

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0918536	<b>(X3) Date Survey Completed</b> 05/23/2018
<b>Name of Provider or Supplier</b> Razmik Ohanjanian, Md, Inc	<b>Street Address, City, State</b> 511 Western Ave, Glendale, 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><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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined 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 performed routine chemistry including, but not limited to the following testing, ALT and AST and elected to enroll its PT program with American Proficiency Institute (API) to meet the CLIA requirement to ensure the accuracy of the testing performance. b. The laboratory attained a scores of 0 % and 60 % for the analyte AST and ALT in the 3rd 2017 and the 1st 2018 PT events, respectively. c. The laboratory failed to attain at least 80% for AST and ALT in the PT events which was unsatisfactory analyte performance for the testing event. c. The laboratory performed AST and ALT in approximately 84 patient samples each month. d. The laboratory staff affirmed (5/23/18 @ 12:15PM) that the laboratory attained a score of 0 % for AST in the 3rd 2017 and 60 % for ALT in the 1st 2018 PT events which was unsatisfactory analyte performance for the testing event.</p>
<b>D2098</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(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 review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined 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 performed T3 Uptake and elected to enroll its PT program with American Proficiency Institute (API) to meet the CLIA requirement to ensure the accuracy of the testing performance. b. The laboratory attained a score of 90% for the analyte T3 uptake in the 2nd 2017 PT event which was unsatisfactory analyte performance for the testing event. c. The laboratory performed T3 uptake in approximately 9 patient samples each month. d. The laboratory staff affirmed (5/23/18 @ 12:15PM) that the laboratory attained a score of 90% for the 2nd 2017 PT event which was 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 proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR 493. The findings included: a. The laboratory performed nowaived routine chmeistry and endocrinology testing, including, but not limited to AST and ALT b. The laboratory failed to attain a score of at least 80% for each analyte to meet the CLIA requirements for accuracy. c. See D-2087 and D-2098