Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0926346	11/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Lab Servi Lab Reference	Fernandez Garcia St 109, Luquillo, 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**
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 routine chemistry and endocrinology quality control records reviewed (years 2021 and 2022) and laboratory testing personnel interview, it was found that the laboratory did not retain the Levy Jennings (LJ) control charts for at least two years. The findings include: a. The laboratory performed the routine chemistry test by the Dimension Exl 200 system and the endocrinology tests by the Access 2 system. b. On November 4, 2022 at 10:00 AM, the endocrinology quality control record showed that the laboratory did not retain the Levy Jennings control charts since August 2022. The laboratory processed Thyroxine (T4) free and Vitamin D tests. c. On November 4, 2022 at 10:30 AM, the routine chemistry quality control records showed that the laboratory did not retain the Levy Jennings control charts since June 2021. The laboratory processed comprehensive metabolic panel and lipid panel tests by the Dimension Exl 200 system . d. The testing personnel confirmed on November 4, 2022 at 10:35 AM, that those LJ control charts were not available in the laboratory. 2. Based on General Immunology lack of quality control records for mycoplasma pneumoniae test, lack of mycoplasma pneumoniae testing record, review of patient final test report and laboratory testing personnel interview, it was found that the laboratory did not retain any documentation of quality control and testing records for at least two years. The findings include: a. On November 4, 2022at 12:43 PM the quality control records for mycoplasma pneumoniae and testing records was requested. No quality control nor testing records for mycoplasma pneumoniae were not available. b. The testing personnel confirmed on November 4, 2022 at 12:50 PM that those quality control records nor testing records were not available. c. The testing

	personnel stated on November 4, 2022 at 12:50 PM that she did not perform any mycoplasma pneumoniae test and neither know who performed it. d. The final patient's test reports reviewed included the testing personnel name printed in the test reports.
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, 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 syphilis serology quality control records, RPR patients worksheet review and laboratory testing personnel interview, it was determined that the laboratory failed to meet the requirements in the subspecialty of Syphilis serology. The findings include: a. The laboratory did not include the three levels of control material (non reactive, minimal to moderate and reactive) each day of testing as required by the ASI's manufacturer. Refer to D 5405. b. The laboratory did not perform the needle calibration, the rotator verification nor monitor the room temperature when it processed and reported RPR patients specimens. Refer to D 5411.
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 Mycoplasma pneumoniae IgM test by Meridian lack of quality control records, lack of testing record, direct observation, mycoplasma test report review and interview with the laboratory testing personal, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology from May 2, 2022 to October 31, 2022 when eight (8) out of eight (8) patient samples was processed and reported. The finding includes: a. The laboratory failed to follow the manufacturer's instructions in the procedural control, temperature of incubation and reagent storage temperature. Refer to D5401. b. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to D5449. b. The laboratory failed to maintain a testing record and include the positive identification of patient specimen. Refer to D5787.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on lack of written instructions for the Mycoplasma pneumoniae test, observation and interview with the laboratory personnel; it was determined that the laboratory failed to have any written instructions for the Mycoplasma pneumoniae tests: The findings include: a. On November 4, 2022 at 12:40 PM a direct observation was performed. The surveyor find a Mycoplasma pneumoniae IgM test by Meridian kit in a drawer at the sample separation area. b. On November 4, 2022 at 12:45 PM the laboratory procedure manual and testing record was requested. No procedure manual or testing record was available. c. On November 4, 2022 at 12:40 PM the laboratory personnel alleged that the laboratory did not perform Mycoplasma pneumoniae patinet test. d. On November 4, 2022 at 12:50 PM the Mycoplasma pneumoniae IgM test reports was review from May 2, 2022 to October 31, 2022. The laboratory performed and reported patient samples without a verification of incubation temperature, verification of procedural control and used a kit that was store at room temperature in the following days: Patient ID Day 08794 5/2/2022 041505 5/9/2022 52873 7/11/2022 56510 10/6/2022 57210 10/14/2022 68714 10/31/2022 68713 10/31 /2022 68712 10/31/2022 e. On November 4, 2022 at 1:18 PM the laboratory testing personal confirmed, that the laboratory failed to follow the manufacturer's instruction when processed and performed eight (8) out of eight (8) samples patients from May 2, 2022 to October 31, 2022. The testing personel stated that she didn't performed the mycoplasma pneumoniae test in the laboratory.
