Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0031662	(X3) Date Survey Completed 11/12/2024
Name of Provider or Supplier Mercy Memorial Hospital	**Street Address, City, State** 904 Scioto Street, Urbana, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with Technical Consultant (TC) #4, the laboratory failed to perform and document quality control (QC) procedures for the qualitative microscopic vaginal wet preparation (wet prep) each day of testing. This deficient practice had the potential to affect 28 out of 28 patients tested from 01/01 /2024 through 11/12/2024 in the subspecialty of Parasitology. Findings Include: 1. Review of the laboratory's policies and procedures failed to find instructions for performing and documenting QC for the microscopic vaginal wet prep test each day of testing. 2. Review of the laboratory's wet prep documentation failed to find evidence that QC was performed and documented for the microscopic vaginal wet prep test each day of testing. 3. The surveyor requested the QC records from TC #4 for the microscopic vaginal wet prep test. TC #4 confirmed that the laboratory failed to perform and document QC for the microscopic vaginal wet prep test each day of testing. The interview occurred on 11/12/2024 at 3:41 PM.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and an interview with Technical Consultant (TC) #3, the Laboratory Director (LD) failed to specify the duties and responsibilities of one out of four TCs listed on the Form CMS-209. This deficient practice had the potential to affect one out of four TCs and 121 out of 121 patients tested under the specialty of Microbiology from 09/09/2024 through 11/12/2024. Findings include: 1. Review of the Form CMS-209 found four individuals listed as TCs. 2. Review of policies and procedures provided on the date of inspection failed to find evidence of the duties and responsibilities delegated to TC #3 in writing by the LD. 3. The inspector requested the approved, signed and dated duties and responsibilities for TC #3 from TC #3. TC #3 confirmed they fulfilled the regulatory role of TC #3 beginning on 09/09/2024, that the LD failed to specify in writing the duties of one out of four TCs listed on the Form CMS-209, and was unable to provide the requested document. The interview occurred on 11/12/2024 at 4:02 PM.