

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2025598	<b>(X3) Date Survey Completed</b>  08/24/2022
<b>Name of Provider or Supplier</b>  Kos Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3033</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and interview with the laboratory staff, it was determined that the laboratory failed to retain records of test system performance specifications that the laboratory established or verified before relocation of the laboratory. The findings included: a. The laboratory was relocated to the current address of 18200 Yorba Linda Blvd., Ste 105, Yorba Linda CA 92886 from 13830 Yorba Linda Blvd., Yorba Linda CA 92886 on 5/25/2021. b. No records and documentations of test system performance specifications that the laboratory established or verified after it was relocated on 5/25/2021 to the new address. c. No copies of documentations of calibration verification for Siemen Dimension testing of ISE (see D-5439)</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory staff, it was determined that the laboratory failed to verify, at least twice annually, accuracy of the test the laboratory performed that is not</p>

included in the subpart I of 42 CFR part 493. The findings included: a. The laboratory performed PSA and 25-OH Vitamin D that are not included in subpart I of 42 CFR part 493. b. The laboratory elected to enroll with API (American Proficiency Institute) PT programs to verify the accuracy of the procedure the laboratory performed. c. The laboratory obtained a score of 50% for 25-OH Vitamin D in Q2 2020 which was unsatisfactory performance. d. The laboratory obtained a score of 50% and 0% for PSA in Q3 2020 and Q1 2021 PT events, respectively which were unsatisfactory performance. e. The laboratory performed PSA and 25-OH Vitamin D in approximately 85 and 137 patient samples each month, respectively. f. The laboratory staff affirmed (8/24/2022 @11:45 am) that the laboratory obtained score of 50% for PSA in Q3 2020 and 0% in Q1 2021 was unsatisfactory performance. g. The laboratory staff affirmed (8/24/2022 @11:45 am) that the laboratory obtained scores of 50% for 25-OH Vitamin D in Q2 2020 was unsatisfactory performance.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's records, and interview with the laboratory staff, it was determined that the laboratory failed to demonstrate that it obtained performance specifications of the instruments the laboratory relocated to the new address comparable to those established by the manufacturer before the relocation of the laboratory before relocation. The findings included: a. The laboratory was relocated to the current address 18200 Yorba Linda Blvd, Ste 105, Yorba Linda, CA 92886 on 5/25 /2021 and began to operate and release patient's reports after 6/6/2021. b. The laboratory used Siemen Dimension, Sysmex XP 300, AIA instruments and others to perform hematology, routine chemistry, and endocrinology testing. c. The laboratory failed to verify and demonstrate that the laboratory can obtain performance specifications of all the instruments relocated to the new address comparable to those established before the relocation of the laboratory.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless

the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory failed to perform and document calibration verification (CV) procedure including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and at least once every 6 months. The findings included: a. The laboratory used Siemen Dimension to perform routine chemistry testing including ISE for electrolytes. b. The laboratory performed and documented calibration verification for ISE electrodes including Sodium, Potassium, Chloride on 5/14/2022. c. No previous records of CV documentations were available for 2021 at the time of survey (8/24/2022@12:25 PM).

**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 records, proficiency testing (PT) test result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for routine chemistry, endocrinology testing. The findings included: a. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for routine chemistry, and endocrinology see D-5217, D-5421, D-5439 and D-3033 to ensure accuracy, reliability and timely of the patient test result reports.