

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1053861	<b>(X3) Date Survey Completed</b>  03/09/2021
<b>Name of Provider or Supplier</b>  Cove Behavioral Health	<b>Street Address, City, State</b>  4422 E Columbus Dr, Tampa, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at DACCO Behavioral Health Inc. on March 09, 2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing and interview with the Laboratory Manager, the laboratory failed to have attestation statements signed by the Laboratory Director's designee, which was the Technical Consultant, for 2 Events (3rd Event 2019 and 2nd Event 2020) out of 6 Events (1st, 2nd, and 3rd Events for 2019 and 2020) for Urine Drug Screening and 2 Events ( 1st Event and 2nd Event for 2020) out of two Events (1st and 2nd Events 2020) for Ethyl Glucuronide Test. Findings Included: Review of American Association of Bioanalysts (AAB) proficiency testing for Urine Drug Screening and American Proficiency Testing (API) proficiency testing for Ethyl Glucuronide records revealed attestation statements for AAB2019 3rd Event Urine Drug Screening and 2020 2nd Event Urine Drug Screening and API 1st and 2nd Event Ethyl Glucuronide had not been signed by the Technical Consultant. Interview on 03 /09/2020 at 3:45 PM, the Technical Consultant stated he thought he didn't have to sign the attestation statements since he submitted all proficiency testing electronically (1st, 2nd, and 3rd Events 2019 - 2020 Urine Drug Screening and 1st and 2nd Events Ethyl Glucuronide).</p>
<b>D5417</b>	<b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b>

CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on observation and interview with the Technical Consultant, the laboratory failed to ensure the K2 (synthetic THC) calibrator (Lot# 73760440) and Urine Creatinine Validity Calibrator (Lot # 73886558) and Urine Creatinine Validity Control ( Lot #73880969) were removed from use after the open expiration date. Findings Include: Observations on 03/09/21 at 10:05 AM revealed the following calibrators and control in use: K2 calibrator ( Lot #73760440) with an expiration date of 02/28/21, the Urine Creatinine Validity Calibrator (Lot # 73886558) expiration date 02/21, and the Urine Creatinine Validity Control (Lot #73880969) expiration date 02 /21. Interview on 03/09/21 at 10:15 a.m., the Technical Consultant stated that Testing Personnel #C had been on sick leave until 03/03/21 and it had been 2 weeks since he had been in the laboratory. Testing Personnel #D did not catch the expired dates. Testing Personnel #C discovered the expired calibrators and control last Wednesday but the new ones had not arrived yet. The Technical Consultant also stated that they had not obtained the Laboratory Director's permission to use expired calibrators and control.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory staff, the Laboratory Director failed to ensure that staff followed a written procedure that described the process for documenting the competency assessment of the Technical Consultant for two out of two years (2019-2020). Findings Include: Record review of competency assessments revealed the Laboratory Director had not performed competency assessment on the Technical Consultant for two out of two years (2019- 2020). Record review of the laboratory's procedure manual showed a procedure for "Performance Assessment" but did not include how to determine the competency for the Technical Consultant. Interview on 03/09/21 at 10:45 AM, the Laboratory Director stated the Technical Consultant did not perform testing and he did not know that the laboratory should have a procedure for determining the competency of the Technical Consultant.