Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0600646	12/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sierra Hematology And Oncology	1580 Creekside Dr Ste 230, Folsom, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory personnel reports (CMS209, LAB116), patients test records, and laboratory hematology proficiency testing documents; and interview with laboratory personnel, the laboratory failed to include proficiency test samples with the regular patient workload to be tested by individuals routinely performing laboratory testing. Findings include: a. The Attestation documents stated the same person performed proficiency testing for 4 out of 4 consecutive events beginning in 2017; and that subsequent 2 out of 2 events in 2018 were performed by another. b. The laboratory personnel reports named two other individuals as testing persons. c. Laboratory personnel affirmed (12/04/18) that the proficiency testing samples had not been integrated into the regular workload to be tested by the individuals routinely testing patients specimen. d. The reliability and quality of results reported could not be assured when the individuals had not tested proficiency samples. Based on the stated annual tests volume (LAB144A Laboratory Testing Declaration, 12/04/18), laboratory testing personnel reported approximately 32,832 hematology results annually in 2017 - 2018.
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 observation of the Celldyn Emerald hematology analyzer, review of proficiency testing reports from CMS (report 155, Individual Laboratory Profile) and MLE (Medical Laboratory Evaluation), laboratory proficiency records, and patients test records; and interview with laboratory personnel, the laboratory failed to attain the score of at least 80% in the 1st event of 2017, for unsatisfactory analyte performance. Findings include: a. CMS and MLE reported the unsatisfactory score of 60% for WBC Differential based on unacceptable elevated results for 2 out of 5 samples. b. Laboratory personnel affirmed (12/04/18) the aforementioned results and score; and thus, unsatisfactory test performances for Differentials. c. The reliability and quality of Differentials reported could not be assured when proficiency testing was unsatisfactory. Based on the stated annual tests volume (LAB144A Laboratory Testing Declaration, 12/04/18), the laboratory reported approximately 456 Differtials each month for the timeframe January to May 2017.
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 the deficiency cited (D2007), the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure that proficiency testing samples are tested by persons testing patients specimen.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the lack of laboratory documents and interview with a laboratory person, the Technical Consultant (Laboratory Director) failed to evaluate the competency of all testing personnel in 2017 and assure they maintain their competency to perform test procedures and report test results promptly, accurately and proficiently using the Celldyn Emerald. Findings include: a. The laboratory failed to provide for review competency assessments for personnel testing patients specimen in 2017. b. A laboratory person affirmed (12/04/18) the lack of aforementioned documents for 2017; and thus, the failure of the Technical Consultant (Laboratory Director) to assess competency by direct observation of routine testing performance including Celldyn Emerald instrument maintenance and function checks, monitoring the recording and reporting of test results, review of test results, quality control records, preventive maintenance records, and proficiency testing records; assessment of test performance

	through proficiency testing, and assessment of problem solving skills. c. Based on the stated annual tests volume, testing personnel reported approximately 32,832 hematology results in 2017.