

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1101214	<b>(X3) Date Survey Completed</b>  01/09/2020
<b>Name of Provider or Supplier</b>  Coba Toxicology Llc	<b>Street Address, City, State</b>  218 W Nasa Parkway Suite A, Webster, TX	
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>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory patient records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for Barbiturate testing on the Olympus AU400 chemistry analyzer. Findings were: 1. Review of the package insert for Siemens Emit II Plus Barbiturate Assay (9D022UL. 12DS_H) under specimen collection and preparation revealed "the recommended pH range for urine specimens is 3.0 - 11.0. Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." 2. Random review of laboratory records from December 2019 revealed 3 of 6 patient results with</p>

pH outside of the acceptable range of 3-11. 12/18/19: Patient ID 57567, pH 2.72 12/10/19: Patient ID 56928, pH 2.78 12/16/19: Patient ID 57570, pH 2.9 3. Review of the above patient records revealed the laboratory analyzed and reported Barbiturate with pH outside of the recommended range of 3.0 - 11.0. 4. An interview with the laboratory director on 1/9/2020 at 1310 hours in the laboratory confirmed the above findings.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of quality assessment records and confirmed in interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5411