Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0682233	03/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Rex	Calle 1 A5 Rexville, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on Prothrombin Time (PT), Partial Thromboplastin Time (PTT) and Mycoplasma pneumoniae tests quality control records reviewed from January 2020 to March 25, 2022 and laboratory supervisor interview, it was determined that the laboratory failed to retain quality control records for at least 2 years. The finding includes: 1. On March 25, 2022 at 1:20 PM, the lack of records showed that the laboratory did not retain the PT, PTT and Mycoplasma pneumoniae tests quality control records for at least 2 years. Refer to D 3031.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on Prothrombin Time (PT), Partial Thromboplastin Time (PTT) and Mycoplasma pneumoniae tests quality control records reviewed from January 2020 to March 25, 2022 and laboratory supervisor interview, it was determined that the laboratory failed to retain the PT, PTT and Mycoplasma pneumoniae tests quality control records for at least 2 years. The findings include: 1. The laboratory processed and reported the PT and PTT tests by the BFT II system from January 2020 to March 25, 2022. 2. On March 25, 2022 at 11:40 AM, the laboratory did not have available the Levy Jennings charts of the PT and PTT controls from June 23, 2020 to March 24, 2022. 3. On March 25, 2022 at 1:20 PM, the laboratory did not retain the Mycoplasma pneumoniae test quality control records from 12/24/2020 to 01/21/2022). Refer to D 5449. 4. The general supervisor confirmed on March 25, 2022 at 1:28 PM that those quality control records are not available in the laboratory. She stated that the Levy Jennings charts of the PT and PTT controls are at her home.
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 laboratory competence schedule, personnel file review and laboratory director interview, it was determined that the laboratory failed to follow the established schedule for the general supervisor competence evaluation since April 30, 2019. The findings include: 1. On March 25, 2022 at 9:45 AM, the competence schedule was reviewed. The schedule showed that the general supervisor competence must be performed every year. 2. On March 25, 2022 at 9:47 AM, the general supervisor personnel file was reviewed, showing that the last competence evaluation was performed on April 30, 2019. 3. The laboratory director confirmed on March 25, 2022 at 9:49 AM, that the competence of the general supervisor is not performed every year since April 30, 2019.
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 personnel competence records, Quality Assessment (QA) procedures manual, QA activities records review and laboratory director interview, it was determined that laboratory failed to follow the established schedule to evaluate and monitor the General Laboratory system requirements since January 2020. The findings include: 1. On March 25, 2022 at 11:00 AM, the laboratory QA procedures manual showed that the evaluation of the following General Laboratory system requirements must be performed monthly: Patient confidentiality, Specimen identification and integrity, Complaint investigations, Communications and

	Proficiency testing performance. The QA manual also showed that the monitoring of the personnel competence procedures must be document every year. 2. On March 25, 2022 at 11:05 AM, review of the QA records showed that the laboratory did not evaluate monthly the General Laboratory System requirements since January 2020, neither monitored the every year personnel competence. 3. The laboratory director confirmed on March 25, 2022 at 11:10 AM, that those evaluations were not performed nor documented as laboratory required.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on QA procedures manual review and laboratory director interview, it was determined that laboratory failed to follow the established schedule to evaluate and monitor the following analytic system requirements since January 2020: test requests. The findings include: 1. On March 25, 2022 at 11:00 AM, the laboratory QA procedures manual showed that the evaluation of the test requests must be performed twice a year. 2. On March 25, 2022 at 11:05 AM, review of the QA records showed that the laboratory did not evaluate the test request during year 2020, during the year 2021 the laboratory evaluated the test request on December 21, 2021. 3. The laboratory director confirmed on March 25, 2022 at 11:10 AM, that those evaluations were not evaluated nor documented as laboratory required since January 2020.
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 Mycoplasma pneumoniae test quality control records (year 2020 to 2022) review, Mycoplasma pneumoniae test report records review and interview with the laboratory supervisor, it was determined that the laboratory did not include each day of testing an external reactive and non reactive control materials when 25 out of 25 patients specimens were tested and reported for of Mycoplasma pneumoniae qualitative test from 12/24/2020 to 01/21/2022. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests since 04/17/2020. The laboratory validate this tests on 02/25/2020. 2. On March 25, 2022 at 1:20 PM, the laboratory did not have available in the laboratory the Mycoplasma pneumoniae quality control records from 12/24/2020 to 01/21/2022. 3. On March 25, 2022 at 1:24 PM, the Mycoplasma pneumoniae tests reports records showed that the laboratory tested and reported 25 out of 25 patients specimens for of Mycoplasma pneumoniae qualitative test from 12/24 /2020 to 01/21/2022: Pt ID Report Date 127215 12/24/2020 128108 05/11/2021

