

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0931291	(X3) Date Survey Completed 12/12/2019
Name of Provider or Supplier Takeshi Matsumoto Md	Street Address, City, State 1245 Wilshire Blvd, Ste 680, Los Angeles, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the POC (Plan of Correction) from the prior CMS 2567 document from 2017 indicated that 'A revised policy will be created' as a follow-up to a failure to achieve at least an 80 percent score for an ALT analyte and interview with the TP, 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. A revised Proficiency Testing (PT) policy was not found. The findings include: a. Medical Laboratory Evaluation (MLE) proficiency program gave an overall PT score for Analyte # 0255 ALT (SGPT) for Event 1 in 2018 was 60%. b. Six (6) out of six (6) random patient sampling test results reviewed covering period 2/10/2018 to 2/12/2018, six (6) patients were analyzed and reported during the time the laboratory received the unsatisfactory proficiency testing score. c. The testing personnel confirmed on 12/12/19 at 12:00 p.m. that there was no revised policy created as part of the laboratory's corrective action for a PT failure.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p>

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment procedures, lack of competency assessment documents available for review and interview with the TP it was determined that the technical consultant (TC) had failed to annually perform and document the competency of the TP as required annually. The findings included: a. At the time of survey (12/12/2019 at 12:15 p.m.), there were no competency evaluation documents for the TP performed by the TC/LD annually after 2008 for Routine Chemistry and Hematology testing. The competency evaluation must include following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. Based on the laboratory's testing declaration submitted for 2018 to 2019, there were 37,892 tests analyzed and reported by the TP without an annual review of competency evaluation by the laboratory director. c. The TP confirmed on 12/12/19 at 12:15 p.m. that no competency assessments had been performed after 2008 to present date.