Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2027247	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Alcala Testing & Analysis Services	3703 Camino Del Rio South, Ste 100-A, San Diego, CA	

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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on the lack of 2017 proficiency testing scores from CMS (report 155D, Individual Laboratory Profile), review of laboratory proficiency testing records and patients tests reports for Immunology, Chemistry, Endocrinology, Toxicology, and Hematology; and interview with laboratory personnel, it was determined that the laboratory failed to authorize CAP to release proficiency testing scores to CMS (HHS), and thus, the public as required in section 353(f)(3)(F) of the Public Health Service Act. Findings included: a. CMS reported no scores for 3 out of 3 events in 2017 for Immunology, Chemistry, Endocrinology, Toxicology, and Hematology. b. Laboratory proficiency testing records revealed CAP reported scores to the laboratory and to COLA (accrediting agency), but not CMS. c. Laboratory personnel affirmed (1 /22/19) the aforementioned error; and thus, the failure to notify CAP to report proficiency testing scores to CMS/CLIA. d. The reliability and quality of patients results reported in 2017 could not be assured in the absence of proficiency testing reports. Four out of 4 laboratory reports selected at random included some or all specialties: Date Accession # ---------- 1/05/17 43464 1/09/17 43630 3/15/17 51639 6/12/17 58813 e. Based on the stated estimated annual tests volumes, the laboratory reported a total of approximately 2,847,600 results in 2017. .
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 reviews of laboratory patients records, proficiency testing reports from CAP (College of American Pathologists), and laboratory records correlating toxicology results with other certified laboratories; the lack of laboratory records, and interview with laboratory personnel, it was determined that the laboratory failed to at least twice annually verify the accuracy of confirmatory testing for each individual drug using the LC-MS/MS system. Findings included: a. The laboratory tested for a total of 299 individual drugs categorized into panels: Drug panel Number of drugs tested ---------- Analgesics/ Opiates ..... 28 Benzodiazepines ..... 20 Anti-psychotics ..... 15 Anti-depressants / SSRI/ SNRI/ TCA ..... 24 Depressants ..... 7 Anti-convulsants ..... 12 Muscle relaxants ..... 5 Stimulants/ ADHD ..... 8 Decongestants ..... 2 Appetite Stimulants ..... 2 Antidotes ....2 Illicits ..... 19 Spice/ Cannabinoids (K2 /Spice) ..... 15 Barbiturates ..... 6 Direct Biomarkers ..... 3 Anti-inflammatory/ NSAIDS .....17 Anti-histamines ..... 7 Cardiovascular .....42 Antimicrobial ..... 2 Gastrointestinal/ Dietary ..... 8 Anti-emetic .....2 Diabetic .....11 Diuretics/ Incontinence .....12 PDE (Phosphodiesterase inhibitors) .....3 Corticosteroids/ Hormone Therapy .....6 Anti-neoplastics / Cancer Therapy .....1 Dementia (Parkinson's/ Alzheimer's) .....3 b. To satisfy the requirement to at least twice annually verify accuracy of testing using the LC-MS/MS system, the laboratory chose to enroll in CAP proficiency testing programs and also perform split sample testing with other laboratories. c. Review of laboratory records revealed that not all 299 drugs were tested and verified at least twice each year using the combination of the aforementioned methods. d. Laboratory personnel affirmed (1/22/19) there were no additional documents verifying the accuracy of testing. e. The reliability and quality of results reported could not be assured when accuracy had not been verified at least twice each year. Based on the stated estimated annual tests volume, the laboratory reported approximately 2,620,000 drug test results annually. A few examples included the following: Date Accession # ---------- 1/09/17 43319 1/09/17 43630 1/03/18 74235 1/22/19 AL-DBS-7323 .
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 the deficiencies cited, the Technical Supervisor is herein cited for deficient practice in providing overall technical oversight of the laboratory. Findings included:

	a. Under the Technical Supervisor's oversight, the laboratory failed to have a system to monitor activities to ensure every analyte was tested and verified to be accurate at least twice each year. See D5217.