Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2160904	12/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mount Carmel Franklinton Emergency	120 South Green Street, Columbus, OH	

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) 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 record review and an interview with the Technical Supervisor (TS), the laboratory failed to ensure the wet preparation policy and procedure was approved, signed and dated by the Laboratory Director (LD) prior to use. This deficient practice had the potential to affect 7440 patients tested under the subspecialty of parasitology from 10/26/2022 through 12/13/2022. Findings Include: 1. Review of the laboratory's wet preparation policy and procedure titled "MCFED Wet Prep" found that it was amended 10/26/2022. 2. Review of the "MCFED Wet Prep" policy failed to find LD approval by signature and date after it was amended on 10/26/2022. 3. An interview with the TS, on 12/13/2022 at 12:19 PM, confirmed the laboratory failed to ensure that the new "MCFED Wet Prep" policy was approved by the LD by signature and date prior to use after it was amended on 10/26/2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Item 1: Based on record review and an interview with the Technical Supervisor (TS), the laboratory failed to perform and document monthly maintenance for the STA

	Compact Max coagulation analyzer as defined by the manufacturer for eight out of 12 months reviewed. All 29,292 patients tested under the speciality of hematology in the year 2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's monthly instrument maintenance record supplied by the manufacturer titled "STA Compact Max CP Maintenance Chart" found the following tasks to be performed monthly: "...Monthly: Replace syringe and O ring..." 2. Review of the laboratory's monthly instrument maintenance record supplied by the manufacturer titled "STA Compact Max CP Maintenance Chart" found that the laboratory failed to perform and document monthly maintenance for eight out of 12 months reviewed. 3. An interview with the TS, on 12/13/2022 at 1:36 PM, confirmed the laboratory failed to perform and document monthly maintenance of the STA Compact Max coagulation analyzer for eight out of 12 months reviewed. Item II: Based on record review and an interview with the Technical Supervisor (TS), the laboratory failed to perform and document weekly maintenance for the STA Compact Max coagulation analyzer as defined by the manufacturer for one out of 12 months reviewed. All 29,292 patients tested under the speciality of hematology in the year 2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's monthly instrument maintenance record supplied by the manufacturer titled "STA Compact Max CP Maintenance Chart" found the following task to be performed weekly: "...Weekly: Decontaminate stir bars as per package insert..." 2. Review of the laboratory's monthly instrument maintenance record supplied by the manufacturer titled "STA Compact Max CP Maintenance Chart" found that the laboratory failed to perform and document weekly maintenance for one out of 12 months reviewed. 3. An interview with the TS, on 12/13/2022 at 1:36 PM, confirmed, the laboratory failed to perform and document weekly maintenance of the STA Compact Max coagulation analyzer for one out of 12 months reviewed. Item III: Based on record review and an interview with the Technical Supervisor (TS), the laboratory failed to perform and document monthly maintenance for the Beckman DXL/DXI immunology analyzer as defined by the manufacturer for one out of 12 months reviewed. All 2148 patients tested under the subspecialty of general immunology in the year 2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's monthly instrument maintenance record supplied by the manufacturer titled "Beckman DXL/DXI Maintenance" found the following tasks to be performed monthly: "...Monthly: Wipe CL tip: Kimwipe/DIH2O [deionized water] Replace CO2 inline filter MC SampleWaste line: Flush with straight Bleach" 2. Review of the laboratory's monthly instrument maintenance record supplied by the manufacturer titled "Beckman DXL /DXI Maintenance" found that the laboratory failed to perform and document monthly maintenance for one out of 12 months reviewed. 3. An interview with the TS, on 12/13 /2022 at 1:36 PM, confirmed, that the laboratory failed to perform and document monthly maintenance of the Beckman DXL/DXI immunology analyzer for one out of 12 months reviewed.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Supervisor (TS), the

	laboratory failed to perform and document alternative quality control for the wet preparation testing procedures performed when commercial control materials were not available. This deficient practice had the potential to affect 7440 patients tested in the subspecialty of parasitology. Findings Include: 1. Review of the laboratory's "MCFED Wet Prep" policy failed to find a procedure for documentation of wet preparation quality control every day of patient testing. 2. Review of the laboratory's quality control data failed to find documentation of wet preparation quality control, every day of patient testing. 3. An interview with the TS, 12/13/2022 at 12:15 PM, confirmed the laboratory failed to perform and document wet preparation quality control every day of patient testing.