Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383021	10/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mercyone Newton Medical Center	204 N 4th Avenue E, Newton, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance specifications for the Sysmex XP-300 hematology analyzer and confirmed by the general supervisor at approximately 2:30 pm on 10/22/2025, the laboratory failed to verify the performance specification of reportable range when the laboratory put into use the Sysmex XP-300 hematology analyzer in November 2024. The findings include: 1. The laboratory director reviewed, signed and dated the Sysmex XP-300 hematology verification of performance specifications on 11/1/2024. 2. At the time of the survey, the general supervisor confirmed the verification of performance specifications for the XP-300 hematology analyzer did not include a verification of the reportable range.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using

	the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of MedTox quality control (QC) records and laboratory procedures and confirmed by interview with the general supervisor at 11:45 am on 10/22/2025, the laboratory failed to perform weekly QC for the MedTox test system for two out of seven weeks from 6/1/2025 - 7/14/2025. The findings include: 1. The procedure titled, "The Rapid Drug Screen using the Profile-V Medtox Scan Drugs of Abuse Test System" and the MedTox Individualized Quality Control Plan procedure both stated that a positive and negative liquid QC would be performed weekly. 2. Review of Medtox QC records revealed that laboratory did not perform a positive and negative QC the week of 6/15/25 - 6/21/25 or the week of 7/6/25 - 7/12/2025. 3. At the time of the survey, the general supervisor confirmed the laboratory did not have Medtox QC records for the weeks of 6/15/2025 - 6/21/2025 and 7/6/2025 - 7/12/2025.