Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2204127	04/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gastro Office	4600 Leap Court, Suite 101, Hilliard, 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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD) and the Testing Personnel (TP) #1, the laboratory failed to retain all analytic system activity records for the technical component of the subspecialty of histopathology performed in the lab. All patients tested in this lab from January 2022 and March through July of 2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the procedure manual found the following statement: "Procedure for Verification of Function Checks ...All function checks will be documented that equipment performs according to expectations for the intended use and within defined tolerance limits, as defined by the manufacturer..." 2. Record review failed to find documentation of instrument maintenance and function checks for the following: Missing Documentation: January 2022 Microtome maintenance H&E (hematoxylin and eosin) Automatic Stainer maintenance Missing Documentation: March 2022 - July 2022 Tissue Processor maintenance Embedder maintenance Microtome maintenance H&E Automatic Stainer maintenance Room Temperature and Humidity Refrigerator Temperature Oven Temperature 3. The Inspector requested the laboratory's missing maintenance and function check logs from January 2022 and from March through July of 2022. The LD and TP #1 confirmed that the laboratory failed to retain instrument maintenance and function check logs from January 2022

	and from March through July of 2022 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/04/2023 at 3:08 PM.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD) and the Testing Personnel (TP) #1, the laboratory failed to document all quality control procedures performed at this location, to include the reactions and observations of the control slides for the technical component of the subspecialty of histopathology. This deficient practice had the potential to affect 1,229 out of 1,229 patients tested at this laboratory from 07/01/2022 to 04/04/2023. Findings Include: 1. Review of the procedure manual found each procedure approved by the LD by signature and date on 07/01/2022. 2. Review of the procedure manual found a quality control policy for the technical component of histopathology: "Routine Microtomy, Staining & QC of Slides...QUALITY CONTROL Quality Control of H&E, Alcian Blue/PAS and Diff-Quick Slides - Slides will be reviewed microscopically by a technician for acceptable quality of sectioning and staining. ... - This QC will be documented..." 3. Record review failed to find documentation of quality control each day of patient testing for the technical component of histopathology performed at this location from 07/01/2022 to 04/04/2023. 4. An interview with the LD and TP #1, on 04/04/2023 at 1:46 PM, confirmed the laboratory failed to document quality control each day of patient testing for the technical component of histopathology performed at this location.