

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0681290	<b>(X3) Date Survey Completed</b> 03/08/2022
<b>Name of Provider or Supplier</b> Los Angeles Hematology Oncology Med	<b>Street Address, City, State</b> 1245 Wilshire Blvd Ste 303, Los Angeles, 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>D2123</b>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records for the second event for 2021 (Q2-2021), five (5) randomly chosen patient test results from 5/14/2020 to 2/14/2022 and interview with the technical consultant (TC); it was determined that the laboratory failed to participate in a testing event which is unsatisfactory performance and results in a score of 0% for the testing event. The findings included: 1. MLE reported an unsatisfactory score of 0% for the hematology performance summary event of Q2-2021, which included: erythrocyte (RBC), hemoglobin (HGB), hematocrit (HCT), leukocyte (WBC) count, platelet count, and three-part white blood (WBC) differential analysis performed on the automated Abbot Cell Dyn 1800. 2. The TC affirmed on March 8, 2022 (survey date) at approximately 11:15 a.m. that the laboratory failed to submit the proficiency challenges for the MLE PT event for Q2-2021. 3. The laboratory's testing declaration signed and dated by the laboratory director states that the laboratory tested and reported 18 ,000 hematology patient tests annually.</p>
<b>D5401</b>	PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory current written standard operating procedure for Hematology and interview with the laboratory's technical consultant (TC), it was determined that the laboratory failed to have available and follow a written procedures for the test performed in the laboratory. The findings included: 1. On the day of the survey on March 8, 2022. at approximately 11:50 a.m. the laboratory failed to provide a written standard operating procedure for the Hematology tests currently performed in the laboratory. 2. The laboratory TC confirmed on March 8, 2022, that the laboratory did not have a written procedure available for the Hematology test using the Abbot Cell Dyn 1800 instrument used in the laboratory. 3. Based on the laboratory annual test volume declaration signed by the laboratory director on 3/8/2022 the laboratory analyzed and reported approximately 18,000 Hematology tests for which no written tests procedures were available for the testing personal to follow.

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(ii)

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the second quarter of 2021 of the Medical Laboratory Evaluation proficiency testing records, random patient test results, and interview with the technical consultant; it was determined that the laboratory director failed to ensure that results are returned within the timeframes established by the proficiency testing program. See D 2123.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on direct observation and interview with the laboratory technical consultant; it

was determined that the laboratory director failed to ensure that an approved written procedure manual is available at all times to all personnel responsible for any aspect of the testing process. See D5401.