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 syphilis serology quality control records, RPR worksheets review and laboratory testing personnel interview on November 4, 2022 at 12:45 PM, it was determined that the laboratory failed to follow the ASI's manufacturer's instruction when patients 55 out of 55 specimens were tested for syphilis serology tests by the rapid plasma reagin (RPR) method from August 2, 2022 to November 3, 2022. The findings include: a. Review the ASI manufacturer's instruction on November 4, 2022 at 12:45 PM, establishes that for the quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. b. The ASI RPR reagents kit provided three control materials for the test performance : reactive control, weakreactive control and nonreactive control. c. On November 4, 2022 at 12: 48 PM, the syphilis serology quality control records showed that the laboratory did not include any control material when it processed and reported 55 out of 55 patients specimens from August 2, 2022 to November 3, 2022. d. The testing personnel confirmed on On November 4, 2022 at 12:48 PM, that the quality control results were not documented from August 2, 2022 to November 3, 2022.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: 1. Based on syphilis serology quality control records, RPR patients reports records review and laboratory testing personnel interview, it was determined that the laboratory failed to follow the ASI's manufacturer's instruction when patients 55 out of 55 specimens were tested for syphilis serology tests by the rapid plasma reagin (RPR) method from August 2, 2022 to November 3, 2022. The findings include: a. Review on the ASI's manufacturer's instructions on November 4, 2022 at 12:48 PM, requires that the laboratory must perform the needle accuracy check, that should deliver 60 +/- 2 drops of antigen suspension per milliliter when held in vertical position; verify the mechanical rotator set at 100 +/- 5 and circumscribing the 3/4 inch diameter and monitor each day of testing the room temperature in the laboratory that it should be between 20 - 30 C. Also, the manufacturer required to remove and wash the needle at the end of each shift. b. On November 4, 2022 at 12:48 PM, the syphilis serology quality control records showed that the laboratory did not perform the needle accuracy check, not verify the rotator rpm, not monitor the room temperature nor wash the needle when they processed and reported 55 out of 55 patients specimens from August 2, 2022 to November 3, 2022.3. c. 4. The testing personnel confirmed on November 4, 2022 at 12:48 PM, that the quality control records showed that the laboratory did not follow the manufacturer's instructions from August 2, 2022 to November 3, 2022. 2. Based on revie of the Mycoplasma pneumoniaemanufacturer instructions, patint's test reports and interview with the laboratory testing personnel on November 4, 2022 at 12:40 PM; it was determined that the laboratory did not follow the manufacturer's instructions when processed and reported eight (8) out of eight (8) patient's samples. a. On November 4, 2022 at 12:40 PM a Mycoplasma pneumoniae reagent kit (manufacturer-meridian) was found in a drawer. b. The laboratory testing personnel was interviewed about the kit, and she stated that she did not perform mycoplasma pneumoniae test at the laboratory, and that she was unaware of the reagent kit existence. c. Review of the laboratory information system on November 4, 2022 at 12:50 PM showed that the laboratory received and reported eight (8) patient samples from May 2, 2022 to October 31, 2022. d. The laboratory did not have any documentation of the following manufacturer instructtions requirements: 1. Specimen storage temperatures, the manufacturer established that the kit need to be store at 2-8C in the refrigerator promptly after each use. The kit was found at a drawer. 2. The manufacturer established an incubator temperature between 22-25C. The laboratory did not have the incubation temperature documentation. 3. The manufacturer established that in order to assure the specimen proper followed reagent performance the procedural control must be present. The laboratory did not havedocumentation of each patient procedural control. e. The testing personnel stated on November 4, 2022 at 1:00 PM that she did not perform any mycoplasma pneumoniae test and neither know who performed it. f. The final patient's test reports reviewed included the testing personnel name printed in the test report.
