Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0696899	10/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Caribe Medical Plaza	Urbanizacion Santa Rita Marginal 1 Caribe Medical, Vega Alta, 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
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 Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records review and technical supervisor interview on October 5, 2018 at 10:20 AM, it was determined that the laboratory failed to follow manufacturer's instruction for the incubator temperature when it processed 603 patient's urine cultures from January 1, 2017 to October 4, 2018. The findings include: 1. The Microscan manufacturer instructed the laboratory to incubate the Microscan identification system and the Microscan susceptibility tests at 35 C. 2. On October 5, 2018 at 10:20 AM, the incubator temperature chart showed that the laboratory recorded temperatures of 37 C +/- 1 C from January 1, 2017 to October 4, 2018. 3. The technical supervisor confirmed on October 5, 2018 at 10:20 AM, that the laboratory established the incubator temperature range from 37 C +/- 1 C from January 1, 2017 to October 4, 2018. 4. The bacteriology testing records showed that the laboratory processed 603 patients' urine cultures from January 1, 2017 to October 4, 2018.
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) program, lack of records of comparison records (years 2017 to 2018) for white blood cells (WBC) differiattial examination and technical superviosr interview on October 5, 2018 at 11:40 AM, it was determined that the laboratory failed to follow the protocol to perform every six months the comparison of the WBC diffeteential performed in the laboratory by the Cell Dyn Ruby system and by manual system. The findings include: 1. On October 5, 2018 at 11:40 AM, the QA program showed that the laboratory establishes a protocol to perform every six months the comparison of the WBC diffeteential performed in the laboratory by the Cell Dyn Ruby system and by manual system. 2. The laboratory did not have available the assessment of this comparison since January 2017. 3. The technical supervisor confirmed on October 5, 2018 at 11:40 AM, that those evaluation were not available, but stated that the laboratory performed the comparison.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on individualized quality control plan (IQCP) for the Microscan system records, Microscan manufacturer's instructions, incubator temperature chart records (years 2017 to 2018) review and technical supervisor interview on October 5, 2018 at 10:30 AM, it was determined that the laboratory director failed to ensure to develop a complete Individualized quality Control Plan for the microorganism's identification and susceptibility by the Micorscan system from January 1, 2017 to October 4, 2018. The findings include: 1. The laboratory establishes the IQCP for the Micorscan system during the year 2017. 2. On October 5, 2018 at 10:30 AM, the IQCP for the Microscan system showed that the Quality Control Plan was not signed by the laboratory director. 3. The IQCP for the Microscan system showed that the Risk Assessment has a potential failure in the environmental component due to the laboratory did not follow the manufacturer's instruction for the incubation temperature from January 1, 2017 to October 4, 2018. Refer to D 5405. 4. The technical supervisor confirmed on October 5, 2018 at 10:30 AM, that the IQCP for the Microscan system was not signed by the laboratory director and confirmed that the laboratory performed the incubation of the Microscan system at temperature range from 37 C +/- 1 C from January 1, 2017 to October 4, 2018.
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 Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records review and technical supervisor interview on October 5, 2018 at 10:20 AM, it was determined that the laboratory director failed to ensure that the laboratory follow manufacturer's instruction for the incubator temperature when it processed 603 patient's urine cultures from January 1, 2017 to October 4, 2018. Refer to D 5405.
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) program, lack of records of comparison records (years 2017 to 2018) for white blood cells (WBC) differiattial examination and technical superviosr interview on October 5, 2018 at 11:40 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the protocol to perform every six months the comparison of the WBC diffeteential performed in the laboratory by the Cell Dyn Ruby system and by manual system. Refer to D 5791.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records review and technical supervisor interview on October 5, 2018 at 10:20 AM, it was determined that the technical supervisor failed to ensure that the laboratory follow manufacturer's instruction for the incubator temperature when it processed 603 patient's urine cultures from January 1, 2017 to October 4, 2018. Refer to D 5405.
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 Microscan manufacturer's instructions, incubator temperature chart, bacteriology testing records review and technical supervisor interview on October 5, 2018 at 10:20 AM, it was determined that the testing personnel failed to follow manufacturer's instruction for the incubator temperature when it processed 603 patient's urine cultures from January 1, 2017 to October 4, 2018. Refer to D 5405.