

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0671792	(X3) Date Survey Completed 11/04/2024
Name of Provider or Supplier Genesee Hematology Oncology	Street Address, City, State 302 Kensington Avenue, Flint, MI	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the technical consultant, the laboratory failed to label its hematology control materials with the expiration date reflecting its opened container stability for three of three opened control materials observed. Findings include: 1. The surveyor observed the three levels of hematology control with "11/1/24" written on each container on 11/4/24 at 9:02 am. 2. A review of the laboratories package insert for the current lot of hematology controls revealed a section stating, "8 consecutive day open-vial Stability." 3. An interview on 11/14/24 at 9:02 am with the technical consultant revealed the date on the vials was the open date and the laboratory did not included the expiration dates on the vials.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on record review and interview with Technical Consultant, the laboratory failed to ensure background checks for the Abbott Celldyn Ruby hematology analyzer were within established limits prior to testing and reporting patient results for 5 (4/25/2024, 04/26/2024, 1/10/2024, 1/11/2024, 1/26/2024, 1/29/2024) of 61 days in 2024. Findings include: 1. A review of the laboratory's Abbott Celldyn Ruby hematology analyzer background count records revealed the background counts failed on the following days: 4/25/2024, 04/26/2024, 1/10/2024, 1/11/2024, 1/26/2024 and 1/29/2024. 2. An interview on 11/04/2024 at 12:15 pm with the Technical Consultant revealed that corrective action was not implemented for the background count failures listed above. A policy addressing failed background counts was requested and was not provided prior to survey exit.