Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1101214	01/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Coba Toxicology Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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: No deficiency details available.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: An unannounced revisit was performed on 01/03/2019. Based on review of the manufacturer's instructions, laboratory records, patient reports, and confirmed in interview, the laboratory failed to ensure expired calibrators were not used for pH validity and specific gravity testing on the Olympus AU400 chemistry analyzer. A. pH Validity Calibrators B. Specific Gravity Validity Findings were: A. pH Validity Calibrators 1. Review of the package insert for the Siemens pH Validity Calibrators (3T082UL.3DS_US_B, 2008-03) revealed under stability "when stored refrigerated at 2-8C, the opened calibrators are stable for 90 days." 2. A tour of the laboratory on 01 /03/19 at 1110 hours revealed opened pH validity calibrators stored in the refrigerator: pH Validity Calibrator 2.0, lot 3T388UL-L1, exp 02/02/19; opened "7/6/18" pH Validity Calibrator 3.0, lot 3T398UL-L1, exp 02/02/19; opened "7/6/18" pH Validity Calibrator 11.0 lot 3T458UL-L1, exp 02/06/19; opened "7/6/18" pH Validity

	Calibrator 12.0, lot 3T478UL-L1, exp 02/08/19; opened "7/6/18" 3. Review of the laboratory calibration records for the Olympus AU400 revealed the laboratory performed pH Validity calibratotion after the 90 day opened stability. 12/26/18 4. Random review of the patient test records from November and December 2018 revealed the laboratory performed pH validity patient testing for the above dates. Date Patient ID pH result 12/5/18 46739 7.8 12/3/18 49158 4.88 11/30/18 49161 5.67 12/12 /18 46723 5.81 12/10/18 46725 7.01 12/12/18 49353 7.14 12/20/18 49019 7.59 12/18 /18 49023 8.69 12/19/18 46709 6.94 12/13/18 49352 5.39 5. An interview with the laboratory director on 01/03/19 at 1115 hours in the laboratory confirmed the above findings. He was unaware the laboratory were not following the revised expiration date. B. Specific Gravity Validity 1. Review of the package insert for the Simens Specific Gravity Validity Calibrators (3T052UL.3DS_US_C, 2018-02) revealed under stability "When stored refrigerated at 2-8C, the opened calibrators are stable for 21 days." 2. A tour of the laboratory on 01/03/19 at 1110 hours revealed opened specific gravity calibrators stored in the refrigerator: Specific Gravitity Calibrator 1.030 lot 3T618UL-L1, exp 03/13/19, opened "10/03/18" Specific Gravitity Calibrator 1.020 lot 3T628UL-L1, exp 03/13/19, opened "10/03/18" 3. Review of the laboratory calibration records for the Olympus AU400 revealed the laboratory performed specific gravityValidity calibratotion after the 21 day opened stability. 12/26/18 4. Random review of the patient test records from November and December 2018 revealed the laboratory performed pH validity patient testing for the above dates. Date Patient ID specific gravity result 12/5/18 46739 1.002 12/3/18 49158 1.0221 11/30/18 49161 1.032 12/12/18 46723 1.0189 12/10/18 46725 1.0111 12/12/18 49353 1.0085 12 /20/18 49019 0.9997 12/18/18 49023 1.0222 12/19/18 46709 1.0148 12/13/18 49352 1.0221 5. An interview with the laboratory director on 01/03/19 at 1115 hours in the laboratory confirmed the above findings. He was unaware the laboratory were not following the revised expiration date.