

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2104354	<b>(X3) Date Survey Completed</b> 05/23/2023
<b>Name of Provider or Supplier</b> Atcg Laboratory	<b>Street Address, City, State</b> 18 Technology Dr, Ste 107, Irvine, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency testing performance documents and interview with the laboratory staff, it was determined that the laboratory at least twice annually failed to perform evaluation of proficiency testing performance by alternative peer reviews to verify the accuracy of SARS-CoV-2 PCR testing procedure which is not listed in the subpart I of 42 CFR part 493. The findings included: a. The laboratory performed SARS-CoV-2 PCR testing using ThermoFisher QuanStudio 12K Flex and reagents. b. The laboratory failed, at least twice annually, to perform evaluation of testing performance to verify the accuracy of SARS - CoV-2 PCR testing in 2020 and 2021. c. The laboratory performed evaluation of proficiency testing performance on 10/30/2020 by sending samples to a CLIA certified laboratory and received total of 75% correlation between this laboratory and the outside laboratory, which was not acceptable according to the CMS PT score of at least 80% being acceptable. d. The laboratory failed to perform evaluation of proficiency testing performance at least twice annually in 2021, the laboratory did it on 3/10/2021 and no more.</p>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policy and procedure for Proficiency Testing (MOL.22.QA04), the proficiency testing performance records, and interview with the laboratory staff, it was determined that the laboratory failed to establish written policy and procedure for SARS-CoV-2 PCR proficiency testing. The findings included: a. The laboratory performed SARS-CoV-2 PCR which is not listed in subpart I of 42 CFR part 493. b. The laboratory's Proficiency Testing (MOL @@.QA04 failed to state at least twice annually to verify and ensure the accuracy of the SARS-CoV-2 PCR testing procedure (see D-5217)

**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 on review of the laboratory's evaluation of proficiency testing performance records, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory performed SARS-CoV-2 PCR testing and elected to verify the accuracy, at least twice annually, of the testing procedures by alternative peer review. b. The laboratory director failed to ensure the quality assessment programs were established and maintained to assure the quality of laboratory services provided, see D-5217 and D-5291