Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2274162	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Mhc El Litoral	183 Ave William Duscombe, Bo Sabalos, 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
D0000	An unannounced CLIA Recertification survey was conducted at the Laboratorio Clnico MHC El Litoral on January 14, 2025 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey on Janury 14, 2025.
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 written policies for personnel competence procedures, personnel records review and laboratory general supervisor interview on January 14, 2025, at 8:30 A.M., it was determined that the laboratory director failed to follow the established schedule for personnel competence evaluation. The findings include: 1. The written policies for personnel competence procedures showed that competence procedures performed twice a year. (Reviewed on January 14, 2025, at 8:35 A.M.) 2. The laboratory director did not perform, as established (twice a year), the competence evaluation for the general supervisor and testing personnel during year 2023 and 2024. (Reviewed on January 14, 2025, at 8:40 A.M.) 4. During interview with the laboratory general supervisor on January 14, 2025, at 8:45 A.M., he stated that the laboratory director no competence evaluations were performed.
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 (QA) program review (years 2023-2024) and laboratory general supervisor interview on January 14, 2025, at 9:30 A.M., it was determined that the laboratory failed to follow the established QA program to monitor and evaluate the following requirements for General laboratory systems: specimen identification and integrity and personnel competency. The findings include: 1. On January 14, 2025, at 9:30 A.M., review of the laboratory QA program showed that: a. Specimen identification and integrity must be evaluated with each event that occurs quarterly. The QA record showed that the last evaluation was performed in December 2023. b. Personnel competency must be evaluated twice a year. The laboratory did not evaluate the QA for personnel competence procedures were followed. 2. The laboratory general supervisor confirmed during interview on January 14, 2025, at 10: 00 A.M., that the general systems QA evaluations for specimen identification and integrity and personnel competency were not followed during the year 2024.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment (QA) program review (years 2023-2024) and interview with the laboratory general supervisor interview on January 14, 2025, at 9:40 A.M., it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests and specimen submission, handling and referral. The findings include: 1. On January 14, 2025, at 9:40 A.M., review of the laboratory QA program showed that: a. Patient test requests must be evaluated twice year. The QA record showed that the last evaluation was performed in November 2023. b. Specimen submission, handling and referral must be evaluated twice year. The QA record showed that the last evaluation was performed in November 2023. 2. The laboratory general supervisor confirmed during interview on January 14, 2025, at 10:00 A.M., that the preanalytic systems QA evaluations were not performed during the year 2024.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) (d)(3)(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and This STANDARD is not met as evidenced by: Based on bacteriology quality control and patient test worksheet records (year 2024), bacteriology quality control procedure manual review, Federal Drug Administration

	access database review and laboratory director interview, on January 14, 2025, at 10: 20 A.M, it was determined that the laboratory failed to process, two control materials for positive and negative reactivity, at least each day of testing, when 193 out of 208 patient samples were processed and reported from May 14, 2024 to December 30, 2024 for the Chlamydia trachomatis and Neisseria gonorrhea. The findings include: 1. The laboratory used Gene Xpert instrument systems to perform Chlamydia trachomatis and Neisseria gonorrhea patient samples. (Reviewed January 14, 2025 at 10:20 A.M.) 2. Review of Federal Drug Administration access database on January 14, 2025 at 10:25 A.M., showed that the Chlamydia trachomatis and Neisseria gonorrhea specimens by Gene Xpert systems were classified as moderate complexity test. 3. Review of the bacteriology quality control procedure manual showed that the controls will be processed with each new lot of reagents. (Reviewed January 14, 2025, at 10:30 A.M). 4. On January 14, 2025, at 10:35 A.M, the bacteriology quality control and patient test worksheet records were reviewed. The records showed that the laboratory did not process, two control materials for positive and negative reactivity, at least each day of testing, when processed and reported 193 out of 208 patient specimens from May 14, 2024, to December 30, 2024, for Chlamydia trachomatis and Neisseria gonorrhea patient samples. 5. The laboratory director confirmed on January 14, 2025 at 10:42 A.M., that she instructed the testing personnel to perform quality control procedures with each new lot of reagents.
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. This STANDARD is not met as evidenced by: Based on quality assessment (QA) program review (years 2023-2024) and interview with the laboratory general supervisor interview on January 14, 2025, at 9:45 A.M., it was determined that the laboratory failed to follow the established QA Program to monitor and evaluate the following requirements for analytic systems: patient test records. The findings include: 1. On January 14, 2025, at 9:45 A.M., review of the laboratory QA program showed that: a. Test records must be evaluated twice a year. The QA record showed that the last evaluation was performed in December 2023. 2. The laboratory general supervisor confirmed during interview on January 14, 2025, at 10:00 A.M., that the analytic systems QA evaluations for patient test records were not performed during the year 2024.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 assessment (QA) program review (years 2023-2024) and interview with the laboratory general supervisor interview on January 14, 2025, at 9:50 A.M., it was determined that the laboratory failed to follow the established QA Program to

	monitor and evaluate the following requirements for postanalytical systems: patient test reports and turn around time (TAT). The findings include: 1. On January 14, 2025, at 9:50 A.M., review of the laboratory QA program showed that: a. Patient test reports must be evaluated twice a year. The QA record showed that the last evaluation was performed in December 2023. b. TAT must be evaluated twice a year. The QA record showed that the last evaluation was performed in December 2023. 2. The laboratory general supervisor confirmed during interview on January 14, 2025, at 10: 00 A.M., that the postanalytic systems QA evaluations were not performed during the year 2024.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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: 1. Based on QA program review and interview with the laboratory general supervisor on January 14, 2025, at 12:00 P.M., it was determined that the laboratory director failed to maintain the QA activities since January 2024. Refer to D5291, D5391, D5791 and D5891. 2. Based on bacteriology quality control review and interview with the laboratory general supervisor on January 14, 2025, at 12:00 P.M., it was determined that the laboratory director failed to ensure compliance with quality control requirements for Chlamydia trachomatis and Neisseria gonorrhea patient's specimen. Refer to D5453.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on personnel records review and laboratory general supervisor interview on January 14,2025, at 12:00 P.M., it was determined that the laboratory director failed to follow the established schedule to monitor and ensure the competency evaluation of the laboratory general supervisor. Refer to: D5209