Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0715748	01/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Borges	Calle Arzuaga Num 168, Rio Piedras, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing (PRPTP) records review (year 2023) and general supervisor interview on January 10, 2024, at 10:30 AM; it was determined that the laboratory director or designee and the testing personnel, did not sign the proficiency attestation statements of the following testing events: diagnostic immunology second testing event 2023, chemistry third testing event 2023 and hematology third testing event 2023. The findings include: 1. On January 10, 2024, at 10:30 AM, the PRPTP attestation statements instructed the laboratory to print, fill, sign and retain the page for laboratory records and inspection purposes. 2. On January 10, 2024, at 10:35 AM, the PRPTP attestation statements records review for diagnostic immunology second testing event 2023, chemistry third testing event 2023 and hematology third testing event 2023, showed that none of them were signed by laboratory director nor designee and the testing personnel. 3. On January 10, 2024, at 10:45AM, the general supervisor stated that the attestation statement were not signed by the director or designee and the testing personnel.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

	This STANDARD is not met as evidenced by: Based on the hematology proficiency testing results printouts review (Puerto Rico Proficiency Program third event 2023), the proficiency samples written protocol and interview with the general supervisor on January 10,2024, at 10:35 AM; it was determined that the laboratory failed to test the hematology proficiency samples, for the third testing event of year 2023, the same number of times that it routinely tests patient samples. The laboratory processed the proficiency samples on November 8,2023 and November 17,2023. The findings include: 1. On January 10,2024 at 10:35 AM, the hematology proficiency testing records were reviewed. 2. On January 10,2024 at 10:37 AM, review of the hematology proficiency samples printouts showed the following: a. On November 8, 2023, at 11:51 AM, the laboratory processed the proficiency sample Id: 2023-911 and on November 17,2023, at 11:23 AM, processed the ID 2023-911ab. b. On November 8, 2023, at 11:53 AM, the laboratory processed the proficiency sample Id: 2023-912 and on November 17,2023, at 11:25 AM, processed the ID 2023-912ab. c. On November 8, 2023, at 11:54 AM, the laboratory processed the proficiency sample Id: 2023-913 and on November 17,2023, at 11:27 AM, processed the ID 2023-913ab. d. On November 8, 2023, at 11: 56 AM, the laboratory processed the proficiency sample Id: 2023-914 and on November 17,2023, at 11:28 AM, processed the ID 2023-914ab. e. On November 8, 2023, at 11:58 AM, the laboratory processed the proficiency sample Id: 2023-915 and on November 17,2023, at 11:30 AM, processed the ID 2023-915ab. 3. On January 10, 2024, at 10:40 AM, the proficiency written protocol: "Normas para procesamiento y reporte de proficiencias" (Standards for processing and reporting proficiencies) section 3, establishes that the samples must be analyzed under the same conditions as the patient samples. 4. On January 10, 2024, at 11:00 AM, the general supervisor was interviewed, she stated that the patients' samples were tested in duplicate only when a critical value was observed. She confirmed that the proficiency sample for the third testing event of year 2023 were processed on more than once, the first run on November 8,2023 and the second run on November 17,2023.
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: A. Based on lack of preventive maintenance written protocols for Cell-Dyn 3200 hematology analyzer and general supervisor interview, it was determined that the laboratory failed to have the procedure written manual for the hematology specialty. (Reviewed on January 10, 2024, at 10:48 AM) The findings include: 1. During interview, the established protocol for preventive maintenance of the Cell-Dyn 3200 hematology analyzer was requested. (Reviewed on January 10, 2024, at 10:48 AM) 2. The laboratory was not able to showed on hematology written procedure manual that, among others, included the protocols for the Cell-Dyn 3200 preventive maintenance procedures. (Reviewed on January 10, 2024 at 11:00) 3. The general supervisor confirmed during interview, that the laboratory did not have the protocol not the hematology written procedures manual. (Reviewed on January 10, 2024, at 12:10 PM) B. Based on lack of quality control written protocols for rapid plasma reagin (RPR) and general supervisor interview, it was determined that the laboratory failed to have

