TIBC in the 2nd 2017 PT event, which was unsatisfactory analyze performance for the testing event. d. The laboratory performed and reported the patient test reports in approximately 45 samples monthly. e. The laboratory staff affirmed (2/12/2018 @ 12:15 PM) that the laboratory attained a score of 0% for TIBC in the second 2017 PT event, which was unsatisfactory analyze performance for the testing event.
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 the laboratory proficiency testing (PT) results reports, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to attained a score of at least 80 % acceptable responses for each analytic each testing event was unsatisfactory analyze performance for the testing event. The findings included: a. The laboratory performed and reported analyze, T3, an endocrinology tests. b. In order to ensure and verify the accuracy of the endocrinology tests, and meet the compliance with CLIA requirements annually, the laboratory enrolled its PT program with API. c. The laboratory attained a score of 20 % for analyze of T3 in the 1st 2017 PT event, which was unsatisfactory analyze performance for the testing event. d. The laboratory performed and reported the patient test reports in approximately 40 samples monthly. e. The laboratory staff affirmed (2/12/2018 @ 12:15 PM) that the laboratory attained a score of 20% for T3 in the 1st 2017 PT event, which was unsatisfactory analyze performance for the testing event.
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 the laboratory proficiency testing (PT) results reports, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to evaluate or take actions to verify the accuracy of the testing system when the laboratory received not graded. The findings included: a. The laboratory implemented a new hematology analyzer, Sysmex XP 300, replaced its Celldyn analyzer, and enrolled its PT with API (American Proficiency Institute) to verify and ensure the accuracy of the testing system for the first time. b. The laboratory received a PT reports from API with "Grade" attained for all parameters including WBC with cell differentials, RBC, Hemoglobin, Hematocrit, Platelets as well as other parameters. c. The laboratory failed to take actions to find alternative procedures to verify and ensure the accuracy of the testing system, especially for the first time when the new instrument was implemented, and failed to document the activity.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the validation records, interview with the laboratory staff and the technical consultant, it was determined that the laboratory failed to follow the manufacture instructions and in a manner that provide test results within the

	laboratory's state performance specifications for the test system, Sysmex XP 300, a hematology analyzer selected. The findings included: a. The laboratory implemented a new hematology analyzer, Sysmex XP 300, a hematology analyzer with automated 5 parts WBC electronic differentials. b. The laboratory staff experienced patient hematology testing result reports failed to provide WBC cell differentials occasionally. c. The manufacture's instrument in the paragraph of "Condition of collection" in Section 7: Specimen requirements states: "If specimens cannot be processed within 4 hours, they should be refrigerated at 2-8 oC. Before processing refrigerated specimens should be allowed to warm up to room temperature (minimum 15 minutes), then mixed, preferably for at least 2 minutes. d. The instruction also states in Section 7, Specimen requirements that "When the specimen is left unrefrigerated for more 4 hours certain changes occurs within blood cells, which may produce misleading results of clinical significance. Erythrocytes swell, the MCV increases, as does the RDW-SD. Platelets also swell resulting in an increase MPV. The total WBC count may decrease and the reliability of electronic differential leukocyte count diminishes. The degree of the change is variable depending on the specimen and the temperature at which it is stored. These changes are largely prevented by storage at 2-8 oC. e. The laboratory performed hematology samples including the specimens collected and delivered by the couriers from the outside of this laboratory located remote distance from the laboratory. The laboratory failed to establish and follow written policies and procedures to ensure the proper storage conditions to meet the CLIA requirements to provide quality laboratory services.
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 proficiency testing (PT) results reports, and interview with the laboratory staff and the technical consultant, it was determined that the laboratory director failed to ensure the proficiency testing .... The findings included: See D-2087, D-2098 and D-5215
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff, and review of the laboratory's instrument

	manuals, it was determined that the laboratory director failed to ensure the quality assessment programs were established and maintained to ensure the quality of laboratory services provided. The findings included: See D-5411