Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2176971	08/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Gi Pathology Consultants Of Arizona, Llc	6525 N 59th Street, Paradise Valley, AZ	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the laboratory director, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2021. Findings include: 1. No documentation was presented for review during the survey conducted on August 2, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of histopathology specimens at least twice annually during 2021. 2. The laboratory director interviewed on 8/02/22 at 9:45am confirmed that the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2021. 3. The laboratory's approximate annual test volume under the sub-specialty of Histopathology is 1,500. The laboratory began patient testing on February 24, 2021.
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 lack of a microscope maintenance policy and interview with the laboratory director, the laboratory failed to establish a microscope maintenance policy that indicates specific routine maintenance procedures, as well as, scheduled preventative maintenance procedures. Findings include: 1. No documentation was presented for review during the survey performed on August 2, 2022 to indicate the laboratory established a microscope maintenance policy, including routine and preventative maintenance. 2. The laboratory director interviewed at 9:55am on 8/02/22 acknowledged that no microscope maintenance policy was established by the laboratory. 3. The laboratory began patient testing in the sub-specialty of Histopathology on 2/24/2021, with an approximate annual test volume of 1,500.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the laboratory director, the laboratory failed to include on the test report the laboratory name and address where the testing was performed. Findings include: 1. The laboratory began patient testing in the subspecialty of histopathology in February 2021, with an approximate annual test volume of 1,500. 2. The test report reviewed during the survey (SWS22-10797) was missing the laboratory name and address where the testing was performed. 3. The laboratory director confirmed that the laboratory name and address where the diagnosis was made was not indicated on the patient test reports issued by the laboratory.