Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383703	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mercyone Des Moines Pediatric Care Clinic	330 Laurel Street, Suite 2100, Des Moines, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by testing personnel identifier #2 (refer to the Laboratory Personnel Report) at 10:12 am on 3/20/2024, the laboratory failed to ensure the laboratory director and testing personnel signed the PT attestation statements for four of out six PT events from 1/1/2022 - 12/31/2023. The findings include: 1. For 2022 testing event 2, the laboratory director failed to sign the hematology attestation statement. 2. For 2023 testing event 1, the laboratory director failed to sign the immunology and chemistry attestation statements. The testing personnel failed to sign the immunology, chemistry, and hematology attestation statements. 3. For 2023 testing event 2, the laboratory director failed to sign the chemistry attestation statement. The testing personnel failed to sign the hematology attestation statement. 4. For 2023 testing event 3, the laboratory director and testing personnel failed to sign the hematology, chemistry and immunology attestation statements.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be

	maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by testing personnel identifiers #1 & #2 (refer to the Laboratory Personnel Report) at 10:12 am on 3/20/2023, the laboratory failed to document corrective action for unacceptable PT scores for two out of six PT events from 1/1/2022 - 12/31/2023. The findings include: 1. For 2023 event 1, the laboratory received an unacceptable score of 80% for the analytes: platelet count and mean platelet volume. 2. For 2023 event 2, the laboratory received an unacceptable score of 80% for the analytes: percent basophil, percent eosinophil, percent immature granulocytes, percent neutrophil, absolute immature granulocytes, mean platelet volume, and red blood cell distribution width. 3. At the time of the survey, the laboratory did not document corrective action for the above unacceptable PT scores.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at 10:12 am on 3/20/23, the laboratory failed to perform a self evaluation of ungraded PT scores for one out of six PT events from 1/1/2022 - 12/31/2024. The findings include: 1. For 2023 event 3, the laboratory received ungraded PT scores for c reactive protein specimens CRP-05 and CRP-06. 2. At the time of the survey, the laboratory did not perform a self evaluation of the ungraded PT scores.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 lack of performance specification records and confirmed by laboratory personnel identifier #2 (refer to the laboratory personnel report) at 11:23 am on 3/20/2024, the laboratory failed to verify the performance specifications of accuracy, precision, reportable range, and reference intervals for the Orion CRP-Go test system

	in November 2022. The findings include: 1. The laboratory began using the Orion CRP-Go to perform c-reactive protein testing on 11/1/2022. 2. The laboratory did not verify performance specifications of accuracy, precision, reportable range and reference intervals before starting patient testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Epoc Individualized Quality Control Plan (IQCP), Epoc quality control (QC) records and patient testing records and confirmed by laboratory personnel, identifiers #1 & #2 (refer to the Laboratory Personnel Report) at 11:16 am on 3/20/2024, the laboratory failed to perform two levels of Epoc external QC with each new lot number and/or shipment of Epoc test cartridges for one out of two lot numbers from 11/1/2023 - 3/20/2024. The findings include: 1. The Epoc IQCP plan states the laboratory will perform two levels of external QC with each new lot number and/or shipment of Epoc test cartridges. 2. On 11/24/2023, the laboratory began performing patient testing using lot number 04-23274-30 of Epoc test cartridges. 3. The laboratory did not perform two levels of external QC on this lot number of Epoc test cartridges. 4. The laboratory performed testing on 23 patients using lot number 04-23274-30 of Epoc test cartridges.