Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0862901	02/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Paseos Ii	Calle Bolivia 76 Suite 102, Hato Rey, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on POC ONE system manufacturer's instructions, urea breath testing records (years 2016 to 2018) review and technical supervisor interview on February 9, 2018 at 8:45 AM, it was determined that the laboratory failed to follow manufacturer's instruction when 49 out of 49 patients breath specimens were tested and reported for urea by the POC ONE system from August 31, 2016 to January 15, 2018. The findings include: 1 The POC one system manufacturer instructed the laboratory to perform and evaluate one per month the reproducibility test as quality control procedure of the POC one system. 2. The urea breath testing records (years 2016 to 2018) showed that the laboratory did not perform nor evaluate the reproducibility test of the POC one system from August 31, 2016 to January 15, 2018. 3. The technical supervisor confirmed on on February 9, 2018 at 8:50, that the laboratory did not perform nor evaluate the reproducibility test of the POC ONE system from August 31, 2016 to January 15, 2018. 4. The urea breath testing records (years 2016 to 2018) showed that the laboratory tested and reported 49 out of 49 patients breath specimens for urea by the POC ONE system from August 31, 2016 to January 15, 2018.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all

	control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on manual and SQAV system sperm count testing records (years 2016 to 2018) review, lack of quality control records for manual sperm count and technical supervisor interview on February 9, 2018 at 10:10 AM, it was determined that the laboratory failed to include one control material each 8 hours of operation when one out of one patient specimen was processed for manual sperm cells counts by the hemocytometer from January 19, 2016 to February 8, 2018 (processed on May 17, 2016). The findings include: 1. The laboratory performed the sperm cell count by the SQAV system and by the the hemocytometer (those patients specimens they can not be counted by the SQAV system from January 19, 2016 to February 8, 2018 . 2. The manual and SQAV system sperm count testing records showed that one out of one patient specimen was processed for manual sperm cells counts by the hemocytometer from January 19, 2016 to February 8, 2018 (processed on May 17, 2016). 3. The laboratory did not perform the quality control procedures when one out of one patient specimen was processed for manual sperm cells counts by the hemocytometer on May 17, 2016. 4. The technical supervisor confirmed on February 9, 2018 at 10:10 AM, that the laboratory did not perform the quality control procedure on May 17, 2016.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on manual and SQAV system sperm cell count testing records (years 2016 to 2018), annual volume records (2016 and 2017) review and technical supervisor interview on February 9, 2018 at 10:10 AM, it was determined that the laboratory failed to evaluates twice a year the relationship of the sperm cell count results between the manual method (hematocytometer) and the SQAV system from January 19, 2016 to February 8,2018. The findings include: 1. The laboratory performed the sperm cell count by the SQAV system and by the the hemocytometer (those patients specimens that they can not be counted by the SQAV system) from January 19, 2016 to February 8, 2018. 2. The manual and SQAV system sperm cell count testing records showed that one out of 22 sperm cell counts was performed by the hemotocytometer method during the year 2016 (on May 17, 2016). 3. The laboratory did not evaluates twice a year the relationship of the sperm cell count results between the manual method (hematocytometer) and by the SQAV system from January 19, 2016 to February 8,2018. 4. The technical supervisor confirmed on February 9, 2018 at 10:10 AM, that the laboratory did not evaluates twice a year the relationship of the sperm cell count results between the manual method (hematocytometer) and by the SQAV system from January 19, 2016 to February 8,2018.
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 manual and SQAV system sperm count testing records (years 2016 to 2018), annual volume records (2016 and 2017) review review, lack of quality control records for manual sperm count and technical supervisor interview on February 9, 2018 at 10: 10 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements for the sperm cells count. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements for the sperm cells count quality control. Refer to D 5543. 2. The laboratory director failed to ensure compliance with the analytic system requirements for the verification of the relationship of the sperm cell count results between the manual method (hematocytometer) and by the SQAV system. Refer to D 5775.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on manual and SQAV system sperm count testing records (years 2016 to 2018), annual volume records (2016 and 2017) review review, lack of quality control records for manual sperm count and technical supervisor interview on February 9, 2018 at 10: 10 AM, it was found that the , it was determined that technical supervisor failed to ensure compliance with the analytic system requirements for the sperm cells count. Refer to D 5543 Refer to D 5775.