Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0857190	02/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Y Bact Oriental	Calle 13 Bc-1 Villa Universitaria, Humacao, 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
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 in 2016-2018 and laboratory director interview on February 7, 2018 at 10:35 AM, 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 Excell Drew 22 and Mindray BC5390 hematology systems. 2. Quality controls records were reviewed from January 2016 to January 2018. 3. The laboratory director stated on February 7, 2018 that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system one time a year. (September 2016 and August 2017).
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) written procedures, quality assessment records review in 2016-2018 and laboratory director interview on February 7, 2018 at 10:45 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate patient tests results for inconsistencies with patient information. The findings include: 1. The QA written procedures stated that the laboratory monitor and evaluate patient tests results for inconsistencies with patient information. 2. The quality assessment records showed that the laboratory did not evaluate nor document any test inconsistency since year 2016. 3. The laboratory director stated on February 7, 2018 at 10: 45 AM that information regarding test inconsistencies were not documented as established in the QA procedure manual since year 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 in 2016-2018 and laboratory director interview on February 7, 2018 at 11:45 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. The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. Refer to D5775. 2. The laboratory failed to follow the established Quality Assessment Program to monitor and evaluate patient tests results for inconsistencies with patient information. Refer to D5777.
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 in 2017-2018 and laboratory director interview at 11:45 AM on February 7, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. Refer to D5775. 2. The laboratory failed to follow the established Quality Assessment Program to monitor and evaluate patient tests results for inconsistencies with patient information. Refer to D5777.
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 in 2017-2018 and laboratory director interview at 11:45 AM on February 7, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.
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 quality control records review in 2016-2018 and laboratory director interview on February 7, 2018 at 11:45 AM, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. Refer to D5775. 2. The laboratory failed to follow the established Quality Assessment Program to monitor and evaluate patient tests results for inconsistencies with patient information. Refer to D5777.
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 in 2016-2018 and laboratory director interview on February 7, 2018 at 11:45 AM, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. Refer to D5775. 2. The laboratory failed to follow the established Quality Assessment Program to monitor and evaluate patient tests results for inconsistencies with patient information. Refer to D5777.