

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1053861	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Cove Behavioral Health	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 for 2 Events out of 6 Events for Urine Drug Screening and Adulterated Urine Drug Test (2017-2018). Findings Included: Review of American Association of Bioanalysts (AAB) proficiency testing revealed attestation statements for 2 Events in 2018 had not been signed by the Laboratory Director (2018 1st Urine Drug Screening and 2018 2nd Event Urine Drug Screening and Adulterated Urine Test) Interview on 01/16 /2019 at 3:45 PM with the Laboratory Manager confirmed the attestation statements for 2018 1st Event Urine Drug Screening and 2018 2nd Event Adulterated Urine Drug Test had not been signed.</p>
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Laboratory Manager, the laboratory failed to retain all equipment maintenance records for 2 out of 2 years reviewed (2017-2018). Findings included: Review of the equipment maintenance documentation</p>

revealed that records were missing for November and October of 2017 and May, April, and March of 2018. Interview on 01/16/2019 at 2:00 PM with the Laboratory Manager confirmed the equipment maintenance documentation for two months of 2017 and 3 months of 2018 were missing and could not be located at the time of inspections.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review of proficiency testing and interview with the Laboratory Manager, the laboratory failed to verify twice annually the 6 - monoacetyl morphine (6-MAM) test procedure for 2 out of 2 years reviewed (2017-2018). Findings included: Review of American Association of Bioanalysts(AAB) proficiency testing records revealed that the AAB proficiency testing did not include 6- MAM for the 2nd and 3rd Event of 2017 and the 2nd and 3rd Event of 2018. Interview on 01/16/2019 at approximately 1:00 PM, with the Laboratory Manager confirmed that the AAB proficiency testing for 6-MAM was missing even though the AAB Drug Screen panel was to include 6-MAM.

D6005

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(c)

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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

This STANDARD is not met as evidenced by:

Based on record review of proficiency testing records and interview with the Laboratory Manager (Technical Consultant), the laboratory failed to have a written delegation for the Laboratory Manager (Technical Consultant) to sign the attestation statement for the Laboratory Director for 3 out of 6 Urine Drug Screening and Adulterated Urine Drug Test Events reviewed (2017-2018). Findings included: Review of American Association of Bioanalysts(AAB) revealed the Laboratory Manager (Technical Consultant) had been signing the AAP proficiency testing attestation statements for 3 out of 6 Urine Drug Screening and Adulterated Urine Drug Test Events (2017 2nd and 3rd Events and 2018 3rd Event). Interview on 01/16/2019 at 12:30 PM with the Laboratory Manager (Technical Consultant) confirmed a written delegation for the Laboratory Manager (Technical Consultant) to sign the AAB proficiency testing attestation statements for the Laboratory Director was not available on the day of survey.