Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658121	07/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Villa Ana	Carr 189 Km 12-7 Centro Comercial, Juncos, 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 Immuno Card Stat Flu A & B manufacturer's instruction, Influenza A & B results reports records review and interview with the technical supervisor on July 5, 2018 at 12:40 PM, it was determined that the laboratory failed to follow manufacturer's instructions when 28 out of 28 patients specimens were tested and reported for Influenza A & B results from April 2, 2018 to June 28, 2018. The findings include: 1. The Immuno Card Stat Flu A & B manufacture instructed the laboratory that the negative test results are presumptive and it is recommended these results be confirmed by viral culture; negative results do not preclude influenza virus infection and should not be used as sole basis for treatment or other management decision. 2. On July 5, 2018 at 12:40 PM, the Influenza A & B results reports records showed that 28 out of 28 patients specimens tested with the The Immuno Card Stat Flu A & B reagent kit were reported without the manufacturer required information . Also, those Influenza A & B reports include the information of the formed method (OSOM). 3. The technical supervisor confirmed on July 5, 2018 at 12:50 PM, that those reports did not include the manufacturer required information.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a

	proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on P.R. Proficiency Testing Program records review (years 2016, 2017 and 2018)and and technical supervisor interview on July 5, 2018 at 9:30 AM, it was determined that the laboratory failed to take and document remedial actions when it obtained an unsatisfactory score of 40 per cent for alkaline phosphatase in the first event of the year 2017. The findings include: 1. On July 5, 2018 at 9:30 PM , the P.R. Proficiency Testing Program records showed that the laboratory did not take nor document remedial actions when it obtained an unsatisfactory score of 40 per cent for for alkaline phosphatase in the February 2017's event. 2. The technical supervisor confirmed on July 5, 2018 at 9:40 AM, that the laboratory did not take nor document remedial actions for the February 2017's event.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records review and technical supervisor interview on July 5, 2018 at 12:15 PM, it was determined that the laboratory failed to meet the requirements for Bacteriology specialty. Refer to D 5405 (The laboratory failed to follow manufacturer's instruction when it processed 6,449 patients' urine cultures from January 2, 2017 to July 5, 2018).
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based Sysmex XN-550 system validation records, complete blood cell count (CBC) reports records, FDA database records, INR calculation records, normal patients Prothrombin Time mean records review , testing personnel and technical supervisor interview on July 5, 2018 at 12:15 PM, it was determined that the laboratory failed to meet the requirements for Hematology. Refer to D 5421 (The laboratory failed to verify the Sysmex XN-550 reference interval (normal values) are appropriate for the laboratory pedriatic population (ages older than 2 years of age) prior to reported reported 7 out 7 pediatric CBC specimens from June 1, 2018 to July 3, 2018). Refer to D 5423 (The laboratory failed to validated the Sysmex XN-550 system for patient population from 0-2 years of age prior to reports 2 out of 2 CBC reports in patients

	under the ages of 2 years from June 1, 2018 to July 3, 2018). Refer to D 5545 (The laboratory failed to follow the INR procedures when it calculated and reports 1,763 INR results by the ACL Elite system from October 18, 2017 to July 5, 2018).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on quality assurance program, technical supervisor competence records review and technical supervisor interview on July 5, 2018 at 12:20 PM, it was determined that the laboratory failed to follow written protocol to assess the general laboratory system requirements. The findings include: 1. The quality assurance program establishes to perform an annual competence for the Technical supervisor. 2. On July 5, 2018 at 12:20 PM, the technical supervisor competence records showed that the laboratory did not evaluate annually her performance as technical supervisor since July, 2016. The laboratory evaluated the technical supervisor as testing personnel. 3. The technical supervisor confirmed on July 5, 2018 at 12:30 PM, that her last competence was not evaluated for the technical supervisor responsibility.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on quality assurance program, technical supervisor competence records review and technical supervisor interview on July 5, 2018 at 12:20 PM, it was determined that the laboratory failed to follow written protocol to assess the general laboratory system requirements. Refer to D 5209 (The laboratory did not evaluate annually the performance of the technical supervisor since July, 2016. The laboratory evaluated the technical supervisor as testing personnel).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records review and technical supervisor interview on July 5, 2018

