Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0692668	04/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Valparaiso	Lizzie Graham Jr 1 Seccion # 7, Toa Baja, 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 lack of routine chemistry quality control records, routine chemistry calibration verification records and laboratory director interview at 11:30 a.m. on April 10, 2018, it was determined that the laboratory failed to keep quality control records and calibration verifications records . Refer to D3031.
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 lack of routine chemistry quality controls records reviewed (2017) , laboratory director interview on April 10, 2018 at 11:00 A.M., it was determined that

	the laboratory failed to retain the routine chemistry quality control records. The findings include: a. The laboratory performed routine chemistry tests in 2017 by Vitros 250 system. b. The laboratory did not have available quality control records since January 2017. c. The laboratory director confirmed on April 10, 2018 at 11:00 A. M. that the laboratory did not have available the quality control records for routine chemistry tests since January 2017. d. The laboratory processed and reported 136 patient's sample since January 2017. 2. Based on lack of routine chemistry calibration verifications records (2017) , laboratory director interview on April 10, 2018 at 11:00 A.M., it was determined that the laboratory failed to retain the routine chemistry calibration verifications records. The findings include: a. The laboratory performed routine chemistry tests by Vitros 250 system. b. The laboratory did not have available calibration verifications records since January 2017. c. The laboratory director confirmed on April 10, 2018 at 11:00 A.M. that the laboratory did not have available the calibration verifications records for routine chemistry tests since January 2017.
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 bacteriology quality control records review from year 2017-2018 and interview with the laboratory director on April 10, 2018 at 11:45 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology. The finding includes: a. The laboratory did not check the ability to support growth of the cultures media used since August 2017. Refer to D 5477.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration verification records review, manufacturer's instructions and laboratory director interview on April 10,2018 at 10:20 A.M., it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the Coulter Act 5 system. The findings include: 1. The laboratory uses a Coulter Act 5 hematology system for CBC (Complete blood

	count) patient's tests. 2. The manufacturer's instructions establishes that the calibration verification procedures must be perform each six months. 3. From June 2016 to April 2018, the calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Coulter Act 5 hematology system. In year 2017 the calibration verification for Coulter Act 5 system was performed on January 2017 and December 2017. 4. The laboratory director confirmed on April 10, 2018 at 10:20 A.M., that the laboratory did not perform at least 6 months the calibration verification procedures for Coulter Act 5 system.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on bacteriology quality control records review (years 2017) and interview with the laboratory director on April 10, 2018 at 11:35 AM, it was found that since August 2017 the laboratory did not check each batch of agar culture media plates for its ability to support growth. The finding includes: a. The laboratory performed bacteriology culture patient samples since August 2017. b. The laboratory performed primary inoculation on Blood agar (BA) , Tryptic soy broth, (TSB), Mac Conkey (MCK) , Muller hinton (MH), Xavier Lindon Dawson agar (XLD), Gram Negative broth (GN broth), Brain heart infusion agar (BHI), Thioglycolate agar (THIO) and Mannitol salt agar (MSA) c. Review of bacteriology quality control records showed that the laboratory did not check the following lot numbers of blood agar culture media plates for it's ability to support growth since January 2018: Lot number Date (mm/dd/yy) 17230 8/28/2017 4111683 12/18/2017 407734 1/15/2018 411168 3/5 /2018 d. Review of bacteriology quality control records showed that the laboratory did not check the following lot numbers of Mac Conkey agar culture media plates for it's ability to support growth: Lot number Date (mm/dd/yy) 17221 8/28/2017 4111431 12 /18/2017 4078104 1/15/2018 411431 3/5/2018 c. Review of bacteriology quality control records showed that the laboratory did not check the following lot numbers of culture media plates for it's ability to support growth: Media Lot number Date (mm/dd /yy) CA 17229 9/5/2017 TSB 17208 12/18/2017 MH 17221 8/28/2017 XLD 17222 8 /28/2017 GN 17186 8/28/2017 BHI 17283 8/28/2017 Thio 17325 1/15/2018 e. The laboratory processed 88 patient's samples from August 2017 to April 2018. d. The laboratory director stated on April 10, 2018 that no evaluation of the ability to support growth was performed since August 2017.
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 director on April 10, 2018 at 11:30 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 the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. 2. From January 2017 to April 2018, the laboratory did not evaluate aspects regarding the analytic system in the following areas: hematology and bacteriology. Refer to D 5437 and D5477.
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 hematology calibration verification records review , bacteriology quality control records and laboratory director interview on April 10, 2018 at 11:30 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and retention requirements. Refer to D6079 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 lack of routine chemistry quality control records and laboratory director interview on April 10, 2018 at 11:30 a.m. , it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory retention requirements. Refer D3031.
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 hematology calibration verification records review,bacteriology quality control records and laboratory director interview on April 10, 2018 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5437 and D5477.