Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2079487	12/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ulster Gastroenterology Pllc	301 Hurley Ave, Kingston, NY	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the lack of proficiency testing (PT) records and an interview with the laboratory testing person, the laboratory failed to enroll in an approved PT program for the sub-specialties bacteriology, parasitology and virology after initiating patient testing in August 2020. Refer to D6088 FINDINGS The laboratory testing person confirmed on December 8, 2022, at approximately 11:00 AM, that the laboratory did not enroll in a PT testing program for sub-specialties bacteriology, parasitology, virology, performed on the BioFire Film Array analyzer, after initiating patient testing in August 2020. a. The laboratory is performing the GI panel (21 organisms/ analyte's) and Respiratory panel (19 organism/analyte's) on the BioFire Film Array analyzer.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

	This STANDARD is not met as evidenced by: Based on a lack of safety procedures, surveyor's observation and an interview with the laboratory testing person, the laboratory failed to establish and have accessible a safety procedure to protect the laboratory staff from physical, chemical, biochemical, biohazard material and electrical hazards. Refer to D6084 FINDINGS: 1. The laboratory failed to establish and follow a safety manual for universal precautions. 2. Surveyor observed the BioFire box containing the pouches used for testing both the GI and Respiratory panel, it stated, " that universal precaution must be followed regarding eye protection , skin irritation and/corrosion, wear protective gloves, clothing, eye and face protection. 3. The laboratory testing person confirmed on December 8, 2022, at approximately 12:00 PM, that she only wears, gloves when performing the testing.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of BioFire operations manual, lack of laboratory procedures, temperature records and an interview with the laboratory director and testing person, the laboratory failed to have a complete procedure manual, validation of new BioFire and room temperature records for bacteriology testing from August 2020 through survey date. Refer to: D5209, D5291, D5311, D5413, D5421 and D5805
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of a training and competency assessment policy, personnel records and an interview with the laboratory director and testing person, the laboratory failed to establish and follow a training and competency assessment policy for the testing personnel, who perform moderate complexity testing. Refer to D6102, D6103 and D6107 FINDINGS: The laboratory failed to establish and follow a training and competency assessment policy to include the following: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skill and capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify

