Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0986272	10/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Uab Cancer Center At Russell Medical	3446 Highway 280, Alexander City, AL	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the reviews of the XP-300 maintenance logs and the Hematology Quality Control (QC)records, the laboratory failed to: a) Document the manufacturer's required quarterly maintenance (refer to D5429). b) Establish a mechanism to monitor for shifts and trends (refer to D5441). c) Provide QC printouts with the lot numbers and expiration dates (refer to D5447).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Hematology Sysmex XP-300 maintenance records, a review of the Sysmex XP-300 Instructions For Use, and an interview with the Technical Consultant (TC), the laboratory failed to document quarterly maintenance for the Hematology analyzer. This was noted for ___ possible months out of _____ months reviewed in 2023 through 2025. The findings include: 1. A review of the Hematology

	maintenance records revealed quarterly (every 3 months) maintenance on the Sysmex XP-300 Maintenance Log was documented for the following dates: January 17, 2025 and May 5, 2025. No documentation of quarterly maintenance from November 2023 - December 2024 and August 2025. 2. A review of the Sysmex XP-300 Instructions For Use revealed in section 12 page 12-12 under Clean SRV "...if either the counter value exceeds 4,500, or if 3 months have passed since the last maintenance, a message will appear prompting the operator to perform periodic maintenance (SRV cleaning)..." 3. The TC confirmed the above findings during the exit conference on 10-01-2025 at 1: 37 PM.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on a review of the Hematology Sysmex XP-300 Quality Control (QC) records and an interview with the Technical Consultant (TC), the laboratory failed to establish a procedure that monitors the shifts and trends of test performance over time. This was noted from the date of the last survey, 07-27-2023, to the date of the current survey, 10-01-2025. The findings include: 1. A review of the Sysmex XP-300 QC records revealed only the daily QC data from the instrument were retained from 2023-2025. No evidence of Levey Jennings charts or peer group data was available for review at the time of the survey. 2. During an interview with the TC at approximately 1:30 PM, the TC stated that the laboratory just recently participated in submitting their QC data for peer group comparison.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on reviews of the Hematology Quality Control (QC) records and an interview with the Technical Consultant (TC), the laboratory failed to retain documentation of the three levels of QC with the Lot Number and Expiration Date each day of patient testing. The surveyor noted there was no QC documentation for 8 of the 31 days in October 2023, 2 of the 31 days in May 2024 and 6 of the 31 days in August 2024. The findings include: 1. A review of the Hematology Quality Control (QC) records revealed the laboratory failed to retain the QC printouts with the Lot Numbers and Expiration dates prior to patient testing for the following days: A) October 2023: 10/2, 10/3, 10/9, 10/12, 10/13, 10/14, 10/27, 10/31 B) May 2024: 5/28, 5/31 B) August

	2024,: 8/20, 8/22, 8/23, 8/28, 8/29, 8/30. 2. During an interview on 10-01-2025 at 1:37 PM, the TC confirmed the above findings.