Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0699931	08/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Beiro, Inc	Palmer St 22 Sur, Guayama, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on bacteriology laboratory area observation and laboratory general supervisor interview on August 9, 2022 at 9:30 A.M., it was determined that the laboratory failed to ensure that an adequate space were available for handling, examination and testing of patient samples and minimized the contamination of urine culture patient specimens in the bacteriology area. The findings include: 1. The laboratory bacteriology area did not have an adequate space to handling urine culture patient samples reviewed at 9:30 AM. 2. The laboratory general supervisor confirmed on August 9, 2022 at 9:45 AM that the laboratory perform the inoculating procedure and testing area for urine culture patient samples were in the general clinical analysis area. 3. The laboratory processed and reported 1,145 urine culture patient samples since January 2021.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation and laboratory general supervisor interview on August 9, 2022 at 9:30AM, it was determined that the laboratory failed to ensure compliance with the

	analytic system requirements of bacteriology. Refer to D5311 (the laboratory failed to ensure that an adequate space were available for handling, examination and testing of patient samples and minimized the contamination of urine culture patient specimens in the bacteriology area)
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation and laboratory general supervisor interview on August 9, 2022 at 9:30 AM, it was determined that the laboratory director failed to fulfill his responsabilities and duties to ensure compliance with the preanalytic system requirements. Refer to D5311 (The laboratory failed to ensure that an adequate space were available for handling, examination and testing of patient samples and minimized the contamination of urine culture patient specimens in the bacteriology area).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, written bacteriology procedures manual reviewin yars 2021-2022 and laboratory general supervisor interview at 9:30 AM, it was determined that the laboratory failed to establish and follow written policies for the specimen handling. The findings include: 1. The laboratory perform bacteriology patient samples (colony count). 2. By observation, the bacteriology incubator was located in the general clinical laboratory area reviewed at 9:35 AM. 3. The laboratory testing personnel place the BA (blood agar) and Mc Conkey agar plates in the incubator located in the general clinical area and wait for 48 hours to report "no growth in 48 hours" to the negative cultures. Otherwise, if there is "growth" the laboratory refer this agar plate to a reference laboratory reviewed at 9:40 AM. 4. The bacteriology procedure manual did not include written procedures of handling of the urine samples for colony count reviewed at 9:45 AM. 5. On August 9, 2022 at 10:00 AM the laboratory general supervisor confirmed that the testing personnel performs the inoculation of the samples in the clinical area of the laboratory out of bacteriology area reviewed at 9:55 AM. 5. The laboratory processed and reported 1,145 urine culture patient samples since 2021. (On year 2021, 719 patient samples, 416 "no

	growth" and 303 sent to reference lab for Identification and sensitivity. On year 2022, 426 patient samples, 243 "no growth" and 183 sent to reference lab for Identification and sensitivity).
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation and laboratory general supervisor interview on August 9, 2022 at 9:30 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory preanalytical system. The finding includes: 1. The laboratory director did not comply with the requirement for preanalytical systems. Refer to D 6021.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation and laboratory general supervisor interview on August 9, 2022 at 9:30 AM, it was determined that the laboratory failed to ensure compliance with the requirements for preanaytic systems. Refer to D5311.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate 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 observation and laboratory general supervisor interview on August 9, 2022 at 9:30 AM, it was determined that testing personnel failed to follow preanalytic procedures. Refer to D5311.
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 observation and laboratory general supervisor interview on August 9, 2022 at 9:30 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results and handling patient samples. Refer to D5311.