Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2269938	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lotus Recovery Centers	129 Deanna Street, Comfort, WV	

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, on site, complaint survey was conducted at Lotus Recovery Centers of Comfort, LLC on November 29, 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. The complaint was found to be Substantiated and specific deficiencies are found below.
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 a tour of the laboratory, document review, FDA CLIA classification database, and interview the laboratory was found to be testing outside the scope of their Certificate of Waiver. Findings: 1. A tour of the laboratory, 11/29/22 at approximately 2:30 PM, identified test kits labeled FTY Single Drug Urine Test Panel in use for testing patient urine specimens for the presence of fentanyl. 2. Review of the fentanyl test strips manufacturer inserts revealed a "For Forensic Use Only"

	statement. 3. Consultation of the FDA CLIA classification database confirmed the fentanyl test strips had no CLIA categorization and were considered a high complexity test method. 4. An interview with the laboratory manager and chief compliance officer, 11/29/22 at approximately 3:30 PM, confirmed the unauthorized high complexity testing and stated the use of the fentanyl test strips would immediately be discontinued as of the date of survey (11/29/22).