Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2280252	09/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Nashville Gastroenterology & Hepatology	330 Wallace Rd, Suite 103, Nashville, TN	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of patient test reports, review of laboratory procedures, and staff interview, the laboratory failed to ensure procedures for histopathology tissue processing and testing were approved by the laboratory director prior to patient reporting which began on 6/24/23. The findings include: 1. Review of patient test reports revealed patient reporting for histopathology began on 6/24/23 (patient: 23-1-1) with a total of 573 patient tests reported at the time of the survey (9/20/23). 2. Review of the "Nashville Gastroenterology & Hepatology Standard Operating Procedures" manual revealed the current laboratory director failed to sign and date the manual indicating approval of the procedures at the time of survey (9/20/23). 3. Interview with the laboratory director on 9/20/23 at 12:15 pm confirmed the laboratory began histopathology patient testing prior to the laboratory director's documentation of procedure manual approval.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer's operating manuals, lack of records, review of patient test reports, and staff interview, the laboratory failed to document ambient temperature and humidity in the laboratory were histopathology tissue processing and testing was performed from 6/24/23 to the date of the survey (9/20/23). The findings include: 1. Observation of the laboratory on 9/20/23 at 8:15 a.m. revealed the following equipment in use for processing tissues for histopathology testing: -Sakura Tissue-Tek VIP tissue processor -Leica HistoCore Arcadia H paraffin embedding station -MICROM Rotary Microtome HM 355 S -Leica Autostainer XL automated slide stainer 2. Review of the manufacturer's operating manuals revealed the following operating limits: -Sakura Tissue-Tek VIP: Temperature range of 10 to 40 degrees Celsius with maximum relative humidity of 85%. -Leica HistoCore Arcadia H: Temperature range of 20 to 30 degrees Celsius with relative humidity range of 20 - 60%. -MICROM Rotary Microtome HM 355 S: Temperature range of 5 to 40 degrees Celsius with maximum relative humidity of 60%. -Leica Autostainer XL: Temperature range of 15 to 35 degrees Celsius with relative humidity range of 20 - 80%. 3. Review of the laboratory's records revealed no documented monitoring of ambient temperature and humidity. 4. Review of final patient test reports revealed patient test reporting began on 6/24/23 (23-1-1) with a total of 573 patient tests reported at the time of survey (9/20/23). 5. Interview with the laboratory director on 9/20/23 at 12:15 pm confirmed the laboratory did not document ambient temperature and humidity in the area the histopathology tissue processing and testing equipment was used for patient testing from 6/24/23 to the date of the survey (9/20/23).