	at 12:15 PM, it was determined that the laboratory failed to follow manufacturer's instruction when it processed 6,449 patients urine cultures from January 2, 2017 to July 5, 2018. The findings include: 1. The Microscan manufacturer instructed the laboratory to incubate the Microscan identification system and the Microscan susceptibility tests at 35 C. 2. On July 5, 2018 at 12:15 PM, , the incubator temperature chart showed that the laboratory recorded temperatures of 37 C +/- 1 C from January 2, 2017 to July 5, 2018. 3. The technical supervisor confirmed on July 5, 2018 at 12:20 PM, that the laboratory established the incubator temperature range from 37 C +/- 1 C 4. The bacteriology testing records showed that the laboratory processed 6,449 patients urine cultures from January 2, 2017 to July 5, 2018.
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 Sysmex XN-550 system validation records, complete blood cell count (CBC) reports records review and technical supervisor interview on July 5, 2018 at 9: 40 AM, it was determined that the laboratory failed to verify the Sysmex XN-550 reference interval (normal values) are appropriate for the laboratory pedriatic population (ages older than 2 years of age) prior to reported reported 7 out 7 pediatric CBC specimens from June 1, 2018 to July 3, 2018. The findings include: 1. The laboratory performed the validation of the Sysmex XN-550 system for the CBC tests in August 2017. 2. On July 5, 2018 at 9:40 AM, the Sysmex XN-550 system validation records showed that the laboratory did not verified that the CBC reference interval (normal values) are appropriate for the laboratory pediatric population since August 2017. The verification of Reference Interval summary showed that the laboratory verifies the following analytes based on the gender (female and male) of the laboratory population: hematocrit, hemoglobin and red blood cell in August 2017. 3. The technical supervisor confirmed on July 5, 2018 at 9:50 AM, that the laboratory did not verified the reference range for the pediatric population since August 2017. 4. The CBC reports records showed that the laboratory reported 7 out 7 pediatric CBC specimens with the CBC normal values included in the adults CBC reports from June 1, 2018 to July 3, 2018: patient number 023097-002, patient number 038701-001, patient number 071971-000, patient number 032446-000, patient number 030792-000, 026594-000 and patient number 004954-002.
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 Sysmex XN-550 system validation records, FDA database records, CBC reports (patients under the age of 2 years) records review and technical supervisor interview on July 5, 2018 at 9:40 AM, it was determined that the laboratory failed to validated the Sysmex XN-550 system for patient population from 0-2 years of age prior to reports 2 out of 2 CBC reports in patients under the ages of 2 years from June 1, 2018 to July 3, 2018. The findings include: 1. The FDA database (510K) for the Sysmex XN-550 determined that the performance of this device has not been established in pediatric patients under the ages of 2 years. 2. The Sysmex XN-550 system validation records showed that the laboratory did not validate this system for pediatric patients under the ages of 2 years. 3. The laboratory reported 2 out 2 CBC results of patients under the age of 2 years from June 1, 2018 to July 3, 2018: patient number 023097-001 with birthdate of September 13, 2017 and patient number 000397-004 with birthdate of April 8, 2017.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on international Normalized Ration (INR) calculation records, normal patients Prothrombin Time mean records review , testing personnel interview on July 5, 2018 at 10:18 AM, it was determined that the laboratory failed to follow the INR procedures when it calculated and reports 1,763 INR results by the ACL Elite system from October 18, 2017 to July 5, 2018. The findings include: 1. The INR calculation records showed that the laboratory calculated the INR results by the ACL Elite system from October 18, 2017 to July 5, 2018. 2. On July 5, 2018 at 10:18 AM, the normal patients Prothrombin Time mean records showed that the laboratory determined the current and pertinent normal patients Prothrombin Time mean of 14.3 seconds, when it placed in use the new lot of thromboplastin N027852 on October 18, 2017. 3. The ACL Elite system showed that the laboratory did not incorporate the current and pertinent normal patients Prothrombin Time mean of 14.3 seconds from October 18, 2017 to July 5, 2018. Instead, the ACL Elite system showed a former normal patients Prothrombin Time mean of 14.0 seconds 4. The testing personnel confirmed on July 5, 2018 at 10:25 AM, that the laboratory did not incorporated the current and pertinent normal patients Prothrombin Time mean of 14.3 seconds in the ACL Elite system since October 18, 2017. 5. The laboratory calculated and reported 1,763 INR results using a the former normal patients Prothrombin Time mean of 14.0 seconds from October 18, 2017 to July 5, 2018.
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 Proficiency Testing Program records, individualized quality control plan (IQCP) for the Microscan microorganisms identification and susceptibility tests record, Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records, Sysmex XN-550 system validation records, complete blood cell count (CBC) reports records, FDA database records, INR calculation records, normal patients Prothrombin Time mean records on quality assurance program, technical supervisor competence records review, testing personnel and technical supervisor interview on July 5, 2018 at 12:20PM, it was determined that the laboratory director failed to fulfil her responsibilities and duties to comply with the analytic system and quality assessment requirements. Refer to D 6079, D6092, D6093 and D6094.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on individualized quality control plan (IQCP) for the Microscan microorganisms identification and susceptibility tests record, Microscan manufacturer's instructions, incubator temperature chart records review and technical supervisor interview on July 5, 2018 at 12:15 PM, it was determined that the laboratory director failed to ensure to develop a complete Individualized quality Control Plan for the Micorscan system from January 1, 2017 to December 28, 2018. The findings include: 1. The IQCP for the Microscan microorganism's identification and susceptibility tests system did not include a written and laboratory director signed Quality control Plan. 2. The Risk Assessment (RA) has a potential failure in the environmental component due to the laboratory did not follow the manufacturer's instruction for the incubation temperature from January 1, 2017 to December 28, 2018. 3. The Microscan manufacturer instructed the laboratory to incubate the Microscan identification system and the Microscan susceptibility tests at 35 C. However, the incubator temperature chart showed that the laboratory recorded temperatures of 37 C +/- 1 C from January 2, 2017 to July 5, 2018. 4. The laboratory failed to follow manufacturer's instruction when it processed 6,449 patients' urine cultures from January 2, 2017 to July 5, 2018. Refer to D 5405.

