Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0904183	05/07/2025
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of maintenance records, patient data logs, and staff interviews, the laboratory failed to retain the Background function check (one of three dates reviewed) for the Sysmex instrument used to perform complete blood count with automated differential (CBC w/Diff) patient testing in 2025. The findings include: 1. Observation of the laboratory on 05/07/2025 at 10:15 am revealed the Sysmex XP-300 (Serial B6106) instrument used for CBC w/Diff patient testing. 2. A review of the laboratory's Medicus laboratory information system (LIS) report titled "Blank Check Results" for 04/01/2025 through 04/30/2025 revealed that the laboratory did not record a background function check for 04/08/2025. Documentation of the background function check from 04/08/2025 was not available on the survey date (05/07/2025). 3. A review of the laboratory's patient data records, titled "Accession Log," revealed that five CBC w/Diff patient samples were reported on 04/08/2025. 4. An interview with the laboratory director on 05/07/2025 at 1:00 pm confirmed the survey findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, a review of the Sysmex XP-300 operator's manual, the laboratory's procedure manual, and staff interviews, the laboratory procedure for complete blood count with automated differential (CBC w/Diff) testing failed to include critical/alert values, normal reference range values, or actions to take for flagged results. The findings include: 1. Observation of the laboratory on 05/07 /2025 at 10:15 am revealed the Sysmex XP-300 (Serial B6106) instrument used for CBC w/Diff patient testing. During the observation testing person one stated that some testing personnel repeated patient CBC w/Diff samples if flags were present, that the laboratory director reviewed all abnormal patient results, and that the laboratory did not have written criteria to follow for for flagged CBC w/Diff patient results. 2. A review of the Sysmex XP-300 Operator's manual used as part of the laboratory's procedure in section "8.3 Histogram flags" revealed the following flags and recommended correction actions: [WL]: "1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. 2) Check smear, etc." [RL]: "1) Manual red blood cell count of sample. 2) Check smear, etc." [PL]: "1) Warm sample at 37C for 30 minutes and repeat analysis. 2) Check smear, etc." [WU]: "1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. 2) Check smear, etc." [RU]: "1) Warm sample at 37C for 30 minutes and repeat analysis. 2) Check smear, etc." [PU]: "1) Manual platelet count of sample. 2) Check smear, etc." [DW] (RBC): "1) Check smear, etc." [DW] (PLT): "1) Check smear, etc. 2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc." [MP] (RBC): "1) Check smear, etc." [MP] (PLT): "1) Check smear, etc." [T1]: "1) Check smear, etc. 2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc." [T2]: "1) Check Smear, etc. 2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc." [F1], [F2], [F3]: "1) Check smear, etc. 2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc." [AG]: "1) Check smear, etc." 3. A review of the laboratory procedure manual revealed that the laboratory did not have a Sysmex XP-300 CBC w/Diff procedure that included critical/panic values, normal reference range values, or actions to take for flagged results. 4. An interview with the laboratory director on 05/07/2025 at 1:00 pm confirmed that the laboratory

	procedure did not include normal reference range or critical/panic values. The laboratory director further confirmed that the laboratory did not perform the correction actions in the Sysmex XP-300 operator's manual for histogram flags and did not have a procedure to follow for actions to take for the flagged results. Word Key: -degree C-Celsius RBC- Red Blood Cell PLT- Platelet