Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2229274	03/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Geisinger Medical Center Muncy	255 Route 220 Highway, Muncy, PA	

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
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 laboratory's non-waived molecular testing Individualized Quality Control Plans (IQCP) and interview with the Operations Director (OD), the laboratory failed to include risk assessment and quality assurance for the FilmArrey and Cepheid GeneXpert Systems when implementing an IQCP from 01/10/2022 to 03 /10/2022. Findings include: 1. On the days of survey, 03/09/2022 and 03/10/2022, the laboratory failed to provide a site specific IQCP for FilmArrey and GeneXpert systems. At the time of the inspection the laboratory provided IQCP for Geisinger Medical Laboratories, Danville, PA 2. the laboratory was unable to provide documentation of the risk assessments and quality assurance to the surveyor for the following: - Cepheid GeneXpert System: - 4 plex (SARS-CoV-2, Flu A, Flu B and RSV) cartridge. - Clostridium Difficile Toxin cartridge. - FilmArrey System: - Respiratory Pathogen Panel. - Blood Culture Identification Panel. 3. The laboratory performed from 1/10/2022 to 03/10/2022 the following number of patient testing: a. Cepheid GeneXpert: - Clostridium Difficile: 29. - SARS-CoV-2, Flu A, Flu B and RSV: 193. b. FilmArrey System: - Blood Culture Identification Panel: 8. - Respiratory Pathogen Panel: 462. 4. The OD confirmed the findings above on 03/10/2021 around 12:00 p.m.

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 lack of documentation and interview with the Operations Director (OD), the laboratory failed to include a positive and a negative control material each day of patient testing for urine sediment microscopic examinations and manual differentials from 01/10/2022 to the date of survey. Findings Include: 1. On the days of survey, 03 /09/2022 and 3/10/2022, the laboratory did not provide urine sediment microscopic examination and manual differential QC records. 2. The laboratory performed 270 urine sediment microscopic examinations from 01/10/2022 to 03/10/2022. 3 The laboratory performed 204 manual differentials from 01/10/2022 to 03/10/2022. 4. The OD confirmed the findings above 03/10/2022 at 12:00 p.m.