

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1062061	(X3) Date Survey Completed 02/10/2022
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's refrigerator temperature logs, ABX Horiba manufacturer's specifications for ambient temperature & humidity, and an interview with the laboratory director and office manager, the laboratory failed to establish criteria used to define room temperature and humidity ranges for the storage of reagents and hematology analyzer itself. Finding: 1. The laboratory failed to establish criteria used to define room temperature and humidity ranges for the storage of reagents and hematology analyzer itself. The manufacture's requirements for the ABX MICROS 60 must operate in a temperature range between 18 to 32C, (65 to 90F). Maximum relative humidity 80% for temperatures up to 31C (88F) 2. No Documentation was available at survey for the room temperature and humidity to date. a. The Horiba ABX Micros 60 was implemented in 2017. 3. The laboratory director and the office manager confirmed on 2/10/2022 approximately at 2:00 PM the laboratory failed to document the room temperature and humidity.</p>
D6024	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on lack of room temperature and humidity records, lack of remedial action records, and confirmed in an interview with the laboratory director and office manager, the laboratory director failed to identify the error and take remedial action when the laboratory failed to establish the criteria used for room temperature and humidity, as required by the manufacturer. Refer 5413