Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2119863	(X3) Date Survey Completed 09/11/2019
Name of Provider or Supplier Recovery Centers Of America At Danvers	**Street Address, City, State** 75 Lindall St, Danvers, MA	
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	A complaint investigation of the Recovery Centers of America at Danvers laboratory was performed on 9/11/19. The complaint alleges that the laboratory was performing non-FDA approved Fentanyl testing outside its certificate type. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: . Based on record review and interview, the facility was performing testing outside the scope allowed by a CLIA Certificate of Waiver. Refer to D8100 and D8201. .
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: . Through record review and interview, it was determined the laboratory failed to meet the requirements for its Certificate of Waiver as it was performing non-waived Fentanyl testing. 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 record review and confirmed through interview with the Director of Nursing (DON) on 9/11/19 the laboratory performed testing outside its certificate type as evidenced by the following: 1. The Clinical Laboratory Program received Form CMS-116 for changes in laboratory director on 9/18/18 and 5/29/19. Section VI. Waived Testing indicated "Urine Fentanyl Test - CLIA Waived Fentanyl Rapid Test." 2. An onsite investigation was performed on 9/11/19. a. Surveyors reviewed the packaging and package insert for Fentanyl testing. The packaging indicated, "Drug Screen Test Dip Card Fen25 For Research Use Only." The package insert indicated "Fentanyl 25 Dip-Card (Urine). For research use only" and "For forensic use only." b. Surveyors reviewed two patient medical records. The review revealed orders for "Inhouse Urine Drug Screen CLIA Waived" with "Special/Additional Instructions: PLEASE INCLUDE FENTANYL." b1: Patient 21233: The "In-House Patient Testing Record" indicated "In-House CLIA Waived Urine Drug Screen Results: Positive" and "Positive Results- Urine Drug Screen: Fentanyl." b2. Patient 21190: The "In-House Patient Testing Record" indicated "In-House CLIA Waived Urine Drug Screen Results: Positive" and "Positive Results- Urine Drug Screen: Buprenorphine (BUPG), Fentanyl." c. The DON confirmed in an interview on 9/11/19 at 9:30 AM that the laboratory is performing Fentanyl testing that is not FDA categorized as CLIA waived in both inpatient and outpatient settings. d. The laboratory performed 2,085 Fentanyl tests since February 2018. e. Refer to D1000.