

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0544111	<b>(X3) Date Survey Completed</b>  08/30/2023
<b>Name of Provider or Supplier</b>  James Richards, Md	<b>Street Address, City, State</b>  6222 W Manchester Ave, Ste A, Los Angeles, 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 Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory technical consultant on August 30, 2023, at 3:00 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for chloride at the 2nd event in 2023 and is unsatisfactory analyte performance for the testing event. The findings include: 1. The laboratory participated in the API PT program for the year 2023. The laboratory scored 40% for chloride at the 2nd event which resulted in an unsatisfactory analyte performance. Therefore, the accuracy of the patient test results reported by the laboratory during the proficiency testing event cannot be assured and might have harmed patients. 2. The laboratory technical consultant on August 30, 2023, at 3:00 pm, affirmed that the laboratory scored 40% for chloride at the 2nd event in 2023. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/30/2023 stated that the laboratory performs approximately 59,248 tests in routine chemistry, annually.</p>
<b>D2094</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <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</p>

proficiency testing event.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory technical consultant on August 30, 2023, at 3:00 pm, the laboratory failed to take remedial action after receiving the unsatisfactory analyte performance at the 2nd event in 2023. The findings include: 1. The laboratory participated in the API PT program for the year 2023. The laboratory scored 40% at the 2nd event which resulted in an unsatisfactory analyte performance. However, the laboratory did not take any remedial action for the failure except re-running the PT sample. The remedial action must address the underlying cause, future prevention and impact on the patients results. Therefore, the accuracy of the patient test results reported by the laboratory during the proficiency testing event cannot be assured and might have harmed patients. 2. The laboratory technical consultant on August 30, 2023, at 3:00 pm, affirmed that the laboratory did not take any remedial or corrective action for the unsatisfactory analyte performance at the 2nd event in 2023. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/30/2023 stated that the laboratory performs approximately 59,248 tests in routine chemistry, annually.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory technical consultant on August 30, 2023, at 3:00 pm, the laboratory failed to review and evaluate the proficiency testing results obtained at the 2nd event in 2023. The findings include: 1. The laboratory participated in the API PT program for the year 2023. It had an unsatisfactory performance for the chloride at the 2nd event however, the laboratory did not have any documentation showing that it had reviewed and evaluated the PT results. Therefore, the accuracy of the patient test results reported by the laboratory during the proficiency testing event cannot be assured and might have harmed patients. 2. The laboratory technical consultant on August 30, 2023, at 3:00 pm, affirmed that the laboratory did not have any documentation for the PT results review and evaluation. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/30/2023 stated that the laboratory performs approximately 59,248 tests in routine chemistry, annually.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If

the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, proficiency testing and patient test records, and interview with the laboratory technical consultant on August 30, 2023, at 3:00 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and thus had impaired the laboratory test quality and potentially harmed patients. The findings include: See D6018, D6019, and D6023.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing (PT) records from API, and interview with the laboratory technical consultant on August 30, 2023, at 3:00 pm, the laboratory director failed to ensure that the PT reports are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: See D5211.

**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 Surveyor review of laboratory's proficiency testing records from API, and interview with the laboratory technical consultant on August 30, 2023, at 3:00 pm, the laboratory director failed to ensure that the laboratory followed an approved corrective action plan when any proficiency testing result is found to be unsatisfactory. The findings include: See D2094.

**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 Surveyor review of laboratory's proficiency testing records from API, and interview with the laboratory technical consultant on August 30, 2023, at 3:00 pm, the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for chloride test. The findings include: See D2087.