Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0692668	05/29/2024
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
D0000	A Proficiency Test Desk Review survey was conducted on May 29, 2024 to Laboratorio Clnico Valparaiso, the laboratory was found out of compliance with the following conditions: 42 CFR 493.803 Proficiency Testing, Successful Participation 42 CFR 493.1441 Laboratory Director, high complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency Testing (PRPT) events and CASPER Report 0155 D review (2023-2024), it was determined that the laboratory obtained a subsequent unsuccessful participation for hematocrit test. Refer to D2130.

D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on PRPT events scores, CASPER Report 0155D, Complete Cell Count (CBC) workload records reviewed and laboratory director interview on May 29, 2024 at 9:00 A.M., it was found that the laboratory failed to attain successful participation in a Proficiency Testing (PT) events for hematocrit tests. The findings include: a. Review of the PRPT scores on May 29, 2024 at 9:30 A.M. and CASPER Report 0155D showed that the laboratory had a subsequent PT failure for analyte hematocrit. The laboratory obtained the following testing scores: 1st event 2023 Hematocrit 20 % 3rd event 2023 Hematocrit 40 % 1st event 2024 Hematocrit 60 % b. During interview the laboratory director confirmed on May 29, 2024, at 9:40 A.M. that the laboratory had three out of four unsatisfactory PT testing events for Hematocrit. c. Review of the CBC workload records showed that laboratory reported 329 CBC tests since April 2024.
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 lack of syphilis serology testing record (year 2023-2024) and laboratory director interview on May 29, 2024 at 12:30 P.M. , it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory failed to follow the manufacturer's instruction when patient specimens were tested for RPR (Rapid plasma reagin) by ASI method. (refer to D5411) 2. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions.(refer to D5411)
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 review of the Mycoplasma pneumoniae IgM quality control records (year 2023-2224) on May 29, 2024 at 11:15 A.M.., and laboratory director interview, it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae IgM test. Refer to D5449.
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: A-Based on syphillis serology records review (year 2023-2024) and laboratory director on May 29, 2024 at 12:30 P.M., it was determined that the laboratory failed to perform syphillis serology test as required by manufacturer's instructions by the ASI-RPR method. The findings include: 1. The laboratory syphillis serology quality control records were review from January 2023 to May 29, 2024. 2. The manufacturer's requires that the laboratory must perform the needle calibration, clean needle, verify the rotator rpm and monitor the room temperature in the laboratory. 3. From January 2023 to May 29, 2024, the lrecords showed that the laboratory did not document nor verify the needle calibration, clean needle , rotator rpm nor the room temperature monitoring in the RPR (Rapid plasma reagin) testing area the following days : year 2023 : 1/23/23, 1/31/23, 2/10/23, 2/16/23, 2/28/23, 3/20/23, 5/8/23, 5/17 /23, 5/23/23, 6/12/23, 8/4/23, 8/7/23, 8/8/23, 8/10/23, 8/11/23, 8/28/23, 9/2/23, 9/19 /23, 9/28/23, 10/4/23, 10/5/23, 10/6/23, 10/7/23, 10/21/23, 11/2/23, 11/3/23, 11/14/23, 11/16/23, 11/29/23, 12/6/23, 12/13/23, 12/16/23 and 12/20/2023. year 2024 : 1/3/24, 1 /15/24, 1/17/24, 2/3/24, 2/5/24, 2/13/24, 2/20/24, 2/24/24, 2/29/24, 3/12/24, 4/4/24, 4 /24/24 and 5/6/2024. 4. The laboratory processed and reported 67 RPR (Rapid plasma reagin) patient's samples tests those days. 5. The director confirmed on May 29, 2024 at 12:50P.M.. that the laboratory failed to perform syphillis serology test as required by manufacturer's instructions by the ASI-RPR method. B- Based on syphillis serology quality control review (year 2023-2024) and laboratory director interview on May 29, 2024 at 12:30 P.M. , it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by RPR card test ASI method. The findings include: 1. The syphillis serology quality control records were reviewed since January 2023. (review on May 29, 2024 at 12: 35 P.M) 2. The manufacturer's instruction establishes that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. (review on May 29, 2024 at 12: 40 P.M .) 3. Review of records from January 2023 to May 29, 2024, showed that the laboratory did not include any control material the following days: year 2023 : 1/23/23, 1/31/23, 2/10/23, 2/16/23, 2 /28/23, 3/20/23, 5/8/23, 5/17/23, 5/23/23, 6/12/23, 8/4/23, 8/7/23, 8/8/23, 8/10/23, 8/11 /23, 8/28/23, 9/2/23, 9/19/23, 9/28/23, 10/4/23, 10/5/23, 10/6/23, 10/7/23, 10/21/23, 11 /2/23, 11/3/23, 11/14/23, 11/16/23, 11/29/23, 12/6/23, 12/13/23, 12/16/23 and 12/20 /2023. For year 2024 the laboratory did not include any control material on 1/3/24, 1 /15/24, 1/17/24, 2/3/24, 2/5/24, 2/13/24, 2/20/24, 2/24/24, 2/29/24, 3/12/24, 4/4/24, 4 /24/24 and 5/6/2024. (review on May 29, 2024 at 12: 45 P.M.) 4. The laboratory processed and reported 67 syphilis serology samples those days. (review on May 29, 2024 at 12: 50 P.M .) 5. The director confirmed on May 29, 2024 at 12:50P.M.. that the laboratory did not include the three levels of control material (non reactive, minimal to moderate and reactive) those days.
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 test) quality control records review (years 2023-2024) and laboratory director interview on May 29, 2024 at 11:15 A.M. , it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. The findings include: 1. General Immunology (Mycoplasma pneumoniae test) quality control records were review on May 29, 2024, at 11:20 A.M., from January 2023 to May 29, 2024. 2. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include any control material each day of patient testing since 2023. 3. The laboratory director confirmed on May 29, 2024 at 11:25 A.M., that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test. 4. The laboratory did not include any control material, when 697 out 697 patient specimen were processed and reported since January 2023. (Review on May 29, 2024 at 11:20 A.M.)
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 review of PRPT event scores and CASPER Report 0155 D (years 2023-2024), it was determined that the laboratory director failed to ensure the laboratory's successful participation in a Proficiency Testing Program for hematocrit tests. Refer to D6079
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 PRPT event scores and CASPER Report 0155 D for the first and second

	testing events of year 2023 and the first testing event of year 2024, it was determined that the laboratory director failed to ensure that the laboratory had a satisfactory participation in the hematocrit tests. Refer to D 2130
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 general immunology and syphilis serology quality control records review (year 2023-2024) , it was determined that the laboratory director did not ensure that quality control procedures related to Mycoplasma pneumoniae IgM and syphilis serology quality control procedures were performed as established by the manufacturer's instructions. Refer to D5411 and D5449. The findings include: 1. This laboratory ia a sole facility practitioner. 2. The laboratory director did not assure that control procedure for Mycoplasma pneumoniae and syphilis serology were performed as established by the manufacturer's instructions.