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 General Immunology , Mycoplasma pneumoniae IgM test immunocard by Meridian, lack of quality control records, lack of testing record, Mycoplasma pneumoniae IgM final test report review from May 2, 2022 to October 31, 2022 and interview with laboratory testing personnel; it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing when eight (8) out of eight (8) samples of patients was performed and reported from May 2, 2022 to October 31, 2022. The findings include: a. On November 4, 2022 at 12:45 PM the quality control record and the testing record for Mycoplasma pneumoniae IgM was requested. No quality control record nor testing record for Mycoplasma pneumoniae IgM was available. b. On November 4, 2022 at 12:50 PM the Mycoplasma pneumoniae IgM patinet's final test reports were reviewed from May 2, 2022 to October 31, 2022. The laboratory performed and reported patient samples in the following days: Patient ID Day 08794 5 /2/2022 041505 5/9/2022 52873 7/11/2022 56510 10/6/2022 57210 10/14/2022 68714 10/31/2022 68713 10/31/2022 68712 10/31/2022 c. On November 4, 2022 at 1:18 PM the laboratory testing personal confirmed, that the laboratory failed to include a negative and positive external control material each day of testing when eight (8) out of eight (8) samples of patients was performed and reported from May 2, 2022 to October 31, 2022. d. The testing personnel stated on November 4, 2022 at 1:18 PM that she did not perform any mycoplasma pneumoniae test and neither know who performed it. e. The final patient's test reports reviewed included the testing personnel name printed in the test report.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of mycoplasma pneumoniae testing record, review of patint final reports and interview with the testing personnel; it was determined that the laboratory did not have test records that reflects the specimen identification, date and time of specimen receipt and identification of the testing personnel. The findings include: a. On November 4, 2022 at 12:45 PM the testing records for mycoplasma pneumoniae IgM was requested. No testing record was available. b. The laboratory final patient test report were reviewed from May 2, 2022 to October 31, 2022 On November 4, 2022 at 12:50 PM. The laboratory performed and reported patient samples in the following days: Patient ID Day 08794 5/2/2022 041505 5/9/2022 52873 7/11/2022 56510 10/6/2022 57210 10/14/2022 68714 10/31/2022 68713 10/31/2022 68712 10/31 /2022 c. The laboratory personnel confirmed on November 4, 2022 at 1:18 PM, that the laboratory failed to maintain and include documentation or records that reflected the positive identification of patient specimen when eight (8) out of eight (8) samples

	patients were processed and reported from May 2, 2022 to October 31, 2022. The testing personal stated that she did not perform the mycoplasma pneumoniae test in the laboratory.
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) activities records review and interview with the laboratory testing personel, it was determined that the laboratory failed to evaluate and monitor the analytic system requirements since April 2022. The findings include: a. On November 4, 2022 at 12:10 PM, the laboratory QA record was requested. b. Review of the QA established schedule showed, that the laboratory must evaluate every month the following: verification of test systems, equipment, instruments, reagent, verification of water quality, test records and comparion of test result. C. The QA analytic system showed that the laboratory did not evaluate the requirements since April 2022 in the following areas: verification of test systems, equipment, instruments, reagent, verification of water quality, test records and comparison of test results. d. On November 4, 2022 at 12:30 PM the laboratory personel confirmed that the analytic system QA evaluation were not performed since April 2022.
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 lack of quality control records, quality assessment review and laboratory testing personel interview on November 4, 2022, at 2:00 PM, it was determined that the laboratory director failed to fulfill his responsabilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D6094 and D6093
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 routine chemistry and endocrinology quality control records reviewed (years 2021 and 2022) and laboratory testing personnel 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. The laboratory did not retain the Levy Jennings (LJ) control charts of routine chemistry and endocrinology quality control for at least two years. Refer to D 3031.
