Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2080109	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Utah Gastroenterology	6360 S 3000 E Suite 310, Salt Lake City, UT	

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 lack of documentation and confirmation by staff, the laboratory failed to enroll in an approved proficiency testing program for the sub specialties of Bacteriology, Parasitology and Virology for molecular stool sample testing for the presence or absence of approximately 21 Bacteriology, Parasitology and Virology organisms. The laboratory performed approximately 10 to 40 tests per month since April 2018 when patient testing began.
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 procedure manual review, lack of documentation, and interview with staff, the laboratory director failed to sign and date as approved 1 of 1 new test procedure

	added in April of 2018, Molecular detection for presence or absence of stool pathogens. The laboratory performed approximately 10 to 40 tests per month. Findings include: 1. Procedure manual review failed to include the signature and date the director approved the Biofire enteric pathogen test procedure. 2. In an interview on 07/26/2018 at approximately 4:00 P.M. staff stated the laboratory technical supervisor approved the procedure.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of the director's approval, quality control documentation review, and confirmation by laboratory staff, the laboratory failed to have an approved Individualized Quality Control Plan (IQCP) or perform 2 levels of quality control each day of stool pathogen testing by molecular amplification for approximately 10 to 20 days of testing. The laboratory performed approximately 1 to 2 tests per day. Findings include: 1. The IQCP reviewed was not approved by the laboratory director. 2. Quality control documentation review included monthly and new lot number quality control performance since April of 2018 when the laboratory started testing and reporting patient tests. 3. In an interview conducted on 07/26/2018 at approximately 4:00 P.M. staff confirmed the technical supervisor approved the IQCP.
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 patient testing observed, patient test report observed and interview with staff, the test report for the presence or absence of approximately 21 Bacteriology, Parasitology and Virology organisms, failed to include the name and address of the laboratory location where the tests are performed for approximately 60 of 60 tests performed from April 2018 to July 26, 2018. Findings include: 1. Patient testing observed on 07/6/2018 at approximately 5:10 P.M. did not include the name and address of the location where testing was performed. 2. In an interview conducted on 07/26/2018 at approximately 5:10 P.M. staff confirmed the test reports for stool pathogen testing did not include the location of the laboratory performing the tests.