Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0666607	01/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Y Patologico Jose De Diego	27 Ave Severiano Cuevas, Aguadilla, 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 personnel records review and laboratory director interview on January 22, 2020 at 1:38 PM, it was determined that the laboratory director failed to follow the written procedures to monitor and ensure the competency evaluations of the pathology testing personnel (M. D. Pathologist # 5). The findings include: 1. The laboratory schedule for testing pesonnel competence evaluation showed that it must be performed every year. 2. The testing personnel records were reviewed since January 2018. 3. The personnel records showed that the laboratory director did not evaluate annually the competence of the pathology testing personnel (M. D. Pathologist # 5) from January 1, 2019.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of written procedures, semen analysis testing records(years 2018 to 2020) and technical supervisor interview at 1:00 PM on January 22, 2020, it was determined that the laboratory failed verify the accuracy at least twice annually the fructose qualitative test when 4 out of 4 patient's semen specimens were processed

	and reported fructose qualitative from January 26, 2018 to October 19, 2019. The findings include: 1. At 1:00 PM on January 22, 2020, the semen analysis testing records showed that the laboratory processed and reported 4 out of 4 patient's semen specimens for fructose qualitative test from January 26, 2018 to October 19, 2019. 2. The laboratory did not verify the accuracy at least twice annually the fructose qualitative test not included in the HHS Proficiency Testing Program from January 26, 2018 to October 19, 2019. 3. The technical supervisor confirmed at 1:00 PM on January 22, 2020, the laboratory did not verify the accuracy at least twice annually the fructose qualitative test not included in the HHS Proficiency Testing Program - 4. The laboratory processed and reported 4 out of 4 patient's semen specimens for fructose qualitative test from January 26, 2018 to October 19, 2019: patient specimen # 1118019 on January 26, 2018, patient specimen # 25742 on December 17, 2018, patient specimen # 37024 on July 1, 2019 and patient specimen # 41926 on October 2, 2019.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Quality Assessment records (years 2018 and 2019) and technical supervisor interview at 1:00 PM on January 22, 2020, it was determined that the laboratory failed to establish and follow a written protocol to verify the accuracy at least twice annually the fructose qualitative test from January 26, 2018 to October 19, 2019 and failed to follow the written procedures to monitor and ensure the competency evaluations of the pathology testing personnel (M.D. Pathologist # 5). Refer to D 5209 and D 5217.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of procedures manual, semen analysis testing records(years 2018 to 2020) and technical superviosr interview at 1:00 PM on January 22, 2020, it was determined that the laboratory failed to have written procedures for the fructose test when 4 out of 4 patient's semen specimens were processed and reported for fructose qualitative test from January 26, 2018 to October 19, 2019. The findings include: 1. At 1:00 PM on January 22, 2020, the semen analysis testing records showed that the laboratory processed and reported fructose qualitative tests from January 26, 2018 to October 19, 2019. 2. The laboratory did not have the following written procedures for the fructose qualitative test: a. Step-by-step performance of the procedure, including test interpretation of results. b. Reagent and control materials used in testing. c. Control procedures. d. Corrective action to take when control results fail to meet the

	laboratory's criteria for acceptability. e. Limitations in the test methodology, including interfering substances. f. Normal values 3. The technical supervisor confirmed at 1:00 PM on January 22, 2020 that the laboratory did not have the required written procedures for the fructose qualitative test. 4. The laboratory processed and reported 4 out of 4 patient's semen specimens for fructose qualitative test from January 26, 2018 to October 19, 2019: patient specimen # 1118019 on January 26, 2018, patient specimen # 25742 on December 17, 2018, patient specimen # 37024 on July 1, 2019 and patient specimen # 41926 on October 2, 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 lack of procedures manual, semen analysis testing records(years 2018 to 2020) and technical superviosr interview at 1:00 PM on January 22, 2020, it was determined that the laboratory director failed to comply with the analytic system requirement for the fructose qualitative test from January 26, 2018 to October 19, 2019. Refer to D 5401.
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 records (years 2018 and 2019) and technical supervisor interview at 1:00 PM on January 22, 2020, it was determined that the laboratory director failed to comply with the General Laboratory System requirement. Refer to D 5209 and D 5291.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel file records review and technical supervisor interview at 1:00 PM on January 22, 2020, it was determined that the laboratory director failed to ensure that the new testing personnel (TP#5) have the appropriate training prior to testing patients' specimens in the hematology and urinalysis specialties. The finding includes:

	1. The laboratory hired a new testing personnel (TP#5) on July 22, 2019. This testing personnel processed and reported patients specimens in the following areas: hematology and urinalysis. However, the personnel file records did not include the documented training in those working areas.
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 lack of procedures manual, semen analysis testing records(years 2018 to 2020) and technical superviosr interview at 1:00 PM on January 22, 2020, it was determined that the technical supervisor failed to ensure compliance with the requirements for the analytic systems of the fructose qualitative test from January 26, 2018 to October 19, 2019. Refer to D 5401.