Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658265	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Immuno Reference Lab	562 Avenida Munoz Rivera, San Juan, 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 Anti-HCV package insert review and interview with the laboratory supervisor on June 12, 2019, it was determined that the laboratory failed to meet the analytic requirements in the subspecialty of general immunology (Anti-HCV). The finding includes: a. The laboratory did not established the performance characteristics of the Anti-HCV test for the following populations: newborns, infants, children, or populations of immunocompromised or immunosuppressed patients. Refer to D 5423.
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 review of the Abbott Architect Anti-HCV package, Architect instrument verification of performance specifications review and interview with the laboratory supervisor on June 12, 2019 at 12:15 PM, it was determined that the laboratory did not established the performance specifications of the Anti-HCV test for which the laboratory did not provide performance specifications. The findings include: a. The laboratory processed the Anti-HCV test by the Abbott Architect instrument. b. The Anti-HCV package insert in the intended use section showed the following: " Assay performance characteristics have not been established for newborns, infants, children , or populations of immunocompromised or immunosuppressed patients. The user is responsible for establishing their own assay performance characteristics in these populations." c. Review of the verification of performance characteristics performed by the laboratory showed that the laboratory did not verify the performance characteristics of the infants, children , nor populations of immunocompromised or immunosuppressed patients. d. The laboratory supervisor stated on June 12, 2019 that the laboratory performed Anti-HCV tests on infants, children and populations of immunocompromised or immunosuppressed patients. e. The laboratory workload from June 2018 to June 2019 for Anti-HCV were the following: 552 pediatric patients samples and 1,294 immunocompromised patient samples.
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 review of the verification of the performance specifications of the Anti-HCV test performed by the Abbott Architect instrument and interview with the laboratory supervisor on June 122, 2019, it was determined that the laboratory failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for the subspecialty of general immunology . Refer to D 6086 (the laboratory director did not established the performance specifications of the modified Anti-HCV test)
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: Based on review of the verification of the performance specifications of the Anti-HCV tests performed by the Abbott Architect instrument and interview with the laboratory supervisor on June 12, 2019 at 12: 20 PM, it was determined that the laboratory director did not ensure that the verification performance specifications were performed for the following patients populations prior to reporting patient tests reports: newborns, infants, children and immunocompromised or immunosuppressed patients. Refer to D 5423