Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2103276	10/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Illuminate Diagnostics Inc	18331 Gridley Road, Ste C, Cerritos, 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
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 review of 2018, 1st event (A) proficiency testing report from CAP (College of American Pathologists), laboratory proficiency testing records, and patients test reports for Meprobamate; and interview with Technical Supervisor-2 (General Supervisor-2), the laboratory failed to verify the accuracy of testing for Meprobamate. Findings include: a. The laboratory chose to participate in CAP's proficiency testing program, "UT" Urine Toxicology, as the means to satisfy the requirement to verify the accuracy of the laboratory-developed LC/MS test for Meprobamate in urine specimen. b. For the 1st event of 2018, the laboratory failed to identify Meprobamate present in Sample UT-05; and thus, accuracy was not verified. c. The Technical Supervisor-2 (General Supervisor-2), affirmed (10/05/18) the aforementioned failure in reporting Meprobamate. d. The reliability and quality of results reported for Meprobamate could not be assured when proficiency testing failed to verify. Based on the laboratory's test run report of 16,203 tests for the timeframe April to October 4, 2018, the laboratory reported approximately 3,240 Meprobamate results each month. A few examples reporting as Negative for Meprobamate are as follows: Date Accession # ---------- 1/07/18 21365 2/19/18 23362 3/04/18 24608 4/06 /18 24980 5/13/18 25535 6/20/18 25812 7/05/18 26141 8/13/18 26667 .
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 laboratory proficiency testing records for 2018: event 1 and patients test reports, the lack of laboratory documents, and interview with General supervisor-2 (Technical Supervisor-2), the laboratory failed to assess the problem identified in the laboratory-developed LC/MS testing and determine corrective action. Findings include: a. The laboratory failed to report Meprobamate for the first event of proficiency testing in 2018. See D5217. b. The laboratory proficiency testing records failed to assess the problem to determine the root cause for the aforementioned error. c. The laboratory failed to assess the effect of the error on patient testing and assure the reliability of Negative results. d. The laboratory failed to determine correction action for the problem identified. e. The laboratory analytic systems include testing in: General Immunology Routine Chemistry Endocrinology Toxicology f. Based on the stated annual test volumes (CMS116, 10/03/18) the laboratory reports approximately 355,162 results annually. .
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of CAP proficiency testing reports, laboratory proficiency testing records, the lack of laboratory documents, and interview with Technical Supervisor-2 (General Supervisor-2), the Laboratory Director is herein cited for deficient practice in ensuring that any unsatisfactory proficiency testing result is addressed with a plan of corrective action. Findings include: a. Under the Laboratory Director's administration, the laboratory failed to provide a plan of correction when proficiency testing revealed the failure to identify a drug present in the sample. .
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on the serious nature of the deficiency cited, the Technical Supervisors (1, 2) are herein cited for deficient practice in providing technical and scientific oversight and responsibility for resolving technical problems. See D5791.