Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D1076493	**(X3) Date Survey Completed** 03/07/2018
Name of Provider or Supplier Lab Clinico Y Molecular Southern Pathology Service	**Street Address, City, State** Edificio De Fomento S-153-074 Calle A-234, Ponce, 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**
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: Based on observations, syphilis serology quality control records review from April 1, 2016 to March 7, 2018 and laboratory general supervisor interview at 9:45 AM on March 7, 2018, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by the ASI RPR (Rapid Plasma Reagin) method. The findings include: 1. The laboratory syphilis serology quality control were review from April 1, 2016 to March 7, 2018. 2. The manufacturer's requires that the laboratory must perform the mechanical rotator calibration (circumference - 2 cm diameter) with humidity cover over the serology test card when performed the RPR tests. 3. From April 1, 2016 to March 7, 2018, the syphilis serology records showed that the laboratory did not document nor verify the mechanical rotator calibration nor provided the humidity cover when performed the RPR (Rapid plasma reagin) tests in those days. 4. The laboratory processed and reported 128 RPR patient's samples tests on 2016 and 74 RPR patient's samples tests on 2017. 5. The laboratory general supervisor confirmed on March 7, 2018, that the laboratory did not perform the mechanical rotator calibration and not used humidity cover when performed the RPR patient's samples tests from April 1, 2016.
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) records review and laboratory general supervisor interview on March 7, 2018 at 11:42 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment manual showed that for each analytic process a log sheet was designate to keep track of the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic systems: a. to perform syphilis serology test as required by manufacturer's instructions by the ASI RPR (Rapid Plasma Reagin) method. Refer to D5411.
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 personnel records review and laboratory general supervisor interview on March 7, 2018 at 10:55 AM, it was determined that the laboratory failed to have a laboratory director qualified for the position. The findings include: 1. The new hiring laboratory director (MD # 18751) was not qualified to manage and direct the high complexity laboratory. Refer to D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and

	continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory general supervisor interview on March 7, 2018 at 10:55 AM, it was determined that the laboratory director does not qualify for the position. The findings include: 1. The laboratory director (MD # 20487) resigned on December 2, 2016. 2. The new laboratory director (MD # 18751) hired on January 1, 2017 does not qualify to manage and direct a high complexity laboratory. 3. The new laboratory director is not certified by the American Board of Pathology. 4. The laboratory general supervisor (laboratory coordinator - MT # 1096) confirmed on March 7, 2018, that the laboratory director is not certified by the American Board of Pathology.
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 quality control records review and laboratory general supervisor and testing personnel interview on March 7, 2018 at 11:55 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to perform syphilis serology test as required by manufacturer's instructions by the ASI RPR (Rapid Plasma Reagin) method. Refer to D5411.
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 review and laboratory general supervisor and testing personnel interview on March 7, 2018 at 11:48 AM, it was determined that

	laboratory failed to ensure compliance with quality assessment (QA) requirements. The finding includes: 1. The laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. Refer to D5791.
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: Based on quality control records review and laboratory general supervisor and testing personnel interview on March 7, 2018 at 11:58 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel failed the following quality control procedures: a. to perform syphilis serology test as required by manufacturer's instructions by the ASI RPR (Rapid Plasma Reagin) method. Refer to D5411.