Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0973051	03/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
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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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the laboratory failed to document the eyewash checks. Findings: 1. The "General Maintenance" procedure stated that the "Eyewash should be checked weekly and cleaned and flushed at a minimum monthly" and to "Record on the eyewash log the date the maintenance was completed and the initials of performing tech." 2. During the survey on 02/21/2024 at 2:00 PM, the TP confirmed that there was no eyewash log to document performance of the eyewash checks.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the procedure manual and proficiency testing (PT) records and interview with the office manager (OM), the laboratory failed to document the review of PT results in three of five PT events reviewed. Findings: 1. The Proficiency Testing Policy stated that "Proficiency testing results will be reviewed within 30 days of receipt of results," "Initially, both the testing personnel and the Laboratory Supervisor should review the PT scores, and if all are satisfactory, the forms are signed and

	dated," and "The Laboratory Director also must sign the forms as reviewed, and reports are filed in the Proficiency Testing Manual." 2. The PT records for 2023 and 2024 were reviewed for a total of five PT events. 3. There was no documentation that PT results from the three 2024 PT events were reviewed by the testing personnel, laboratory supervisor, or laboratory director. 4. During the exit interview on 02/21 /2025 at 2:30 PM, the OM confirmed that there was no documentation that the PT results from 2024 were reviewed by laboratory personnel.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on observation, review of the procedure, and interview with the testing personnel (TP), the laboratory failed to document the hematology quality control (QC) opened and expiration dates on the QC vial. Findings: 1. The "Sysmex XP-300 Automated Hematology Analyzer" procedure stated that the QC open vial stability was 14 days when promptly refrigerated after each use and instructed the TP to record the opened date on each vial upon opening. 2. The QC vials stored in the refrigerator were not labeled with the opened and expiration dates. 3. During the survey on 02/21 /2025 at 2:00 PM, the TP confirmed that the opened and expiration dates were not recorded on newly opened vials of QC material.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of quality control (QC) records, and interview with the testing person (TP) and office manager (OM), the laboratory had multiple procedures for parallel testing new QC lots for verification prior to use and no documentation that new lots of QC had been parallel tested for verification. Findings: 1. The "Sysmex XP-300 Automated Hematology Analyzer" procedure stated to "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. The "Quality Control and Assessment" procedure (QC procedure) stated that "Assessment of a new lot of quality control material should be performed while the previous lot is still in use," "After 5 repetitions on 5 separate days with alternating operators, if the new control results are within the manufacturer's established range, the lot has been verified," "Attach the QC verification runs to the QC package insert," and "Lab director sign the verification worksheet and date as approval of verification." 3. The "Procedure for Change in Lot of Assayed Control Material" section of the QC procedure stated that "Each level of new control material must be evaluated 5 times, with alternating personnel and on multiple days when possible, to verify that control results fall within manufacturer stated 2SD ranges" and "Results may be compared against those found within the package insert and filed in the quality control binder, or documented on the chart template, to show acceptability of new lot control material." 4. On 02/21/2025 at 2:10 PM, the TP stated that new QC lots were tested with the old QC lots, but the results weren't printed and saved with the QC records. 5. During the exit interview on 02/21/2025 at 2:30 PM, the OM confirmed that there were multiple procedures with differing instructions for performing parallel testing on new QC lots and no documentation showing that new QC lots were parallel tested prior to use.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on observation and interview with the testing personnel (TP), the laboratory was not consistently documenting the identity of the TP who performed each hematology test. Findings: 1. The Sysmex XP-300 hematology analyzer included a field for the TP to enter their initials for each patient specimen that was tested. 2. During the survey on 02/21/2025 at 2:10 PM, the TP confirmed that the TP were not consistently entering their initials into the instrument to identify which TP performed testing for each patient specimen.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the office manager

	(OM), the hematology Levy-Jennings (L-J) graphs were unable to be printed and reviewed as stated in the procedure. Findings: 1. The "Quality Control and Assessment" procedure stated that "A pictorial representation of quality control results, such as Levy-Jennings graphs, is a valuable tool for assessing control results" and "Problems with the instrument, reagents, control materials, and operators can be assessed by examining these graphs at least weekly to look for unexpected patterns." 2. There were no L-J graphs printed for review from 2023 and 2024. 3. During the exit interview on 02/21/2025 at 2:30 PM, the OM stated that the L-J charts and summary QC data was currently unable to be printed from the analyzer and was therefore not reviewed.