

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2080109	(X3) Date Survey Completed 09/23/2020
Name of Provider or Supplier Utah Gastroenterology	Street Address, City, State 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control records review, manufacturer's package insert review, lack of documentation, IQCP review, and interview with staff, the laboratory Individualized Quality Control Plan (IQCP) failed to include the number of controls the lab is to perform monthly and with each new lot number of Biofire Gastroenterology test kits received. Quality control review included testing from September 2018 to September 2020. The laboratory performed approximately 3 to 5 tests per week. Findings include: 1. Quality control records review failed to include documentation the laboratory performed a negative control with each new lot number of test kits received and monthly for 24 months of tests reviewed (September 2018 to September 2020). 2. Manufacturer's package insert stated good laboratory practice should include control materials that include the presence and absence of bacteria, fungi, parasites, and viruses with each new lot number of test kits received. 3. The IQCP review failed to include the number and type of quality controls to be performed with each new test kit lot number received and monthly. 4. In an interview with staff on 09/23/2020 at approximately 10:45 A.M. testing staff confirmed they did not perform a negative control since it was not included in the number of control required in the IQCP</p>