	the procedure written manual for serology (RPR) quality control. (Reviewed on January 10, 2024, at 1:05 PM) The findings include: 1. During interview, the established protocol for RPR quality control was requested. (Reviewed on January 10, 2024, at 1:05 PM) 2. The laboratory was not able to showed on serology (RPR) written procedure manual that, among others, included the protocols for the RPR quality control procedures. (Reviewed on January 10, 2024, at 1:08 PM) 3. The general supervisor confirmed during interview, that the laboratory did not have the protocol not the serology (RPR) written procedures manual. (Reviewed on January 10, 2024, at 1:38 PM)
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 rapid plasma reagin (RPR) quality control records (years 2022-2023), manufacturer's test system insert review and general supervisor interview on January 10, 2024, at 1:00 PM, it was determined that the laboratory did not include a weakly reactive control each day of patient testing, when 1055 out of 1055 syphilis serology tests were processed and reported by the Aim RPR test method from January 10,2023 from January 10,2024. The findings include: 1. The laboratory uses the Aim RPR test method for the syphilis serology tests. (Reviewed January 10,2024, at 1:00 PM) 2. On January 10, 2024, at 1:10 PM, the manufacturer's test system insert was revised. The insert stated the following: a. Reagent: the kit contains the following reagents reactive control, weakly reactive control, and non-reactive control. b. Quality Control: When testing with a negative control, no aggregation should be observed. When testing with a weekly reactive control, slight aggregation should be observed. When testing with a reactive control, medium to large aggregates should be observed. When these reactions are found, this will indicate proper procedural technique, specimen volume, and test performance. 3. On January 10, 2024, at 1:20 PM, the RPR quality control records showed that the laboratory did not include the weakly reactive control materials each day of patient testing, when processed and reported 1055 out of 1055 syphilis patient's samples. 4. On January 10,2024, at 1:38 PM, the general supervisor confirmed during interview, that the laboratory processed only the reactive and non-reactive control material each day of testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the preventive maintenance label for Cell-Dyn 3200 Automated Hematology Analyzer (year 2023) and general supervisor interview on

	January 10, 2024, at 11:20 AM, it was determined that the laboratory failed to perform the semi-annual preventive maintenance of Cell-Dyn 3200 analyzer, with at least, the frequency specified by the manufacturer, the laboratory performed only one out of two required preventive maintenance. The findings include: 1. The laboratory uses the Cell-Dyn 3200 Automated Hematology Analyzer to perform hematology tests. (Reviewed January 10,2024 at 11:20 AM) 2. During the survey on January 10, 2024, at 11:25 AM, the Cell-Dyn 3200 instrument was observed. A preventive maintenance label was attached th the instrument. The label showed that an external company performed the preventive maintenance on May 8, 2023. The label also showed hat the next preventive maintenance was schedule for November 2023. 3. On January 10, 2024, at 11:35 AM, during interview with the general supervisor the schedule preventive maintenance was requested (November 2023). The general supervisor stated that the scheduled was not performed. She also stated that the laboratory processed and reported 214 Complete blood count (CBC) patient's samples from November 9,2023 to January 9,2024.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program record review (diagnostic immunology second testing event 2023, chemistry third testing event 2023 and hematology third testing event 2023) and general supervisor interview on January 10,2024 at 1:38 PM; it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the proficiency testing program. Refer to D2009 and D2010.
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: A. Based on hematology procedure written manual requested, Cell-Dyn 3200 Automated Hematology Analyzer preventive maintenance records and interview with the general supervisor on January 10,2024 at 1:38 PM, it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. The findings include: 1. The laboratory failed to have the procedure written manual for hematology. Refer to D5401. 2. The laboratory failed to follow the semi-annual preventive maintenance of Cell-Dyn 3200 Automated Hematology Analyzer preventive maintenance with at least the frequency specified by the manufacturer. Refer to D5431. B. Based on serology (rapid plasma reagin - RPR) procedure written manual requested, RPR quality control records review and interview with the general supervisor on January 10,2024 at 1:38 PM, it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. The findings include: 1. The laboratory failed to have the procedure written manual for

	serology (RPR) procedure manual. Refer to D5401. 2. The laboratory did not include a weakly reactive control each day of testing for syphilis serology tests by the Aim RPR test method. Refer to D5405.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on rapid plasma reagin (RPR) quality control review, semi-annual preventive maintenance of Cell-Dyn 3200 and general supervisor (sole testing personnel) interview on January 10,2024 at 1:38PM, it was determined that she failed to fulfill his responsibilities and duties to ensure compliance with analytical systems. Refer to D5405 and D5431. The findings include: 1. The laboratory did not include a weakly reactive control each day of testing for syphilis serology tests by the Aim RPR test method. Refer to D5405. 2.The laboratory failed to follow the semi-annual preventive maintenance of Cell-Dyn 3200 Automated Hematology Analyzer preventive maintenance with at least the frequency specified by the manufacturer. Refer to D5431.