Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0717799	02/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Comerio	Calle Jose De Diego #4, Comerio, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on lack of Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to December 2020 and laboratory director interview on February 9, 2021 at 10:35 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Proficiency Testing (PRPTP) records were reviewed from February 2019 to December 2020. 2. Review of proficiency testing records from February 2019 to December 2020, showed that the laboratory did not maintain the following proficiency testing event records: September 2020, October, 2020, November 2020 and December 2020. 3. The laboratory director confirmed on February 9, 2021, that the laboratory did not maintain these proficiency testing event records.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons

	other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review and laboratory director interview on February 9, 2021 at 10:40 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were reviewed from February 2019 to December 2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Partial Thromboplastin Time (PTT) tests on April 2020 (PRPTP First testing event). No remedial actions were taken. 3. The laboratory director confirmed on February 9, 2021, that the laboratory did not take corrective actions on April 2020 testing event.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records from February 2019 to December 2020 and laboratory director interview on February 9, 2021 at 12: 48 PM, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 years. The findings include: 1. Proficiency Testing (PRPTP) records were reviewed from February 2019 to December 2020. 2. The laboratory did not have the proficiency testing records nor testing scores from September 2020 (PRPTP - second testing event), October 2020 (PRPTP - third testing event), November 2020 (PRPTP - third testing event) and December 2020 (PRPTP - third testing event). 3. The laboratory director confirmed on February 9, 2021 at 1248 PM, that the laboratory did not have these PRPTP testing records.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review from January 2019 to February 2021 and laboratory director interview on February 9, 2020 at 1:35 PM, it was determined that the laboratory director failed to follow the written procedures to monitor and ensure the competency evaluations of the Clinical Consultant. The findings include: 1. The

	personnel records showed that the laboratory director did not evaluate annually the competence of the Clinical Consultant. 2. This last competence of the Clinical Consultant was performed on December 20, 2019.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on refrigerator / freezer temperature worksheet reviewed from January 1, 2020 to February 9, 2021 and laboratory director interview on February 9, 2021 at 11:30 A. M., it was determined that the laboratory failed to follow written instructions when monitoring the refrigerator temperature uses for storing laboratory reagents. The findings include: 1. The laboratory refrigerator / freezer temperature worksheet were reviewed from January 1, 2020 to February 9, 2021. 2. The laboratory failed to document the freezer (0 to -20 C) temperature in the worksheet from January 1, 2020 to February 9, 2021. 3. The laboratory director confirmed on February 9, 2021, that the laboratory did not document the freezer temperature since January 1, 2020 to February 9, 2021.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology procedures manual, quality control records review from January 2019 to February 9, 2021 and laboratory director interview on February 9, 2021 at 1: 36 PM, it was determined that the laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. The findings include: 1. The laboratory establish in the procedures manual, that the laboratory check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. 2. Review of hematology quality control records showed that the laboratory did not check nor document the reactivity of Wright's stain reagent (lot # 0518-00, exp. date 2022 - 01 -31), each day of use, from January 1, 2020 to February 9, 2021. 3. The laboratory director confirmed on February 9, 2021, that the laboratory did not check nor document the reactivity of Wright's stain reagent from January 1, 2020 to February 9, 2021.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on hematology quality control records review from January 2019 to February 9, 2021 and laboratory director interview on February 9, 2021 at 1:20 PM, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. The findings include: 1. The laboratory performed automatic cell differential by Cell Dyn 3200 hematology system. 2. The hematology quality controls records were reviewed from January 2019 to February 9, 2021. 3. Review of the hematology quality control records on February 9, 2021 at 1:20 PM, showed that the laboratory did not evaluated twice a year the relationship of the WBC differential results between the manual method and the Cell Dyn 3200 hematology system since July 9, 2021. 4. The laboratory director stated on February 9, 2021 at 1:20 PM, that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system since July 9, 2019.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: 1. Based on hematology quality controls records review from January 2019 to February 9, 2021 and laboratory director interview on February 9, 2021 at 1:12 PM, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the automatic and manual calculation of the hematology media (MCV, MCH and MCHC) calculated values. The finding includes: a. The laboratory uses Cell Dyn 3200 to perform Complete Blood Count (CBC) samples tests. b. The hematology quality control records were reviewed from January 2019 to February 9, 2021. c. The laboratory written policies establishes that the laboratory verify each six months the transmitted results of the hematology media (MCV, MCH and MCHC). d. The laboratory director confirmed on February 9, 2021, that the laboratory failed to evaluate twice a year the relationship between the automatic and manual calculation of the hematology media (MCV, MCH and MCHC) calculated values from July 9, 2019. 2. Based on routine chemistry quality controls records review and laboratory director interview on February 9, 2021 at 1:12 PM, it was determined that the

	laboratory failed to evaluate and define twice a year the relationship between the automatic and manual calculation of the routine chemistry ratios (A/G, BUN /Creatinne, Chol/HDL, LDL/HDL) calculated values. The finding includes: a. The laboratory uses Envoy 500 to perform routine chemistry samples tests. b. The hematology quality control records were reviewed from January 2019 to February 9, 2021. c. The laboratory written policies establishes that the laboratory verify each six months the transmitted results of the routine chemistry ratios (A/G, BUN/Creatinne, Chol/HDL, LDL/HDL) calculated values. d. The laboratory director confirmed on February 9, 2021, that the laboratory failed to evaluate twice a year the relationship between the automatic and manual calculation of the routine chemistry ratios (A/G, BUN/Creatinne, Chol/HDL, LDL/HDL) calculated values from July 9, 2019.
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 routine chemistry and hematology procedures manual, routine chemistry and hematology quality control records review from January 1, 2019 to February 9, 2021 and laboratory director interview on February 9, 2021 at 1:55 PM, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow written instructions when monitoring the refrigerator temperature uses for storing laboratory reagents. Refer to D5413. 2. The laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. Refer to D5473. 3. The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. Refer to D5775. .
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on testing personnel records review from January 2019 to February 2021 and laboratory director interview on February 9, 2021 at 11:20 AM, it was determined that the technical supervisor (Director) failed to provide the competence evaluation that performed the high complexity tests. The findings include: 1. The technical supervisor failed to perform the annual competency evaluation to the testing personnel (MT # 5694, MT # 2729) that include at least the following requirements from January 1, 2019: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or

	worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. The laboratory director confirmed on February 9, 2021, that the competence evaluation were not performed as established from January 1, 2020.