

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0990631	<b>(X3) Date Survey Completed</b>  08/17/2023
<b>Name of Provider or Supplier</b>  Executive Physical Program	<b>Street Address, City, State</b>  8900 Wilshire Blvd, Ste 360, Beverly 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>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</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 17, 2023, at 12:35 pm, the laboratory testing person and director failed to attest to the routine integration of the PT samples into the patient workload using the laboratory's routine methods in one PT event out of 6 events reviewed. The findings include: 1. The laboratory participated in the API PT program for the year 2021, 2022 and 2023. However, the laboratory did not have any documentation showing that its testing person and director had attested to the routine integration of the CBC PT samples into the patient workload for the 2nd event in 2023. Therefore, it cannot be assured that the laboratory did not handle the PT samples differently than the patients' samples and the correct PT results might not reflect the laboratory's patients result accuracy. 2. The laboratory technical consultant on August 17, 2023, at 12:35 pm, affirmed that the laboratory did not have the attest documentation for the CBC PT 2nd event in 2023. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/16/2023 stated that the laboratory performs approximately 23,000 CBC tests, annually.</p>
<b>D2087</b>	<p><b>ROUTINE CHEMISTRY</b> 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>

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 17, 2023, at 1:00 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for calcium, CO2, glucose and total protein at the 1st 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 60% for calcium, 40% for CO2, 60% for glucose and 40% for total protein at the 1st 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 17, 2023, at 1:00 pm, affirmed that the laboratory scored 60% for calcium, 40% for CO2, 60% for glucose and 40% for total protein at the 1st event in 2023. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/16/2023 stated that the laboratory performs approximately 67,600 tests in routine chemistry, annually.

**D2094**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(e)

(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 Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory technical consultant on August 17, 2023, at 1:10 pm, the laboratory failed to take remedial action after receiving the unsatisfactory analyte performance at the 1st event in 2023. The findings include: 1. The laboratory participated in the API PT program for the year 2023. The laboratory scored 60% for calcium, 40% for CO2, 60% for glucose and 40% for total protein at the 1st 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 17, 2023, at 1:10 pm, affirmed that the laboratory did not take any remedial or corrective action for the unsatisfactory analyte performance at the 1st event in 2023 except re-running the failed PT sample. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/16/2023 stated that the laboratory performs approximately 67,600 tests, 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 reappoints 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 17, 2023, at 1:10 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 D2009, D2087, and D2094.

**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 17, 2023, at 1:00 pm, the laboratory director failed to assure 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 17, 2023, at 1:00 pm, the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for calcium, CO2, glucose and total protein test. The findings include: See D2094.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

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 17, 2023, at 12:35 pm, the laboratory director failed to document that the proficiency testing samples are tested as required. The findings include: See D2009.