

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1096011	(X3) Date Survey Completed 08/15/2019
Name of Provider or Supplier Granite Peaks Gi, Llc	Street Address, City, State 1393 E Segoe Lily Dr, Sandy, 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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on laboratory test records review, lack of documentation, and interview with staff, the laboratory failed to enroll in an approved proficiency testing (PT) program for 3 of 3 subspecialties (Bacteriology, Parasitology, and Virology) included in the BioFire FilmArray Gastrointestinal (GI) Panel and required in subpart I. The laboratory began patient testing in 03/2019 and had tested approximately 36 samples. Findings include: 1. The BioFire GI Panel reports include testing for 22 targets in the subspecialties of Bacteriology, Parasitology, and Virology. 2. The laboratory lacked documentation of enrollment in approved PT programs for Bacteriology, Parasitology, and Virology. 3. Staff confirmed on 08/15/2019 at approximately 10:00 AM, they had not enrolled in approved PT programs for the 3 subspecialties.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the Individualized Quality Control Plan (IQCP), lack of documentation, and interview with staff, the laboratory director failed to establish a quality assessment program. The laboratory began patient testing in 03/2019 and had performed testing on approximately 36 samples. Findings include: 1. The laboratory's IQCP requires "continual participation in this institutions quality program that addresses specimen handling and erroneous specimen labeling". 2. The laboratory lacked documentation of a written quality program. 3. Staff stated on 08/15/2019 at approximately 11:00 AM the laboratory lacked a written quality assessment program to monitor, assess, and when indicated, correct problems identified in all phases of testing.