Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0990895	02/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Concentra - Largo	1400 East Bay Dr, Largo, FL	

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 complaint survey, #2020001075, was conducted on 02/25/2020 at Concentra-Largo. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to follow manufacturers' instructions (MI) for the Urine pregnancy testing and Urine dipstick testing. Findings Included: 1. Review of the MI for Urine pregnancy testing revealed that an external control must be ran for each new shipment of kits and each new kit with different log number. Review of the Urine pregnancy log revealed that controls were performed on 11/05/19 on Lot # HCG8010063. Review of the Urine pregnancy testing in use revealed the Lot # HCG9072003. Interview on 02/25/2020 at 4:04 PM with the Office Manager confirmed that no external controls were ran on the new lot of Urine Pregnancy tests. 2. Review of the MI for Urine dipstick testing revealed that an external control must be ran for each new shipment of kits and each new kit with different log number. Review of the Urine dipstick log revealed that controls were performed on 05/02/19 on Lot # 803004. Review of the Urine dipstick testing in use revealed the Lot # 909061. Interview on 02/25/2020 at 4:04 PM with the Office Manager confirmed that no external controls were ran on the new lot of Urine dipstick tests.
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 record review and staff interview the laboratory failed to follow their procedures for hand washing and specimen labeling. Findings Included: Review of the "Venipuncture" procedure, revised 12/05/2019, revealed that the staff member must "Wash hands in the presence of the patient and put on gloves (proper PPE)." The policy also stated to "Always label blood collection tubes in the presence of the patient, and place in appropriate transport carrier." Interview on 02/25/2020 at 4:20 PM with Staff Member #B revealed that he did not always wash hands prior to drawing blood. He also stated that the label maker was at his desk (outside of the drawing room) and that if he did not print labels prior to drawing the patient, he would go to the desk to label. Observation of the desk revealed it was not in view of the drawing room.