Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0327211	(X3) Date Survey Completed 12/06/2022
Name of Provider or Supplier Ohiohealth Grady Memorial Hospital	**Street Address, City, State** 561 West Central Avenue, Delaware, 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
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: Based on record review and an interview with the Director of Laboratory Quality and Accreditation, the laboratory failed to perform and document monthly maintenance for the Cobas 6000 analyzer as defined by the manufacturer for one out of 12 months reviewed. All 238,729 patients tested under the subspecialties of routine chemistry, endocrinology and toxicology 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 "Cobas 6000 analyzer series Sampling Unit Maintenance Log" found the following tasks to be performed monthly: "...Monthly Clean: Rack sampler unit filter Inspect/Clean: DI water tank Delete: QC view data (recommended)..." 2. Review of the laboratory's monthly instrument maintenance record supplied by the manufacturer titled "Cobas 6000 analyzer series found that the laboratory failed to perform and document monthly maintenance for the month of November 2022. 3. An interview with Director of Laboratory Quality and Accreditation, on 12/06/2022 at 3:19 PM, confirmed, that the laboratory failed to perform and document monthly maintenance of the Cobas 6000 analyzer for the month of November 2022.