Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2244069	06/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Center Of Advanced Wellness	3107 Tpc Parkway Suite 102, 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	Intake: TX00419527 An unannounced complaint investigation was performed on June 3, 2022. The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D8100 - 42 C.F.R. 493.1771 Condition: Inspections Requirements Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the manufacturer's information for the ORAL RAPID SARS CoV2 Antigen Rapid Test kit, and interviews with testing personnel, it was revealed the laboratory performed COVID 19 testing utilizing a test kit that was not approved for use under a certificate of waiver (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 review of the manufacturer's information for the ORAL RAPID SARS CoV2 Antigen Rapid Test kit and interviews with testing personnel, it was revealed the laboratory performed COVID 19 testing utilizing a test kit that was not approved for use under a certificate of waiver. The findings include: 1. Review of the manufacturer's information for the ORAL RAPID SARS CoV2 Antigen Rapid Test kit revealed the kit was not FDA approved nor had the FDA issued an EUA (Emergency Use Authorization) for it. Thus, the kit was classified as high complexity and could only be used under a certificate of compliance or a certificate of accreditation. 2. In an interview with testing personnel during the unannounced complaint investigation on 06/03/2022 at 0920 hours in the reception area the testing personnel were questioned about the types of COVID 19 test kits that were used by the facility. They stated that the facility had performed oral fluid testing for COVID, however, they could not remember the name of the test kit. They were shown a picture of the ORAL RAPID SARS CoV2 Antigen Rapid Test kit and both confirmed that it was the kit the laboratory performed testing with. They also stated that the laboratory had ceased using the kits tow or three months prior and had returned all of the remaining kits to its main lab at 8723 Botts Lane, San Antonio Texas 78217. The facility could not provide the exact dates of use or identify the patients tested utilizing the kit.