Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1102356	12/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Health System/Belpre	799 Farson Street, 1st Floor, Belpre, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on direct observation and an interview with the Director of Laboratory Services, the laboratory failed to be constructed, arranged, and maintained to ensure the space necessary for conducting all phases of testing processes. This deficient practice had the potential to affect 3,706,530 patients tested under the specialties of Microbiology, Chemistry, Hematology, Diagnostic Immunology, and Immunohematology from 01/01/2022 through 12/04/2023. Findings Include: 1. The inspector directly observed the laboratory on 12/04/2023 at 1:00 PM and found the laboratory was located in a 972 square foot room. 2. The laboratory contained two Roche Cobas 6000s, one Sysmex DI-60, 18 benchtop testing instruments, one Sure-Grip EX 45 gallon flammable cabinet, one 12 gallon flammable cabinet, four Thermo TSX single door refrigerators, one Thermo TSX single door freezer, one Thermo Revco single door freezer, two Thermo Revco double door refrigerators, one under cabinet Thermo refrigerator, two sinks, a closed system molecular preparation hood, a blood bank preparation hood, one floor model water filtration system, and a small specimen accessioning area. 3. The Director of Laboratory Services stated the laboratory had been cited during previous accreditation inspections. The interview occurred on 01/26/2017 at 1:50 PM.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and

	procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Quality Coordinator and the Director of Laboratory Services, the laboratory failed to ensure a post analytic quality assessment program was maintained to assure the quality of laboratory services provided, and to identify failures in laboratory quality. This deficient practice had the potential to affect 3,706,530 patients tested under the specialties of Microbiology, Chemistry, Hematology, Diagnostic Immunology, and Immunohematology from 01/01/2022 through 12/04/2023. Findings Include: 1. Review of the laboratory's policy and procedure plan titled, "Continual Improvement Policy 110866.194", signed and dated by the Laboratory Director on 07/03/2019 revealed the following statements: "Processes Each laboratory compiles monthly quality data and investigates metrics not meeting thresholds. MHS Laboratories Reviewing and implementing changes to processes to achieve the desired outcomes." 2. Review of the laboratory's "Belpre Campus Quality Monitors FY 2022" spreadsheet revealed incomplete and no entries in the "Action Taken" rows for monthly quality goals not met as follows: Indicator Goals Not Met Action Taken ABG 4 None Chemistry 22 None Hematology 28 None Microbiology 13 None Phlebotomy 31 Report Sent Alert Values 32 None 3. Review of the laboratory's "Belpre Campus Quality Monitors FY 2023" spreadsheet revealed no entries and redundant information in the "Action Taken" rows for monthly quality goals not met as follows: Indicator Goals Not Met Action Taken ABG 6 None Chemistry 22 Supervisor Notified Hematology 29 None Phlebotomy 23 Report Sent Alert Values 8 None 4. The Inspector requested documentation of investigations for metrics not meeting thresholds and the changes made to achieve the desired outcomes from the Laboratory Quality Coordinator. The Laboratory Quality Coordinator and the Director of Laboratory Services confirmed there was no investigations for metrics not meeting thresholds, and the changes made to achieve the desired outcomes, and was unable to provide the requested information. The interview occurred on 12/04/2023 at 12:00 PM.