Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0931074	03/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mercyone Waterloo Cancer Center	200 East Ridgeway Avenue, Waterloo, IA	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and instrument operator's manuals and confirmed by interview with Technical Consultant #1 (TC #1) and personnel identifier #2 at 12:30 pm on 03/18/2025, the laboratory director failed to approve, sign, and date all laboratory policies and procedures, including instrument operator's manuals, from 01/01/2023- 03/18/2025. The findings include: 1. At the time of the survey, the laboratory had its written policies and procedures in binders with the following titles: *Covenant Medical Center Cancer Treatment Center Laboratory Hematology Notebook General Procedures *Cancer Treatment Center Procedure Manual *Covenant Medical Center Cancer Treatment Center Laboratory General Policies, Quality Control, and Procedure Notebook 2. The laboratory also used the Sysmex XN-450 operator's manual as the procedure manual for the hematology test system. 3. Personnel identifier #2 stated the new laboratory director began overseeing the laboratory in January 2023. 4. At the time of the survey, TC #1 confirmed the laboratory director did not approve, sign, and date the policy and procedure manuals or instrument operator's manual listed above from 01/01/2023- 03 /18/2025.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable

	limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration and calibration verification records and confirmed by interview with Technical Consultant (TC) #1 at 11:50 am on 03/18/2025, the laboratory failed to perform calibration verification procedures for sodium, chloride, and potassium testing every six months for one out of two time periods from 01/01 /2024 - 12/31/2024. The findings include: 1. The laboratory used the Siemens Dimension EXL test system to perform sodium, chloride, and potassium testing. 2. Review of reagent calibration documentation for sodium, chloride, and potassium showed two calibration points for each analyte. 3. The laboratory performed calibration verification procedures for sodium, chloride, and potassium on 03/22 /2024. 4. At the time of the survey, TC #1 confirmed the laboratory did not perform calibration verification procedures which included a minimal (zero) value, a mid-point value, and maximum value for sodium, chloride, and potassium testing for the time period between 03/22/2024- 12/31/2024.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, personnel records, and confirmed by interview with Technical Consultant #1 (TC#1) at 12:50 pm on 03 /18/2025, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for five out of five testing personnel in 2023. The findings include: 1. The CMS-209 Laboratory Personnel Report listed testing personnel (TP) #3- #7 as performing moderate complexity testing. 2. At the time of the survey, TC #1 confirmed TP #3- #7 did not have annual competency evaluations performed and documented for moderate complexity testing in 2023.