D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on P.R. Proficiency Testing Program records review (years 2016, 2017 and 2018)and and technical supervisor interview on July 5, 2018 at 9:30 AM, it was determined that the laboratory director failed to ensure to that a remedial action plan is follow when a proficiency testing results is found to be unsatisfactory. Refer to D 2094 (The laboratory did not take nor document remedial actions when it obtained an unsatisfactory score of 40 per cent for alkaline phosphatase in February , 2017).
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 Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records, Sysmex XN-550 system validation records, complete blood cell count (CBC) reports records, FDA database records, INR calculation records, normal patients Prothrombin Time mean records review , testing personnel and technical supervisor interview on July 5, 2018 at 12:15 PM, it was determined that the laboratory director failed to ensure that the laboratory comply with the analytic system requirements. Refer to D 5002 (The laboratory failed to meet the requirements for Bacteriology specialty). Refer to D 5024 (The laboratory failed to meet the requirements for Hematology specialty).
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: Based on quality assurance program, technical supervisor competence records review and technical supervisor interview on July 5, 2018 at 12:20 PM, it was determined that the laboratory director failed to comply with the general laboratory system requirements. Refer to D 5291 (The laboratory failed to follow written protocol to assess the general laboratory system requirements).
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification

	requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records, Sysmex XN-550 system validation records, complete blood cell count (CBC) reports records, FDA database records, INR calculation records, normal patients Prothrombin Time mean records review , testing personnel and technical supervisor interview on July 5, 2018 at 12:15 PM, it was determined that the technical supervisor failed to fulfill her responsibility to establish and maintain the quality control program in Hematology and Bacteriology specialties. Refer to D 6117.
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 Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records, Sysmex XN-550 system validation records, complete blood cell count (CBC) reports records, FDA database records, INR calculation records, normal patients Prothrombin Time mean records review , testing personnel and technical supervisor interview on July 5, 2018 at 12:15 PM, it was determined that the technical supervisor failed to ensure compliance with the analytic system requirements. Refer to D 5405 (The laboratory failed to follow manufacturer's instruction when it processed 6,449 patients urine cultures from January 2, 2017 to July 5, 2018). Refer to D 5421 (The laboratory failed to verify the Sysmex XN-550 reference interval (normal values) are appropriate for the laboratory pedriatic population (ages older than 2 years of age) prior to reported reported 7 out 7 pediatric CBC specimens from June 1, 2018 to July 3, 2018). Refer to D 5423 (The laboratory failed to validated the Sysmex XN-550 system for patient population from 0-2 years of age prior to reports 2 out of 2 CBC reports in patients under the ages of 2 years from June 1, 2018 to July 3, 2018). Refer to D 5545 (The laboratory failed to follow the INR procedures when it calculated and reports 1,763 INR results by the ACL Elite system from October 18, 2017 to July 5, 2018).