	128441 07/09/2021 128643 08/11/2021 128690 08/19/2021 128700 08/23/2021 128716 08/24/2021 128831 09/10/2021 128869 09/17/2021 128915 09/24/2021 128930 09/27/2021 128948 09/29/2021 128993 10/06/2021 129019 10/11/2021 129169 11/05/2021 129223 11/16/2021 129234 11/18/2021 129290 12/01/2021 129345 12/13/2021 129390 12/22/2021 129404 12/24/2021 129452 01/04/2022 129487 01/07/2022 129556 01/14/2022 129625 01/21/2022 4. The laboratory supervisor confirmed on March 25, 2022 at 1:28 PM, that the Mycoplasma pneumoniae quality control records from 12/24/2020 to 01/21/2022 were not available in the laboratory. She stated that the laboratory run each day of testing, the external reactive and the non reactive control materials but did not record the controls results those days. 5. The laboratory tested and reported 25 out of 25 patients specimens for of Mycoplasma pneumoniae qualitative test from 12/24/2020 to 01/21/2022.
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 QA procedures manual review and laboratory director interview, it was determined that laboratory failed to follow the established schedule to evaluate and monitor the analytic system requirements since January 2020. The findings include: 1. On March 25, 2022 at 11:00 AM, the laboratory QA procedures manual showed that the evaluation of the analytic system requirements must be performed monthly for the following specialties: parasitology, syphilis serology, general serology, endocrinology, urinalysis, virology, hematology and immunohematology. 2. On March 25, 2022 at 11:05 AM, review of the QA records showed that the laboratory did not evaluate monthly the analytic system requirements since January 2020. 3. The laboratory director confirmed on March 25, 2022 at 11:10 AM, that those evaluations are not documented since January 2020.
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 PT, PTT and Mycoplasma pneumoniae tests quality control records retention, Mycoplasma pneumoniae test quality control records, QA records reviewed, laboratory supervisor and laboratory director interview, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory records retention requirement, Mycoplasma pneumoniae analytical system and QA requirements. The findings include: 1. On March 25, 2022 at 1:20 PM, the laboratory director did not comply with the Laboratory records retention requirements. Refer to D 6079 2. On March 25, 2022 at 1:20 PM, the laboratory director did not not comply with the Mycoplasma pneumoniae analytical systems

	requirements. Refer to D 6093. 3. On March 25, 2022 at 9:45 AM, the laboratory director did not not comply with the QA requirements. Refer to D 6094.
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 PT, PTT and Mycoplasma pneumoniae tests quality control records reviewed from January 2020 to March 25, 2022 and laboratory supervisor interview, it was determined that the laboratory director failed to ensure that the laboratory retain the quality control records for at least 2 years. The finding includes: 1. Review of the PT, PTT and Mycoplasma pneumoniae tests quality control records on March 25, 2022 at 1:20 PM, showed that the laboratory did not retain quality control records for at least 2 years. Refer to D 3000
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 Mycoplasma pneumoniae test quality control records (year 2020 to 2022) review, Mycoplasma pneumoniae test report records review and interview with the laboratory supervisor, it was determined that the laboratory director failed to maintain the quality control procedures for the Mycoplasma pneumoniae qualitative test. The finding includes: 1. On March 25, 2022 at 1:20 PM, the quality control records reviewed, showed that the laboratory did not include each day of testing an external reactive and non reactive control materials when 25 out of 25 patients specimens were tested and reported for of Mycoplasma pneumoniae qualitative test from 12/24/2020 to 01/21/2022. Refer to D 5449.
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 personnel records, QA records reviewed and laboratory director interview, it was determined that laboratory director failed to ensure compliance with QA requirements. The findings include: 1. On March 25, 2022 at 9:45 AM, the QA records reviewed showed that the laboratory director did not follow the annual schedule evaluations in the QA program for the laboratory supervisor competency requirement. Refer to D 5209 2. On March 25, 2022 at 11:00 AM, the QA records reviewed showed that the the laboratory director did not follow the schedule evaluations in the QA program for the General Laboratory system requirements. Refer to D 5291 3. On March 25, 2022 at 11:00 AM, the QA records reviewed showed that the the laboratory director did not follow the schedule evaluations in the QA program for the Test request requirement. Refer to D 5391. 4. On March 25, 2022 at 11:00 AM, the QA records reviewed showed that the the laboratory director did not follow the schedule evaluations in the QA program for the Analytic system requirements. Refer to D 5791