Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2055250	09/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Apollogen Inc	15375 Barranca Parkway Ste A-105-106, Irvine, 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 laboratory records including a list of tests reported, the lack of laboratory documents verifying the accuracy of testing, and interview with the Technical Supervisor (General Supervisor/Testing person), it was determined that the laboratory failed to verify the accuracy of the Cardiomyopathy test in 2016 and at least twice in 2017 for iGene Cancer and Breast Cancer. Findings include: a. 2016 1) A list of specimen for 2016 revealed accession # A16-0368SNA was received on 9/01 /16 and tested for Cardiomyopathy. 2) The laboratory failed to provide 2016 documents for verifying the accuracy of the Cardiomyopathy test to identify mutations in 44 genes. b. 2017 1) A list for 2017 revealed specimens tested for iGene Cancer and Breast Cancer. 2) The laboratory failed to provide documents verifying the accuracy of testing for the iGene Cancer Panel (20 genes) and Breast Cancer (19 genes, including BRCA1 and BRCA2) a second time in 2017. c. The Technical Supervisor (General Supervisor/Testing person) affirmed (9/11/18) the aforementioned lack of documents, and thus the failure to verify testing accuracy in 2016 and at least twice in 2017. d. The reliability and quality of results reported could not be assured. Based on the listing, the laboratory reported results for one Cardiomyopathy in 2016, and approximately 63 iGene Cancer Panels and 3 Breast Cancer in 2017.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces

	a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation of the Norgen [Biotek Corporation] "Saliva DNA Collection and Preservation Device" used for patients' specimen, review of manufacturer's information, interview with laboratory personnel, and the lack of validation documents, the laboratory failed to establish performance specifications for the non-FDA approved device prior to use. Findings include: a. The laboratory provided the aforementioned device to collect and transport saliva specimen. b. Manufacturer's information stated the device as "Research Use Only". c. The laboratory failed to provide documents establishing the performance characteristics of the device for specimen stability and the effects of interfering substances. d. Laboratory personnel affirmed (9/11/18) the aforementioned information and the failure to establish criteria for acceptable specimen stability and interfering substances using this device. e. The reliability and quality of results reported could not be assured when specimen stability and interfering substances in saliva had not been established. Based on the stated estimated annual test volume, the laboratory tested more than 200 Saliva specimen annually in 2016 and 2017.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of a laboratory record for specimen received and tested in 2017, the lack of documents, and interview with the Technical Supervisor (General Supervisor /Testing person), the laboratory failed to include control materials in the extraction of Blood specimen. Findings include: a. The laboratory received and extracted blood specimen in 2017 for testing. For 4 out of 7 blood specimen from February to September 2017, the laboratory failed to provide documents for including blood control materials in the extraction processes. b. The Technical Supervisor (General Supervisor/Testing person) affirmed (9/11/18) the failure to include control materials when extracting blood specimen. c. The reliability and quality of results reported for Blood specimen could not be assured in the absence of control materials during extraction processes.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the cumulative effect of the deficiencies cited, the Laboraotry Director is herein cited at the Condition level for deficient practice in providing overall management and direction of the laboratory performing high complexity testing. See D6086, D6093, and D6094.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: The Laboratory Director is herein cited for deficient practice in ensuring that verification procedures are adequate to determine accuracy and other pertinent performance characteristics of testing. Findings include: a. The laboratory failed to establish performance characteristics of specimen stability and interfering substances for specimen transport prior to use. See D5423.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: The Laboratory Director is herein cited for deficient practice in ensuring that quality control programs are established to assure the quality of laboratory testing and identify failures in quality as they occur. Findings include: a. The laboratory failed to include control materials when extracting blood specimen. See D5453.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by:

	The Laboratory Director is herein cited for deficient practice in ensuring that quality assessment programs are maintained. Findings include: a. The laboratory failed to verify the accuracy of testing at least twice annually. See D5217.