Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1004121	08/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Michael I Keller Laboratory	3633 Camino Del Rio S Ste 106, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: D2016 Based on review of CMS proficiency testing (PT) record, Casper Report 0096D, and interview with the laboratory testing personnel, it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of general immunology constituting unsuccessful PT performance. (See D2085)
D2085	GENERAL IMMUNOLOGY

	CFR(s): 493.837(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of CMS PT record Casper Report 0096D and interview with the laboratory testing personnel, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, RA/RF, resulting in unsuccessful performance. The findings include: a. The laboratory performed RA/RF testing and enrolled its proficiency testing with CAP (College of American Pathologists) PT program. b. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analyte, RA/RF, as follows: 2017 Q2 (0%) 2018 Q1 (0%) Q1 = First Testing Event Q2 = Second Testing Event c. The laboratory performed RA/RF in approximately 66 patient samples monthly. d. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an initial unsuccessful performance for the analyte, RA/RF.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016) _____
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of CMS PT records, Casper Report 0096D and interview with the laboratory testing personnel, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H of this part. The findings included: For the analyte, RA/RF, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in

	two out of three consecutive testing events, resulting in unsuccessful PT performance. (See D2016 and D2085)