Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1013895	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Morse	Calle Morse I 203, Arroyo, 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 white blood cells (WBC) differential results comparison records (2016-2018) and laboratory general supervisor interview on April 5, 2018 at 10:00 AM, it was determined that the laboratory failed to evaluate twice a year the relationship of the WBC differential results between the manual method and the Cell Dyn 3200 hematology system. The findings include: 1. The laboratory performed the WBC differential results by two method: manual examination and Cel Dyn 3200 hematology system . 2. Review of the WBC differential results comparison records showed from April 1, 2016 to April 4, 2018 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 system. The laboratory performed the WBC differential results the last comparison evaluation was done in February 2017. 3. The laboratory general supervisor confirmed on April 5, 2018 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 the last comparison evaluation was done in February 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 (2016-2018) and laboratory general supervisor interview on April 5, 2018 at 10:00 AM, it was determined that the laboratory did not follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: comparison of test results. The findings include: 1. The laboratory performed and reported white blood cells differential counts by the Cell Dyn 3200 and the manual slide reading method. 2. Review of the quality assessment program from April 2016 to April 2018 the records showed that evaluations related to comparison of test results (white blood cell differential count) must be evaluated every six months. 3. The quality assessment record showed that the last evaluation was performed in February 2017. 4. The laboratory general supervisor confirmed that the last comparison evaluation was done in February 2017. Refer to D5775.
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: Based on Quality Assessment records review (QA) in 2016-2018 and laboratory general supervisor interview on April 5, 2018 at 10:35 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: Turn Around Time. The findings include: 1. The Quality Assessment procedure manual showed that evaluations of the laboratory turn around time (TAT) must be performed one time a year. 2. The laboratory did not evaluate the turn around time since May 2016. 3. The laboratory general supervisor confirmed on April 5, 2018 that the laboratory did not evaluate the turn around time since May 2016.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assesment (QA) records review in 2016-2018 and laboratory general

	supervisor interview on April 5, 2018 at 10:35AM, it was determined that the laboratory failed to monitor problems identified in the post analytical systems (turn around time) . The finding includes: 1. The laboratory Quality Assessment records schedule for turn around time evaluation showed that it must be performed every year. 2. The laboratory did not perform any evaluation to the post analytic system since May 2016. 3. The laboratoy general supervisor confirmed on April 5, 2018 that the laboratory did not performed a turn around time evaluation since May 2016. Refer to D5801.
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 quality control records review in 2016-2018 and laboratory general supervisor interview at 11:30 AM on April 5, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5775 and D5801.
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 2016-2018 and laboratory general supervisor interview at 11:30 AM on April 5, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791 and D5891.
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 general supervisor interview on April 5, 2018 at 11:30 AM, it was determined that the general supervisor failed to follow quality control procedures. Refer to D5775 and D5801.