Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658007	07/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Center Hospital-Orlando Health- Bayamon	Callej #9 Hermanas Davilas, Bayamon, PR	

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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on IM performance specification procedures , quality control records review (year 2018-2019) and laboratory general supervisor and laboratory director interview at 2:30 P.M. on July 2, 2019, it was determined, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology for IM tests. Refer to : D5421- failed to perform the verification of performance specification of the new IM test. D5449- The laboratory did not include positive and negative control material.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on Infectious Mononucleosis (IM) quality control records reviewed (year

	2018-2019) and laboratory general supervisor interview at 1:00 P.M. on July 2, 2019, it was determined that the laboratory failed to perform the evaluation of the performance specifications of the new IM method (Acceava Mono Cassette). The findings include: 1. The laboratory begin to performed the IM rapid test by a one step antibody test (Acceava Mono cassette) that uses direct solid-phase immunoassay technology to detect IM heterophlies antibodies in human serum in November 2018. 2. From November 2018 to June 2019, the IM quality control records showed that the laboratory did not verify the performance specifications of the new test. 3. The laboratory processed and reported 26 IM test since November 2018.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on IM quality control records review(year 2018-2019) and laboratory general supervisor interview at 1:00 P.M. on July 2, 2019, it was determined that the laboratory failed to include a negative and positive control material when performed IM test by One Step antibody test method (Acceava monocassette). The findings include : 1. The laboratory performed IM (Infectious mononucleosis test) by one step antibody test method. 2. The IM quality control records were review from January 2018 to June 2019. 3. The records showed that the laboratory did not include a negative and a positive control material the following days : March 3, 15, 27, 31, 2019 and June 27, 2019. The laboratory processed and reported seven IM patient samples those days. 4. The laboratory general supervisor confirmed on July 2, 2019 at 2:30 P. M. that the laboratory failed to include a negative and a positive IM control material those days.
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 quality assessment (QA) records review (year 2018-2019), laboratory general supervisor and laboratory director interview on July 2, 2019 at 3:00 P.M. , it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment manual showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic system in the following area: general immunology. Refer to D5421 and D5449.

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 general immunology quality control records review (year 2018-2019) and laboratory director interview at 3:00 p.m. on July 2, 2019, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D 6093 and D 6094.
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: Based on IM test quality control records review (year 2018-2019) and interview with the laboratory director on July 2, 2019 at 3:00 P.M., it was determined that the laboratory failed to ensure compliance with the requirements for analytic system for IM tests. The findings include: 1. The laboratory failed to include a negative and positive control material when performed IM test by One Step antibody test method. Refer to D5449. 2. The laboratory failed to perform the evaluation of the performance specifications of the new IM method (Acceava Mono Cassette) Refer to D5421.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on IM test quality control records review (year 2018-2019) and interview with the laboratory director on July 2, 2019 at 3:00 P.M., it was determined that the laboratory general supervisor failed to ensure compliance with the requirements for analytic system for IM tests. The findings include: 1. The laboratory failed to include a negative and positive control material when performed IM test by One Step antibody test method. Refer to D5449. 2. The laboratory failed to perform the evaluation of the performance specifications of the new IM method (Acceava Mono Cassette) Refer to D5421.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's

	quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on IM test quality control records review (year 2018-2019) and interview with the laboratory general supervisor and laboratory director on July 2, 2019 at 3:00 P.M., it was determined that the laboratory testing personnel failed to ensure compliance with the requirements for analytic system for IM tests. The finding includes: 1. The laboratory failed to include a negative and positive control material when performed IM test by One Step antibody test method. Refer to D5449.