Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0680931	(X3) Date Survey Completed 05/21/2024
Name of Provider or Supplier Laboratorio Clinico Beauchamp	**Street Address, City, State** Dr Vazquez Colon # 4, Florida, 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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review (2023-2024) and laboratory director interview on May 21, 2024 at 11:30 AM, it was determined that the laboratory failed to maintain the patient records used to monitor and evaluate the laboratory activities (pre-analytic,and post-analytic systems). The findings include: 1. The laboratory Quality Assessment documentation were reviewed since January 2023. The records showed that the laboratory did not have available the patient test request and patient test results used to perform the evaluations of the pre-analytic and post analytic system during year 2023. 2. The laboratory director stated that the laboratory establishes evaluate ten (10) patient test request and ten (10) patient tes results each year, however , the data used , were not available with the evaluations. 3. The laboratory director confirmed on May 21, 2024 at 11:40 A.M. , that the laboratory did not have available the patient test records used to perform the Quality Assessment evaluations.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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) records review (year 2023-2024) and interview with the laboratory director interview on May 21, 2024 at 9:20 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests. The findings include: 1. Review of the quality assessment program showed that evaluations to patient test request must be evaluated every year. (review on May 21, 2024 at 9:20 A.M) 2. Review of the quality assessment records showed that the last evaluation to patient test requests was performed in February 2023. The laboratory did not perform the patient test request evaluation during february 2024. (review on May 21, 2024 at 9:25A.M) 3. The laboratory director confirmed that the laboratory failed to follow the established Quality Assessment Program evaluations (review on May 21, 2024 at 9:30 A.M)
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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) records review (year 2023-2024) and interview with the laboratory director interview on May 21, 2024 at 9:40 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for post analytic systems: test results and turn around test (TAT) . The findings include: 1. Review of the quality assessment program showed that evaluations to post analytic system must be evaluated every year. (review on May 21, 2024 at 9:40 A.M) 2. Review of the quality assessment records showed that the last evaluation to post analytic system was performed in February 2023. The laboratory did not perform evaluation to post analytic system during february 2024. (review on May 21, 2024 at 9:45A.M) 3. The laboratory director confirmed that the laboratory failed to follow the established Quality Assessment Program evaluations (review on May 21, 2024 at 9:50 A.M).
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 (year 2023-2024) and laboratory director interview on May 21, 2024 at 10:00 A.M., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records (2023-2024) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory preanalytic and postanalytic systems. (review on May 21, 20224 at 10:00 A.M.) 2. The laboratory director confirmed on May 21, 2024 at 10:10 A.M. , that failed to evaluate the requirements for laboratory preanalytic and postanalytic systems. Refer to D5391 and D5891.