

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1062061	(X3) Date Survey Completed 11/27/2018
Name of Provider or Supplier Advanced Hematology Oncology Pllc	Street Address, City, State 42-35 Main Street, Suite 3 H, Flushing, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory policies/procedures, annual competency records and an interview with the laboratory director and testing person, the laboratory failed to have a complete policy and procedure for personnel competency. Finding Include: It was confirmed by the laboratory director and testing person on November 27, 2018, at approximately 11:00 am that the laboratory failed to include direct observation for the performance of patient test management and complete instrument performance for two of two testing personnel who perform hematology testing from the date of the last survey (March 20, 2017) to the date of this survey.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

	<p>This STANDARD is not met as evidenced by: Based on a lack of instrument validation records and confirmed an interview by the laboratory director and testing person on November 27, 2018, at approximately 12:15 pm, the laboratory failed to perform validation for the new Horiba Micros 60 hematology analyzer prior to patient testing. Patient testing began in July 2017. Approximately 6600 patient specimens have been tested and results reported in July 2017 through the date of this survey.</p>
<p>D5481</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of hematology quality control (QC) records and an interview with the laboratory manager/testing person, the laboratory failed to ensure that hematology QC results performed on the Horiba Micros 60 hematology analyzer was within an acceptable range prior to testing patient specimens. Findings Include: It was confirmed with the laboratory director and testing person on November 27, 2018, at approximately 12:15 pm, that the laboratory tests three levels of QC material. Platelets and Hemoglobin were out of acceptable range and remediation was not performed. Approximately 1066 patient specimens were tested and results reported on the dates listed below. November 5, 2018 - Hemoglobin - low and high controls; Low control for Platelets: October 2018 - 18 of 28 days September 2018 - 6 of 23 days High control for Platelets: October 2018 - 16 of 28 days September 2018 - 3 of 23 days Normal control for Hemoglobin: October 2018 - 4 of 23 days September 2018 - 16 of 23 days High control for Hemoglobin: November 2018 - 4 of 9 days October 2018 - 14 of 28 days September 2018 12 of 28 days</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of QC records, and confirmed in an interview with the laboratory director and testing person, the laboratory director failed to ensure that the QC program for hematology was maintained to assure the quality of laboratory services. Refer to: Refer to D5481</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policy/procedure manual and an interview with the laboratory director and testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to D5209 & D5421