

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1071362	<b>(X3) Date Survey Completed</b>  05/15/2019
<b>Name of Provider or Supplier</b>  Scripps Clinic Medical Laboratories	<b>Street Address, City, State</b>  9535 Waples St Ste 150, San Diego, 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>D2075</b>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the laboratory testing personnel and Quality Assurance (QA) personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for IgM by Vista and HIV viral load by Architect for each testing event was unsatisfactory analyte performance. The findings included: a. The laboratory attained score of 60% for analyte of IgM in the 2nd 2018 PT, was unsatisfactory performance. b. The laboratory attained score of 60% for analyte HIV viral load in the 3rd 2018 PT, was unsatisfactory performance for that event. c. The laboratory performed IgM for approximately 9 patient specimens monthly. d. The laboratory performed HIV viral load for approximately 117 patient specimens monthly. e. The laboratory testing personnel and QA personnel affirmed (5/15/19 @ 12:40 PM) that the laboratory attained a score of 60% for IgM in the 2nd 2018 PT event, was unsatisfactory performance. f. The laboratory testing personnel and QA personnel affirmed (5/15/19 @ 12:40 PM) that the laboratory attained a score of 60% for HIV viral load in the 3rd 2018 PT event, was unsatisfactory performance.</p>
<b>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(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 College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the laboratory testing personnel and Quality Assurance (QA) personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable response for Prothrombin time (PrT), INR, and Partial Thromboplastin time (PTT) by Sysmex CA 1500 instrument was unsatisfactory performance. The findings included: a. The laboratory attained score of 60% for analyte of PrT, in the 1st 2019 PT event, was unsatisfactory performance. b. The laboratory attained score of 60% for analyte of INR, a calculated value, in the 1st 2019 PT event, was unsatisfactory performance. c. The laboratory attained score of 60% for analyte of PTT in the 1st 2019 PT event, was unsatisfactory performance. c. The laboratory performed PrT in approximately 3,766 patient specimens monthly. d. The laboratory performed PTT in approximately 697 patient specimens monthly. e. The laboratory testing personnel and QA personnel affirmed (5/15/19 @ 12:40 PM) that the laboratory attained scores of 60% for PrT, INR, and PTT in the 1st 2019 PT event were unsatisfactory performance.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
 CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the testing personnel and the Quality Assurance (QA) personnel, it was determined that the laboratory failed to, at least twice annually, verify the accuracy of the testing systems for Anti-smooth muscle (ASM) by PHD instrument, and serum Beta-2-Microglobulin (Beta-2) by Imulite the laboratory performed which were not listed in the subpart I of 42 CFR part 493. The findings included: a. The laboratory elected to enroll with CAP PT programs to meet the requirements for evaluation of proficiency testing performance for ASM and Beta-2 testing, were not listed in the subpart I of 42 CFR part 493. b. The laboratory attained score of 0% for ASM in the 2nd 2017 PT event was unsatisfactory performance. c. The laboratory attained score of 60% for Beta-2 in the 2nd 2018 PT event was unsatisfactory performance. d. The laboratory performed ASM for approximately 85 patient specimens monthly. e. The laboratory performed Beta-2 for approximately 57 patient specimens monthly. f. The laboratory testing personnel and QA personnel affirmed (5/15/19 @ 12:40 PM) that the laboratory failed to attained a score of at least 80%, acceptable responses for ASM in the 2nd 2017 was unsatisfactory performance. g. The laboratory testing personnel and QA personnel affirmed (5/15/19 @ 12:40 PM) that the laboratory failed to ensure, at least twice annually, the accuracy of the testing systems for ASM and Beta-2.

**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 College of American Pathologists (CAP) proficiency testing (PT) result reports, and interview with the laboratory testing personnel and the Quality Assurance (QA) personnel, 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 part 493. The findings included: a. The laboratory failed to perform PT satisfactory for analyte of IgM in the 2nd 2018 PT event, and HIV viral load in the 3rd 2018 PT. See D-2075 b. The laboratory failed to perform PT satisfactory for analyte of PrT, INR, and PTT in the 1st 2019 PT event. See D-2121 c. The laboratory did not ensure the accuracy of the testing systems for at least twice annually for analyte of ASM and Beta-2. See D-5217