Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1077487	09/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sierra Hematology & Oncology Medical Center	8100 Bruceville Rd, Sacramento, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) result reports, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Leucocyte Count (WBC), WBC Differential, and Platelet Count (Plt), in each testing event were unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used Abbott Cell-Dyn Emerald to perform complete blood cell count (CBC) including WBC and WBC Differential, Erythrocyte Count (RBC), Hemoglobin (Hgb), Hematocrit (Hct), and Platelet Counts (Plt). b. The laboratory enrolled its PT programs with Medical Laboratory Evaluation (MLE) PT provider to ensure the accuracy of the CBC testing performances annually. c. The laboratory attained scores of 60% for the following analyte, WBC and Plt in the 3rd 2016 PT event, which were unsatisfactory analyte performance for the testing event. d. The laboratory attained a score of 66% for the following analyte, WBC Differentials in the 3rd 2016 PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed CBC in approximately 300 patient samples each month. e. The laboratory personnel affirmed (9/20/2018 @ 1 PM) that the laboratory failed to attained at least 80% of acceptable responses for WBC, WBC Differential, and Plt in the 3rd 2016 Hematology PT event which were 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 proficiency testing (PT) result reports, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the laboratory attained a score of at least 80 percent of acceptable responses for CBC testing in the 3rd 2016 Hematology PT event and failed to perform the tests as required under subpart H of 42 CFR part 493. The findings included: a The laboratory used Abbott Cell-Dyn Emerald to perform CBC and enrolled its PT with MLE PT provider. b. The laboratory failed to attain a score of at least 80 percent of acceptable responses for WBC, Cell Differential, and Plt in the 3rd 2016 Hematology PT event were unsatisfactory analyte performance for the PT testing event. c. See D-2121.