Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0457328	**(X3) Date Survey Completed** 08/28/2023
Name of Provider or Supplier Alere Toxicology Services, Inc	**Street Address, City, State** 1111 Newton Street, Gretna, LA	
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 Certification survey was performed at Alere Toxicology Services, INC, CLIA ID # 19D0457328, on August 28, 2023. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
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: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the laboratory failed to ensure reagents did not exceed their expiration date. Findings: 1. Observation by surveyors during the laboratory tour on August 28, 2023 at 9:55 am revealed the following expired items: Lab Chem Carbonate Buffer pH 9.2, Lot M174-17, Quantity: ten (10) bottles "Received 7/20/22, Expire 7/20/23" 2. Further observation by surveyors revealed the identified carbonate buffer was labeled with a sticker that included an extended expiration date of "7/20/24." 3. Review of the laboratory's "Clinical Standard Operating Procedures: Lab Policies-US Toxicology Laboratories" under the "Reagent Receipt and Storage" section revealed "When reagents are removed from storage to be put into use, they will be examined for problems, and the expiration date will be checked. If the expiration date has passed, the reagent expiration may not be extended." 4. In interview on August 28, 2023 at 4:08 pm, the laboratory's Site Director confirmed the laboratory's policy is to not extend the expiration dates of clinical reagents. The Site Director and Technical Supervisor confirmed the identified reagents were expired.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)

	The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of policies, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D5417.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of policies, and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight for the laboratory. Refer to D5417.