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: 1. Based on syphilis serology quality control records, RPR patients reports records review and laboratory testing personnel interview, it was determined that the laboratory director failed to maintain the quality control procedures for Syphilis serology. The finding include: a. The laboratory did not to meet the requirements in the subspecialty of Syphilis serology. Refer to D 5012. 45605 2. Based on Mycoplasma pneumonia IgM lack quality control records, lack of testing record, mycoplasma pneumoniae test report review and interview with the laboratory testing personal on November 4, 2022 at 2:10 PM, it was determined that the laboratory director full filled his responsibility to comply with General Immunology specialty. Refer to D5014.
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 Assessment (QA) records reviewed and interview with the laboratory testing personnel; it was determined that the laboratory director failed to ensure compliance with QA requirements. Refer to D5791.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on personnel records review and testing personnel interview , it was determined that the laboratory director failed to ensure that the new testing personnel have the appropriate training prior to testing patients' specimens. The findings include: 1. On November 4, 2022 at 1:30 PM, the personnel record showed that the laboratory hired a new testing personnel on May 16, 2022. This testing personnel processed and reported patients specimens in the following areas: routine chemistry, endocrinology and syphilis serology. However, the personnel records did not include the documented training. 2. The testing personnel confirmed on November 4, 2022 at 1:35 PM, that the documented training is not available.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel records files and interview with the testing personnel, it was determined that the laboratory director did not evaluate annually the competence of the laboratory technical supervisor. The findings include: a. On November 4, 2022 at 1:30 PM, the personnel records files showed that the laboratory director did not perform annually the last competence of the technical supervisor. The last competence evaluation in record was performed on 12/10/2020. b. The testing personnel confirmed on November 4, 2022 at 1:35 PM, the documentation of the personnel records files.
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: 1. Based on syphilis serology quality control records, RPR patients reports records review and laboratory testing personnel interview, it was determined that the laboratory technical supervisor did not maintain the quality control program for syphilis serology test when the laboratory did not perform the quality control procedures when it processed and reported 55 out of 55 patients specimens from August 2, 2022 to November 3, 2022. Refer to D 6117. 2. Based on general immunology lack of quality control records for mycoplasma pneumoniae test, final patient test reports and laboratory testing personnel interview; it was determined that the laboratory technical supervisor failed to follow quality control procedures for mycoplasma pneumoniae test. 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: 1. Based on syphilis serology quality control records, RPR patients reports records review and laboratory testing personnel interview, it was determined that the laboratory technical supervisor did not maintain the quality control program for syphilis serology test. The finding include: a. The laboratory did not to meet the requirements in the subspecialty of Syphilis serology. Refer to D 5012. 2. Based on general immunology lack of quality control records for mycoplasma pneumoniae test, final patient test reports and laboratory testing personnel interview; it was determined that the laboratory technical supervisor failed to follow quality control procedures for mycoplasma pneumoniae test. The findings include: a. The laboratory did not meet the requirements in the subspecialty of Mycoplasma pneumoniae. Refer to D 5449.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: 1. Based on syphilis serology quality control records, RPR patients reports records review and laboratory testing personnel interview, it was determined that the laboratory testing personnel failed to follow quality control procedures for syphilis serology test. Refer to D 6177 2. Based on general immunology lack of quality control records for mycoplasma pneumoniae test, final patient test reports and laboratory testing personnel interview; it was determined that the laboratory testing personnel failed to follow quality control procedures for mycoplasma pneumoniae test. Refer to D 6177
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: 1. Based on syphilis serology quality control records, RPR patients reports records review and laboratory testing personnel interview, it was determined that the laboratory testing personnel failed to follow quality control procedures for syphilis serology test. The finding include: a. The laboratory did not to meet the requirements

	in the subspecialty of Syphilis serology. Refer to D 5012. 2. Based on general immunology lack of quality control records for mycoplasma pneumoniae test, final patient test reports and laboratory testing personnel interview; it was determined that the laboratory testing personnel failed to follow quality control procedures for mycoplasma pneumoniae test. The findings include: a. The laboratory did not meet the requirements in the subspecialty of Mycoplasma pneumoniae. Refer to D 5449.