

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0693081	<b>(X3) Date Survey Completed</b> 02/13/2020
<b>Name of Provider or Supplier</b> Ter-Zakarian Medical Clinic	<b>Street Address, City, State</b> 5250 Santa Monica Blvd Ste 310, 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>D2089</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy &amp; procedure, patient test records, quality control testing records, proficiency testing records, and interview with the Laboratory testing personnel, the laboratory failed to participate in the 2nd event of 2019 which is unsatisfactory performance and resulted in a score of 0 for the testing event. The findings include: a. The laboratory's proficiency testing results from American Proficiency Institute (API) shows that the laboratory scored 0% in chemistry for the 2nd event of 2019. b. The laboratory testing personnel, on 2/13/2020 at 12:10 pm, affirmed that the laboratory received a score of 0% in chemistry for the 2nd event of 2019, and mentioned that the laboratory was closed during the proficiency testing time. c. The laboratory's testing declaration form, signed by the laboratory Director on 1/30/2020, stated that the laboratory performs 1,500 tests, annually.</p>
<b>D2094</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 Surveyor review of laboratory's policy & procedure, patient test records, quality control testing records, proficiency testing records, and interview with the Laboratory testing personnel, the laboratory failed to take any remedial action for an unacceptable result obtained for sodium in the 3rd event of 2019 proficiency testing. The findings include: a. The laboratory received 5 samples for the 3rd event of 2019 proficiency testing to test sodium however, the laboratory's reported result of 1 sample was unacceptable by the proficiency testing organization. The laboratory did not take any remedial action for that unacceptable result. b. The laboratory testing person, on 2/13/2020 at 1:30 pm, affirmed that the laboratory's following reported result was unacceptable by the proficiency testing organization and the laboratory did not take any remedial action. Sample ID Reported Result Expected Result (mmol/L) CH-11 99 120 - 129 c. The laboratory's testing declaration form, signed by the laboratory Director on 1/30/2020, stated that the laboratory performs 1,500 tests, annually.

**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 policy & procedure, patient & quality control test records, API proficiency testing records, and interview with the laboratory testing personnel, it was determined that the laboratory Director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D2089 and D2094.