Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2187734	**(X3) Date Survey Completed** 06/03/2022
Name of Provider or Supplier Center Of Advanced Wellness	**Street Address, City, State** 8723 Botts Lane, San Antonio, 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	An unannounced onsite complaint investigation for TX00419524 was conducted on 06/03/2022. The laboratory was found out of compliance with the following condition: 42 CFR 493.1771 Inspection Requirements
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 direct observation, review of the U.S. Food & Drug Administration (FDA) database, instructions for use (IFU), patient test results, and interview with staff, the laboratory failed to meet requirements for its certificate of waiver. The laboratory performed severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) patient testing with a method that was not approved for use under a certificate of waiver for 42 of 42 patients (sampling from 2022). 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 direct observation, review of the U.S. Food & Drug Administration (FDA) database, instructions for use (IFU), patient test results, and interview with staff, the laboratory performed SARS-CoV-2 patient testing with a method that was not approved for use under a certificate of waiver for 42 of 42 patients (sampling from 2022). Findings included: 1. According to the FDA's Categorization of Tests database website, "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay" was not listed for use in high/moderate or waived settings. Review of "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay" IFU stated, "Laboratory Developed Test (LDT)". The laboratory was testing SARS-CoV-2 beyond the scope of their certificate type (certificate of waiver). 2. During an interview on 06/03/2022 at 9:59 am, Medical Assistant - 1 (MA-1) was provided a picture of "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay" and asked whether the kits were used for patient testing, he stated yes, until they were recalled in March or April and was instructed to repackage and "send them back." He stated patients were tested and provided results by this method. During an interview on 06/03/2022 at 10:04 am, MA-2 was provided a picture of "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay" and asked whether the kits were used for patient testing, he stated yes, "for about two months." He confirmed patients were tested and provided results by this method. He stated he was unsure what happened to the kits after he was instructed to repackage in a box. 3. During an interview on 06/03/2022 at 10:22 am, MA-2 was asked whether using the "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay" for patients yielded inconclusive or invalid results, he stated yes, there were many. He confirmed that patients were provided inconclusive/invalid results in a final test report. MA-2 was asked whether any of the other SARS-CoV-2 test kits used yielded inconclusive or invalid results, he stated no, only the "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay." 4. Review of patient SARS-CoV-2 test results from 01/21/2022 through 03/07/2022 were documented on paper logs. MA-2 (on 06/02/2022 at 10:25 am) identified the following sampling of 42 patients with "Inconclusive" antigen results via "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay": 01/26/2022 - Patient #1, Patient #2, and Patient #3 01/27/2022 - Patient #32, Patient #39, and Patient #51 02/01/2022 - Patient #18, Patient #22 02/02/2022 - Patient #5, Patient #18, Patient #20, and Patient #21 02/05/2022 - Patient #9, Patient #22, Patient #27 and Patient #28 02/08/2022 - Patient #4 and Patient #6 02/09/2022 - Patient #39b 02/10/2022 - Patient #15 02/14 /2022 - Patient #5 02/23/2022 - Patient #7 (results documented, "Unconclusive" [sic] performed at "CAW-Killeen") Patient logs from 01/21/2022 through 03/07/2022 included an additional 18 "Inconclusive" antigen results without documentation of testing dates. 5. During a tour of the second floor storage room on 06/03/2022 at 10: 44 am, one open cardboard box was observed and included 38 boxes (20 test kits in each) of "ORAL RAPID SARS CoV 2 Antigen Rapid Test Kit Lateral Flow Immunoassay." Each box of test kits was labeled with the information, "SML, LLC ... Batch B8 Lot FLAUSA02 Expires 10/1/22." The cardboard box included a FedEx shipping label with a ship date of "19JAN22" and tracking number 775797239428. The laboratory performed and reported SARS-CoV-2 patient test results using a test kit that was not listed in FDA's Categorization of Tests database for use under a certificate of waiver.