Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2241990	06/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gl Ca Clia Llc	5500 Stewart Ave Ste 108, Fremont, CA	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical supervisor on June 9, 2023, at 11:25 am, the laboratory failed to verify, at least twice annually, the accuracy of its ANDiS SARS-CoV/FluA /FlueB/RSV test for the year of 2022. The findings include: 1. The laboratory used ANDiS SARS-CoV/FluA/FlueB/RSV PCR test from 3DMed Diagnostics to detect SARS-CoV2, Influenza A, Influenza B and respiratory syncytial virus in oropharyngeal or nasopharyngeal swabs. However, it did not have any documentation showing that it had verified its test accuracy for the year of 2022. Therefore, the accuracy of the laboratory's test results provided to the patients for the year of 2022 cannot be assured and may have harmed patients. 2. The laboratory technical supervisor on June 9, 2023, at 11:25 am, affirmed that the laboratory did not verify its PCR test accuracy for the year 2022, and it signed up with the API proficiency organization for the year of 2023 to verify its test accuracy. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/1/2023, stated that the laboratory performs 1,400 tests, annually.
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 Surveyor review of laboratory's policy & procedure, and interview with the specimen collection person #1 on June 9, 2023, at 11:15 am, the laboratory failed to follow the test manufacturer's procedure to collect swab specimens. The findings include: 1. The laboratory used ANDiS SARS-CoV/FluA/FlueB/RSV PCR test from 3DMed Diagnostics to detect SARS-CoV2, Influenza A, Influenza B and respiratory syncytial virus in oropharyngeal or nasopharyngeal swabs. The applicable specimen type for the test is oropharyngeal or nasopharyngeal swabs according to the manufacturer's instructions. However, upon interview it was found that the specimen collection staff was not collecting oropharyngeal or nasopharyngeal swabs but nasal swab instead. The manufacturer did not instruct to use nasal swab and the laboratory did not validate the test to use with the nasal swab. Therefore, the accuracy of the laboratory's test results provided to the patients cannot be assured and may have harmed patients. 2. The laboratory technical supervisor on June 9, 2023, at 11:15 am, affirmed that the laboratory's sample collection personnel were not following the appropriate technique to collect the oropharyngeal or nasopharyngeal swabs but collecting nasal swab instead. 3. The laboratory's testing declaration form, signed by the laboratory director 6/1/2023, stated that the laboratory performs 1,400 tests, annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, proficiency testing records, and interview with the laboratory technical supervisor and specimen collection staff #1 on June 9, 2023, at 11:15 am, it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of preanalytical and analytical performance for its test. See D5217 and D5311.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical supervisor on June 9, 2023, at 11:25 am, it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for its test since it did not verify the test accuracy in 2022. See D5217.