

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2124997	(X3) Date Survey Completed 12/08/2022
Name of Provider or Supplier Ohm Labs Llc	Street Address, City, State 2340 Sw Poma Dr, Palm City, 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	A recertification survey was conducted on December 8, 2022. OHM Labs Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the Reagent Calibration Log, and interview, the laboratory failed to ensure the Synermed Negative DAU (Drugs of Abuse) Calibrator used on the Synermed IR-500 toxicology analyzer was not expired prior to performing the calibration for the analyte Buprenorphine on 11/22/2022. Findings: Observations made during a tour of the laboratory on 12/08/2022 at 9:55 AM, revealed the opened bottle of Synermed Negative DAU Calibrator lot number 122111-0 expired on 11/12/2022 Review of the Reagent Calibration Log revealed the calibration of Buprenorphine was performed on 11/22/2022 using the expired Synermed Negative DAU Calibrator lot number 122111-0. On 12/08/2022 at 10:04 AM, the General Supervisor stated she used the expired calibrator for the Buprenorphine calibration.</p>