Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0672484	04/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mas Clinical Lab	Condominio Doctors Center, Oficina 107,, Mayaguez, 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
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 review of testing personnel records and laboratory general supervisor interview at 10:00 A.M. on April 26, 2018, it was determined that the laboratory failed to ensure that a comprehensive mechanism is used to evaluate the competency of testing personnel. The findings include : 1. The testing personnel records (MT -1, MT-2) showed that the laboratory did not include the following requirements in the competency evaluation performed in 2017 and 2018: a. Direct observations of routine patient test performance , including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing record and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of problem solving skills.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration verification records review, manufacturer's instructions and laboratory general supervisor interview on April 26, 2018 at 10:40 A. M., it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the Cell Dyn 3200 system. The findings include: 1. The laboratory uses a Cell Dyn 3200 hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that for the Cell Dyn 3200 system, the calibration verification procedures must be perform each six months. 3. From April 2016 to April 2018, the calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn 3200 hematology system. The last calibration verification for Cell Dyn 3200 system was performed on February 2017. 4. The laboratory general supervisor confirmed on April 26, 2018 at 10:40 A.M., that the laboratory did not perform at least 6 months the calibration verification procedures for Cell Dyn 3200 system.
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 general supervisor interview on April 26, 2018 at 11:30 AM, it was determined that the laboratory failed to monitor and evaluate the requirement for analytic systems. The finding includes: 1. The laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the Cell Dyn 3200 system. Refer to D5437.
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 calibration verification records review and laboratory general supervisor interview on April 26, 2018 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5437.
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 11:00 a.m. on April 26, 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 hematology calibration verification records review in 2016-2018 and laboratory general supervisor interview on April 26, 2018 at 11:30 AM, it was determined that the general supervisor failed to follow calibration verification procedures. Refer to D5437.