

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0566592	<b>(X3) Date Survey Completed</b> 02/15/2022
<b>Name of Provider or Supplier</b> Michael N Rutman Do Amc	<b>Street Address, City, State</b> 2355 S Melrose Dr, Vista, 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 review of the laboratory's records and the American Proficiency Institute (API) proficiency testing (PT) testing result reports, and interview with the technical consultant (TC), 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 was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory failed to attain a score of 80% of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event b. The laboratory used Olympus AU 400 chemistry analyzer to perform routine chemistry panel including, but not limited to the following analytes: Alkaline Phosphatase (Alk P), total Bilirubin (tBi), Sodium (Na). c. The laboratory failed to attain a score of at least 80% of acceptable responses for the following analytes in the following PT testing event which were unsatisfactory analyte performance for the testing events. PT Analyte score (%) Q2 2020 Alk P 0 Q3 2020 Na 40 Q3 2021 tBi 20 Q3 2021 Na 40 d. The laboratory performed Alk P, Na and tBi in approximately 50 patient sample for each analyte monthly. e. The laboratory TC affirmed (2/15/2022 @ 10:35 am) that the laboratory failed to attain a score of at least 80 percent of acceptable responses for analyte of Alk P, Na, and tBi in various 2020 and 2021 PT testing events (item c) were unsatisfactory analyte performance for the testing event.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

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 the laboratory's records and the American Proficiency Institute (API) proficiency testing (PT) testing result reports, and interview with the technical consultant (TC), it was determined that the laboratory failed to verify at least twice annually, the accuracy of any test or procedure it performs that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory used Olympus AU400 chemistry analyzer to perform chemistry testing including, but not limited to the following analytes: 25-OH Vitamin (Vit D), direct Bilirubin (dBi), CO<sub>2</sub>, Phosphorus (iP) which are not in the list of subpart I of 42 CFR part 493. b. The laboratory elected to enroll with American Proficiency Institute (API) PT program to verify the accuracy of the testing results at least twice annually. c. The laboratory failed to attain a score of at least 80% of acceptable responses for the following analytes in the following PT testing events which were unsatisfactory analyte performance for the testing events. PT Analyte score (%) Q2 2020 Vit D 0 Q2 2020 CO<sub>2</sub> 40 Q3 2020 CO<sub>2</sub> 40 Q1 2021 iP 60 Q2 2021 dBi 40 c. The laboratory performed Vit D, CO<sub>2</sub>, iP and dBi in approximately 50 patient samples for each analyte monthly. d. The laboratory TC affirmed (2/15/2022 @ 10:35 am) that the laboratory failed to attain a score of at least 80 percent of acceptable responses for analyte of Vit D, CO<sub>2</sub>, iP, and dBi in various 2020 and 2021 PT testing events (item c) were unsatisfactory analyte performance for the testing event

**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's records and the American Proficiency Institute (API) proficiency testing (PT) testing result reports, and interview with the technical consultant (TC), it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required to verify the accuracy, reliability of the patient test results reports. The findings included: a. The laboratory director failed to ensure that the proficiency testing samples were tested as required to verify the accuracy, reliability of the patient test results reports b. The laboratory used Olympus AU 400 chemistry analyzer to perform routine chemistry including, but not limited to the following analytes: Alkaline Phosphatase (Alk P), total Bilirubin (tBi), Sodium (Na). c. The laboratory failed to attain a score of at least 80% of acceptable responses for the analyte identified above item (a), which were unsatisfactory analyte performance for the testing events. see D-2087 d. The laboratory used Olympus AU400 chemistry analyzer to perform chemistry testing including, but not limited to the following analytes: 25-OH Vitamin (Vit D), direct Bilirubin (dBi), CO<sub>2</sub>, Phosphorus (iP) which are not in the list of subpart I of 42 CFR part 493. e. The laboratory elected to enroll with API PT program to verify the accuracy of the testing results at least twice annually. f. The laboratory failed to attain a score of at least 80%

of acceptable responses for the analytes identified above item (c) were unsatisfactory  
analyte performance for the testing events, see D-5217