	the technical consultant, clinical consultant or director; and document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. 2. The laboratory implemented moderate complexity testing in August 2020, no training documents and competency assessment records for the testing person who is performing the testing was available for review at this survey, confirmed by the laboratory director and laboratory testing person at this survey.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the lack of a written Quality Assessment (QA) procedure/policy and confirmed in an interview with the laboratory director, at the time of this survey, the laboratory failed to establish a written QA procedure/policy for monitoring and when indicated correct problems identified for both technical and non-technical systems in the laboratory. Refer to D3011, D5209, D5311, D5413, D5421, D5805 and D6094 FINDINGS: The laboratory failed to establish and follow a QA policy/procedure to address the entire laboratory process, from the time a patient sample is obtained and arrives in the laboratory, to processing and the moment results are recorded in the electronic medical records (EMR) patient charts. There are three phases of laboratory testing: pre-analytic, analytic and post-analytic.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on lack of a written laboratory procedure, review QC records for the BioFire analyzer and interview with the laboratory testing person, the laboratory failed to establish written policies and procedures for specimen labeling, storage, acceptability and rejection. Refer to D6076 and D6094 FINDINGS: 1. The laboratory failed to provide written policies and procedures for specimen labeling. 2. The laboratory failed to provide written policies and procedures for specimen storage. 3. The laboratory failed to provide written policies and procedures for specimen acceptability and rejection. 4. The laboratory testing person confirmed on December 8, 2022, at approximately 11:00 AM, the laboratory failed to establish written procedures and policies for both stool and nasopharyngeal specimens.
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 the review of the BioFire Film Array operations manual for ambient temperature requirements, lack of laboratory temperature log sheets for 2020, 2021 through survey date, direct observation of the laboratory area and an interview with the laboratory testing person, the laboratory failed to monitor the room temperatures for the laboratory area for the calendar years 2020, 2021 through survey date. Refer to D6076 and D6094 FINDINGS: 1. The BioFire manufacturer's temperature requires are: ambient 18-30 C. 2. No Temperature log sheets for ambient/room temperatures were available for review at survey. 3. The laboratory testing person confirmed on December 8, 2022, at approximately 11:30 AM, that the testing person was aware that the room temperature for the BioFire was to be monitored.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of a completed validation study for the BioFire Film Array, review of Quality Control records and an interview with the laboratory testing person, the laboratory failed to perform and document a complete method validation for the new BioFire Film Array analyzer prior to patient testing in August 2020 through survey date. Refer to D6076 and D6086 FINDINGS: 1. The laboratory performed precision using control material over a 14-day period was performed and verified the BioFire manufacturer's specification as detected, not detected and/or invalid, however, the laboratory failed to perform accuracy segment of the validation study, prior to implementing patient testing in August 2020. 2. The laboratory testing person confirmed on December 8, 2022, at approximately 11:15 AM, that she was not aware that accuracy was not performed for BioFire Film Array used to test Respiratory and GI panels, prior to patient testing in August 2020. 2. Approximately 130 patient specimens were tested and reported for Respiratory/GI Panel during above time frame.
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 random review the BioFire analyzers printed patient test reports, laboratory test logs and EMR patient reports and an interview with the laboratory testing person, the patient reports reviewed failed to include the name and address of the laboratory location where the test is performed. Refer to D6076 and D6094 FINDINGS: 1. The testing person confirmed on December 8, 2022, at approximately 10:30 AM, the BioFire analyzer printed patient's test reports failed to include the name and address of the laboratory where the test is performed. The laboratory prints the reports and scans them into the EMR system. A printed copy is also given to the provider for review.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the BioFire operations manual, lack laboratory's manual for moderate complexity testing, direct observation and an interview with laboratory director and testing person the director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The laboratory director failed to ensure that: 1. The physical and environmental conditions provide a safe environment for laboratory personnel; Refer to D6084, 2. The verification for the new analyzer was completed , prior to patient testing, Refer to D6086; 3. The laboratory was enrolled in a PT program for the sub-specialties' bacteriology, parasitology and virology, Refer to D6088; 4. The laboratory established ad followed a QA policy, Refer to D6094; 5. The testing person receive the appropriate training for the type and complexity of the tasks they perform, Refer to D6102; 6. The laboratory established polices to monitor personnel that perform all three phases of laboratory testing, Refer to D6103; 7. The laboratory specified in writing job description, responsibilities, and duties for the laboratory testing personnel, Refer to D6107.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by:

	Based on review of the BioFire operation's manual, direct observation and confirmed in an interview with the laboratory testing person, the director must provide a safe environment in which employees are protected from physical, chemical and biological hazards. Refer to D3011
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on lack of a completed validation study for the BioFire Film Array, review of Quality Control (QC) records and an interview with the laboratory testing person, the laboratory director failed to perform and document a complete method validation for the new BioFire Film Array analyzer prior to patient testing in August 2020 through survey date. Refer to D5421
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of PT records and documentation for the sub-special.lties bacteriology, parasitology and virology and confirmed in a interview with the laboratory testing person at the time of this survey, the laboratory director failed to ensure that the laboratory was enrolled in approved PT program for the moderate complexity testing performed on the BioFire analyzer. Refer to D2000
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based of review of lack of a written procedure manual for the moderate complexity testing, lack of QA records and confirmed in an interview with the laboratory testing person, the laboratory director failed to establish a QA program to assure the quality of laboratory services and identify failures in quality as they occur. Refer to D5291 and D5805
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all

	personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of job descriptions policy, training records and competency assessment policy & records and confirmed in an interview with the laboratory testing person, the laboratory director failed to ensure that, all personnel receive the appropriate training for the type and complexity of the tasks they perform. Refer to D5209 and D5291
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on the lack of competency assessment polices and procedures and confirmed in an interview with the laboratory testing person, the laboratory director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the testing personnel performing moderate complexity testing. Refer to D5209
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the lack of a written job description & responsibilities for the testing personnel and confirmed in an interview with the laboratory director, the laboratory director failed to specify, in writing, job description, responsibilities and duties for the laboratory testing personnel who perform moderate complexity testing.