

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0860502	<b>(X3) Date Survey Completed</b>  06/26/2024
<b>Name of Provider or Supplier</b>  Allan Kurtz Do / Warner Medical Center	<b>Street Address, City, State</b>  6325 Topanga Canyon Blvd, Ste 501, Woodland Hills, 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>D2087</b>	<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 the survey conducted on June 26, 2024, at approximately 1:00 p.m. and review of American Proficiency Institute (API) proficiency testing (PT) records, interviews with the technical consultant (TC) and laboratory assistant (LA), and review of five (5) randomly chosen chemistry patients records; it was determined that the laboratory failed to attain at least 80% of the acceptable score in routine chemistry for Chloride and Sodium analytes. The findings included: 1. Based on review of PT records for the second event of 2021 (Q2-2021), API reported an unsatisfactory score report as follow: Chloride PT Q2-2021 Overall score 60% Specimen Reported Expected CH-06 96 86 - 96 CH-07 101 91 - 102 CH-08 *113 101 - 112 CH-09 *110 98 - 109 CH-10 115 106 - 118 Sodium PT Q2-2021 Overall score 60% Specimen Reported Expected CH-06 127 123 - 131 CH-07 135 130 - 139 CH-08 146 144 - 153 CH-09 *193 139 - 148 CH-10 *150 151 - 160 2. The TC and LA affirmed on June 26, 2024 at approximately 1:00 p.m. that the laboratory obtained PT scores in statement #1. 3. According to the submitted laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 16,000 routine chemistry test samples including Chloride and Sodium during the time the laboratory had unsatisfactory proficiency testing results. Thus, the reliability and quality of chemistry patient results reported could not be assured.</p>
<b>D2105</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(e)</p>

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing (PT) performance records, corrective actions log for the year 2021, and interview with the laboratory's technical consultant (TC) and laboratory assistant (LA) on June 26, 2024, at approximately 1:00 p.m.; the laboratory failed to document any remedial actions for unsatisfactory results for Vitamin D PT performance. The findings include: 1. The laboratory participated in the API PT program for the second event of 2021 (Q2-2021), obtaining an unsatisfactory analyte performance score of 50 percent for Vitamin D and failed to document any corrective actions. 2. The TC and LA affirmed on June 26, 2024, at approximately 1:00 p.m. that the laboratory received an unsatisfactory score for Vitamin D analyte for the Q2-2021 and missed to conduct any corrective actions for the unsatisfactory performance. 3. According to the laboratory's testing declaration form submitted on June 26, 2024, that the laboratory performed approximately 1,000 Vitamin D test samples annually.

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the deficiencies cited, the Laboratory Director is herein cited for deficient practice in responsibility to ensure that systems for the analytic and postanalytic phases of laboratory were monitored and followed. Findings include: a. The laboratory received unsatisfactory performance results for Chloride and Sodium. See D2087 b. The laboratory failed to conduct and document corrective action for Vitamin D analyte. See D2105. c. The technical consultant missed to review preventive maintenance log. See D6036.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on the survey conducted on June 26, 2024, interviews with the laboratory's technical consultant (TC) and laboratory assistant, review of eight (8) randomly chosen patient records, document review of preventive maintenance log, and review of corrective action reports; the technical consultant is herein cited for the deficient practice in overlooking review of laboratory records. The findings include: 1. Based on the 8 randomly chosen patients, one (1) out of 8 was missing maintenance log for preventive maintenance on March 18, 2024 for Chemistry analyzer. 2. Based on the review of corrective action reports, none were found for analytes that scored at least 80 percent at the time of survey: a. Second event of 2021: Testosterone and Vitamin D scored 50 percent, b. First event of 2023: Amylase scored 80 percent, b. Third event of 2023: Potassium scored 80 percent, c. First event of 2024: ALT scored 80 percent. 3. The TC affirmed that maintenance was missed to be recorded as documented on statement #1. TC also confirmed that most analytes that scored unsatisfactory were not reviewed and missed to document a corrective action report as stated on statement #2. 4. According to the submitted laboratory testing declaration on June 26, 2024, the laboratory performed 16,000 tests for Chemistry that included Amylase, Potassium and ALT analytes and 4,000 tests for Endocrinology that included Testosterone and Vitamin D analytes.