

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0958295	(X3) Date Survey Completed 01/30/2025
Name of Provider or Supplier Hematology And Oncology Lexington	Street Address, City, State 107 West Medical Park Drive, Suite 101, Lexington, NC	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of DxH 520 validation records, review of 2023 and 2024 maintenance logs, and interview with testing personnel (TP #2) 1/30/25, the laboratory failed to perform and document maintenance for the DxH 520 hematology analyzer at the frequency specified by the manufacturer. Findings: Review of the Beckman Coulter "DxH 520 Instructions for Use" revealed in Chapter 12 "Cleaning Procedures" a list of maintenance procedures to be performed at specified frequencies. The procedures included: 1. Cleaning the instrument daily or as needed, based on visual inspection; 2. Performing a bleach cycle every 1,000 cycles or monthly, whichever comes first; 3. Cleaning the WBC bath filter monthly; 4. Lubricating pistons yearly. Review of the laboratory's DxH 520 validation records revealed the instrument was installed in March 2021, and patient testing began 3/17/21. Review of maintenance logs revealed: 1. There were no maintenance logs for 2021, 2022, and January 2023 available for review. 2. 2023 maintenance logs for February - December and 2024 logs did not include documentation of cleaning the instrument daily as specified by the manufacturer. 3. 2023 maintenance logs for February - December and 2024 logs for January - October listed the monthly requirement "Perform bleach cycle on DXH". a. Performance of the monthly bleach cycle was not documented 2 of 11 months in 2023 (February and September). b. Performance of the monthly bleach cycle was not documented 1 of 12 months in 2024 (July). 4. "Perform bleach cycle and Clean filter on DXH" was added to the monthly tasks on the November 2024 log. Cleaning of the WBC bath filter monthly was not documented for 11 of 11 months in 2023 (February - December) and</p>

10 of 12 months in 2024 (January - October). 5. 2023 maintenance logs for February - December and 2024 maintenance logs did not include documentation of annual piston lubrication. During interview approximately 11:15 - 11:25 a.m., TP #2 stated that maintenance was performed but not documented prior to February 2023. She stated that service was onsite several times shortly after the instrument was installed so they could have performed some of the maintenance, but they did not provide any documentation.