Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0697841	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cedars-Sinai Plm Tower Hematology Oncology Lab	9090 Wilshire Blvd, 2nd Fl, Beverly Hills, 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
D2077	GENERAL IMMUNOLOGY CFR(s): 493.837(c) 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. This STANDARD is not met as evidenced by: Based on interviews with the staff on March 21, 2019, and review of American Association of Bioanalysts proficiency testing records from the 1st testing event of 2017 through the 3rd testing event of 2018, for one out of six proficiency testing events reviewed, the laboratory failed to participate in a testing event in the specialty of immunology. The findings included: a. Laboratory proficiency testing records showed the laboratory attained a score of 0% for Immunoglobulin A (IgA), Immunoglobulin G (IgG), and Immunoglobulin M (IgM) testing during the 3rd proficiency testing event of 2017. b. A testing person affirmed on March 21, 2019 at approximately 10:30 am, the unsatisfactory score of 0% obtained by the laboratory for Immunoglobulin A (IgA), Immunoglobulin G (IgG), and Immunoglobulin M (IgM) testing during the 3rd proficiency testing event of 2017. c. Based on the annual test volume reported for 2016, the laboratory performed and reported approximately 5,985 tests for the specialty of General Immunology.
D2123	HEMATOLOGY CFR(s): 493.851(c)

	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. This STANDARD is not met as evidenced by: Based on interviews with the staff on March 21, 2019, and review of American Association of Bioanalysts proficiency testing records from the 1st testing event of 2017 through the 3rd testing event of 2018, for one out of six proficiency testing events reviewed, the laboratory failed to participate in a testing event in the specialty of hematology. The findings included: a. Laboratory proficiency testing records showed the laboratory attained a score of 0% for White Blood Cell (WBC) differential, Red Blood Cell (RBC) count, Hematocrit, Hemoglobin, White Blood Cell (WBC) count, Platelets, Partial Thromboplastin Time (PTT), and Prothrombin Time (PT) testing during the 3rd proficiency testing event of 2017. b. A testing person affirmed on March 21, 2019 at approximately 10:30 am, the unsatisfactory score of 0% obtained by the laboratory for White Blood Cell (WBC) differential, Red Blood Cell (RBC) count, Hematocrit, Hemoglobin, White Blood Cell (WBC) count, Platelets, Partial Thromboplastin Time (PTT), and Prothrombin Time (PT) testing during the 3rd proficiency testing event of 2017. c. Based on the annual test volume reported, the laboratory performed and reported approximately 33,709 tests for the specialty of Hematology.
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 laboratory records and interview with the staff, it was determined that the laboratory director failed to ensure that proficiency testing samples are tested as required under subpart H of this part. The findings included: a. See D2077. b. See D2123.