

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0894010	<b>(X3) Date Survey Completed</b>  07/17/2018
<b>Name of Provider or Supplier</b>  Medical Sciences Laboratory Inc	<b>Street Address, City, State</b>  1761 W Romneya Dr Ste A, Anaheim, 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>D2109</b>	<p>TOXICOLOGY CFR(s): 493.845(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 proficiency testing (PT) test result reports, and interview with the laboratory personnel, it was determined that the laboratory failed 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. the findings included: a. The laboratory performed toxicology and reported the following therapeutic drugs (TDM), including but not limited to Phenytoin. b. In order to ensure the accuracy of the testing systems, the laboratory enrolled its proficiency testing with American Association of Bioanalysts (AAB) PT provider. c. The laboratory obtained a score of 60 % for Phenytoin in the 1st 2017 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed Phenytoin in approximately 40 patient samples per month. e. The laboratory affirmed (07/17/2018 @ 11:05 am) that the laboratory obtained a score of 60% for Phenytoin in the 1st 2017 PT event which was unsatisfactory analyte performance for the testing event.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) result report records, and</p>

interview with the laboratory staff, it was determined that the laboratory failed to verify the accuracy of any test or procedure it performed that was not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed analyte which is not included in the subpart I of 42 CFR part 493 including but are not limited to the followings analyte, PTH, Folate and CA 15-3. b. In order to ensure the accuracy of the mentioned above testing systems, the laboratory elected to enroll with AAB PT provider for the analyte identified in item (a). c. The laboratory failed to verify the accuracy at least twice annually for the testing systems it performed and the laboratory obtained scores of 50% for PTH, Folate, and CA 15-3 in the 3rd 2017 AAB PT event. d. The laboratory performed PTH in approximately 75 patient samples each month. e. The laboratory performed Folate in approximately 83 patient samples each month. f. The laboratory performed CA-15-3 in approximately 17 patient samples each month.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation and interview with the laboratory staff, it was determined that the laboratory failed to label with dates to indicate the reagents preparation and expiration dates. The findings included: a. Observing the reagents and supplies in the laboratory storage areas, noted that the HBsAg control material opened in use have not been labeled to indicate the preparation and expiration dates for current testing systems. b. The laboratory personnel affirmed (7/17/18 @ 1:15 PM) that the laboratory failed to label the reagent bottles with dates to indicate the preparation and expiration dates of the reagents in use.

**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 report, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of 42 CFR part 493. The findings included; See D-2109 and D-5217

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, interview with the laboratory staff, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: See D-5415