Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2169655	(X3) Date Survey Completed 08/23/2022
Name of Provider or Supplier Lutherville Hematology And Oncology Services	**Street Address, City, State** 7602 Belair Rd, Mercy Personal Phys At Overlea, Baltimore, MD	

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
D5401	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 standard operating procedure manual (SOPM) and hematology quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not follow written procedures for validating new lot numbers of hematology QC. Findings: 1. The procedure "Sysmex XP-300 Automated Hematology Analyzer CLSI Procedure," "Starting a New Lot of Controls" in the SOPM states, "Parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated and values are running within assay ranges, the lot may be placed into production." 2. During an interview at 12:00 PM, the TC stated that each new lot number of hematology QC is run for 3 days in parallel with the old lot number before being put into use. 3. A review of hematology QC from May through July 2022 showed that the "old" lot number of QC (lot #: 2109, expiration date: 07/27/2022) was run in parallel with the "new" lot number of QC (lot #: 2193, expiration date: 10/19/2022) for 3 days on 07/25/2022, 07/26/2022, and 07/27/2022. 4. During an interview on 08/23/2022 at 12:30 PM, the TC confirmed that the written SOPM did not accurately reflect the actual practice of the laboratory.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	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. This STANDARD is not met as evidenced by: Based on observation, temperature log record review, and interview with the technical consultant (TC), the laboratory failed to define, monitor, and document laboratory reagent refrigerator temperature to ensure proper reagent storage and reliable test system operation. Findings: 1. During a tour of the laboratory at 10:45 AM on the day of the survey it was observed that the in-use "Eightcheck-3UP X-TRA" hematology quality control (QC) vials were stored in a small refrigerator in the laboratory. The remaining stock of QC was stored in another refrigerator in a storeroom. 2. A review of temperature logs from January through August 2022 showed that there were temperature logs for one refrigerator labeled "P2." 3. During an interview on 08/23 /2022 at 11:00 AM the TC stated that "P2" was the refrigerator in the storeroom. The TC confirmed that temperatures were not being monitored and recorded for the refrigerator in the laboratory where the in-use hematology QC was stored.