Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2167395	(X3) Date Survey Completed 08/03/2021
Name of Provider or Supplier Total Primary Care	**Street Address, City, State** 2800 E Whitestone Blvd #123, Cedar Park, TX	
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
D0000	Based on an unannounced complaint investigation conducted on August 3, 2021, the complaint was substantiated. The laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories. TX00382142.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the patient records and interview with facility personnel, the laboratory failed to report negative SARS-COV-2 antibody test results as required for 106 of 106 days reviewed between October 1, 2020 and July 30, 2021. The findings included: 1. Based on review of patient records, the laboratory performed 269 negative SARS-CoV-2 antibody patient tests on 106 days reviewed between October 1, 2020 and July 30, 2021. a. The laboratory performed 43 negative antibody tests on 16 testing days in October 2020 b. The laboratory performed 72 negative antibody tests on 14 testing days in November 2020 c. The laboratory performed 46 negative antibody tests on 19 testing days in December 2020 d. The laboratory performed 51 negative antibody tests on 19 testing days in January 2021 e The laboratory performed 27 negative antibody tests on 11 testing days in February 2021 f. The laboratory performed 9 negative antibody tests on 8 testing days in March 2021 g. The laboratory performed 10 negative antibody tests on 9 testing days in April 2021 h. The laboratory performed 5 negative antibody tests on 5 testing days in May 2021 i. The laboratory performed 1 negative antibody tests on 1 testing days in June 2021 j. The laboratory

	performed 5 negative antibody tests on 4 testing days in July 2021 2. At 10:28 hours on August 3, 2021, the surveyor requested documentation of reporting SARS-COV-2 patient results to public health authorities. The facility provided 3 fax coversheets dated 7/30/2021, 7/15/2021, and 7/1/2021 and patient results that were positive for SARS-COV-2 antigen and antibody tests. No negative only results were included in the documentation. 3. In an interview on August 3, 2021 at 11:00 hours in the laboratory, the Assistant Manager of the North locations stated the laboratory had not reported negative COVID-19 tests results to HHS.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on surveyor observations, review of the Food and Drug Administration Emergency Use Authorization records for the SARS-CoV-2 test kits, review of laboratory procedures, review of patient testing records, and interview with facility personnel, the laboratory failed to perform only those tests approved or authorized for use in a waived setting by the FDA and meet the requirements in 493.1773. Refer to D8201.
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on surveyor observations, review of the Food and Drug Administration Emergency Use Authorization records for the SARS-CoV-2 test kits, review of laboratory procedures, review of patient testing records, and interview with facility personnel, the laboratory failed to perform only those tests approved or authorized for use in a waived setting by the FDA for 344 patient tests between 9/21/2020 and 8/2 /2021 (10 months, 12 days). The findings included: 1) Based on surveyor observations at 09:07 hours on 8/3/2021 in the facility laboratory, one box of Healgen One Step Rapid Test - COVID-19 IgG/IgM Rapid Test Cassettes were on the counter. There were 15 cassettes in the open box labeled as Lot 2004159, Expiration 2022-04, Reference Number GCCOV-402a. The box of Healgen One Step Rapid Tests had the letters "AMR" written in in the top left corner of the box on the same side as the lot number, reference number, and expiration dates. On the top shelf about the testing

	area, the surveyor observed another unopened box of Healgen One Step Rapid Tests at 09:10 hours on 8/3/2021 in the laboratory. 2. Based on review of the FDA letter sent to Healgen on 5/29/2020, the Healgen COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was authorized as follows: "Authorized Laboratories: Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests." 3. Based on review of the laboratory policy "COVID-19 HEALGEN ANTIBODY SCREENING", last revised on 12/07/2020, the procedure stated "Intended Use: The COVID-19 lgG/lgM CONTROL Kit is an external qualitative quality control for anti-SARS-CoV-2 lgM and anti-SARS- CoV-2 lgG for use with the COVID-19 lgG/lgM Rapid Test Cassette (Whole Blood/Serum/Plasma), a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of lgG and lgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma to aid in the diagnosis of COVID-19 infection." 4. Based on review of the laboratory's logs titled "COVID-19 Testing Log", the laboratory performed 344 patient COVID-19 antibody tests between 9/21/2020 and 8/2/2021 (10 months, 12 days). 5. In an interview at 10:02 hours on 8/3/2021 via telephone, when the surveyor asked if the facility was using any other COVID-19 antibody test other than the Healgen Rapid test, the laboratory owner stated "We had some other vendors early on, but the company has been primarily using the Healgen". In an interview at 10:28 hours on 8/3/2021 in the laboratory, when the surveyor asked if the facility was using any other COVID-19 antibody test other than the Healgen Rapid test the Assistant Manager for the North Locations stated "no, not that I'm aware of". During an exit conference at 13:00 hours on 8/3/2021, when the surveyor explained the Healgen COVID-19 antibody IgG/IgM rapid test was only authorized for use in CLIA laboratories authorized to perform moderate or high complexity tests, the laboratory owner stated "I did not realize that the test wasn't waived."