

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0613463	<b>(X3) Date Survey Completed</b> 12/06/2018
<b>Name of Provider or Supplier</b> Sierra Hematology & Oncology	<b>Street Address, City, State</b> 6555 Coyle Ave Ste 301, Carmichael, 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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel reports (CMS209, LAB116), 2017 and 2018 laboratory proficiency testing records and patients test records; and interview with Testing Person-1, the laboratory failed to have all routine testing personnel participate in the proficiency testing process. Findings include: a. Laboratory personnel reports named three individuals as testing persons performing hematology testing. b. For all 6 out of 6 events in 2017 - 2018, laboratory proficiency testing documents revealed only Testing Person-1 performed proficiency testing. c. Testing Person-1 affirmed (12/06/18, 12:00pm) that the three individuals named on the laboratory personnel reports routinely tested patients specimen, and that 2 out of 3 had never tested proficiency samples; and thus, the failure to test proficiency samples with the regular workload by personnel routinely doing the testing. d. The reliability and quality of results reported by 2 out of 3 testing persons could not be assured when they had never participated in proficiency testing. Based on the stated annual tests volume, the three testing persons combined reported approximately 58,200 hematology results each year.</p>
<b>D2121</b>	<p><b>HEMATOLOGY</b> 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 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 2018, for unsatisfactory analyte performance. Findings include: a. CMS and MLE reported the unsatisfactory score of 60% for WBC (White Blood Cell count) based on unacceptable results for 2 out of 5 samples. b. A laboratory person affirmed (12/06/18; 12:00 PM) the aforementioned results and score; and thus, unsatisfactory test performances for WBC. c. The reliability and quality of WBC counts 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 WBC counts each month in 2018 for the timeframe January to May. A few examples are as follows: Date Number of patients tested  
 ----- 1/09/18 47 2/07/18 48 3/16/18 21 .

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
 Based on observation of the Celldyn Emerald hematology analyzer, review of laboratory personnel reports (CMS209, LAB116) and patients test records, the lack of laboratory document(s), and interview with a laboratory person, it was determined that the Laboratory Director was deficient in the practice of ensuring each Testing person demonstrated the performance of all testing procedures reliably to provide and report accurate results prior to testing patients. Findings include: a. Testing Person-3 had begun testing and reporting patients results in 2017. b. The laboratory failed to provide for review laboratory documents including testing records and Celldyn Emerald instrument printouts from Testing Person-3 demonstrating testing and providing reliable results, prior to testing patients in 2017. c. A laboratory person affirmed (12/06/18; 12:00 PM) the aforementioned lack of documents and policy. d. The Laboratory Director failed to ensure the laboratory had a written policy and practice to require each testing person demonstrate the ability to perform all preanalytic, analytic, and postanalytic procedures reliably to provide and report accurate results prior to testing patients. e. The reliability and quality of results reported by Testing Person-3 could not be assured in the absence of demonstrating the ability to provide accurate results prior to testing patient specimen. Examples of testing performed by Testing Person-3 in 2017 are as follows: Date Number of patients tested ----- 1/18/17 50 2/23/17 40 7/11/17 42 10/24/17 48 12/29/17 24 .

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on observation of the Celldyn Emerald hematology analyzer, review of laboratory personnel reports (CMS209, LAB116) and documents for annual competency assessment, the lack of laboratory documents, and interview with laboratory personnel, the Technical Consultant (Laboratory Director) failed to evaluate the performance of Testing Person-3 at least semiannually during the first year of testing. Findings include: a. Documents for 2018 annual competency assessment were provided for three testing persons named on the laboratory personnel reports. b. The laboratory failed to provide for review document(s) for competency assessment at least semiannually during the first year for Testing Person-3. c. A laboratory person affirmed (12/06/18; 12:00 PM) the lack of aforementioned semiannual competency assessment for Testing Person-3, who began testing patients specimen in 2017; and thus, the failure of the Technical Consultant (Laboratory Director) to evaluate and document testing performance at least semiannually during the first year. d. The reliability and quality of results reported could not be assured when competency was not assessed and documented at least semiannually during the first year of testing. Examples of testing performed by Testing Person-3 in 2017 are as follows: Date Number of patients tested ----- 1  
/18/17 50 2/23/17 40 7/11/17 42 10/24/17 48 12/29/17 24 .