Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0912847	(X3) Date Survey Completed 04/24/2024
Name of Provider or Supplier Laboratorio Clinico Villa Ana Aguas Buenas Iii	**Street Address, City, State** Carr 174 Km 21 , Hm 7, Aguas Buenas, 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
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 lack of Quality Assessment (QA) activities records (years 2022-2023) and laboratory director interview on April 24, 2024 at 1:17 PM, it was determined that the laboratory failed to evaluate and monitor the patient confidentiality, specimen identification and integrity, complaint investigation, communication, and personnel competency in the general laboratory system since January 2022. The findings include: 1. On April 24, 2024 at 1:00 PM, the general laboratory system QA 2022-2023 records were requested. The general laboratory system QA was not available for evaluation. 2. The laboratory director confirmed on April 24, 2024 at 1:03 PM, that the QA general laboratory system activities records were not evaluated or monitored since January 2022.
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 lack of Quality Assessment (QA) activities records (years 2022-2023) and

	laboratory director interview on April 24, 2024 at 1:05 PM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirements for pre-analytic systems since year 2022. The findings include: 1. On April 24, 2024 at 1:00 PM, the laboratory pre-analytic systems QA records 2022-2023 were requested. The pre-analytic system QA since year 2022 was not available for evaluation at the time of inspection. 2. Since January 2022 the laboratory did not evaluate practices related to: test request, specimen submission and handling, and specimen referral. 3. The laboratory director confirmed on April 24, 2024 at 1:05 PM, that the laboratory pre-analytic systems QA records 2022-2023 were not evaluated or monitored since January 2022.
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 lack of Quality Assessment (QA) activities records (years 2022-2023) and laboratory director interview on April 24, 2024 at 1:08 PM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirements for analytic systems since year 2022. The findings include: 1. On April 24, 2024 at 1:00 PM, the laboratory analytic systems QA records 2022-2023 were requested. The analytic system QA since year 2022 was not available for evaluation at the time of inspection. 2. Since January 2022 the laboratory did not evaluate practices related to: test procedures, accurate and reliable test system, equipment instruments, reagents, materials, specimen and reagent storage conditions, system naintenance and fucntion checks, verification of method performance specifications, calibration, control procedures, test records, corrective actions, and comparison of test results. 3. The laboratory director confirmed on April 24, 2024 at 1:08 PM, that the laboratory analytic systems QA evaluation records 2022-2023 were not evaluated or monitored since January 2022.
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 lack of Quality Assessment (QA) activities records (years 2022-2023) and laboratory director interview on April 24, 2024 at 1:11 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for postanalytic systems since year 2022. The findings include: 1. On April 24, 2024 at 1:00 PM, the laboratory postanalytic systems QA records 2022-2023 were requested. The postanalytic system QA since year 2022 was not available for evaluation at the time of inspection. 2. Since January 2022 the laboratory did not evaluate practices related to: turn around time and the patient's final

	test reports. 3. The laboratory director confirmed on April 24, 2024 at 1:11 PM, that the laboratory postanalytic systems QA evaluation records 2022-2023 were not evaluated or monitored since January 2022.
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 lack of the Quality Assessment (QA) records review (year 2022-2023) and laboratory director interview on April 24, 2024 at 1:27 PM, it was determined that laboratory director failed to ensure compliance with QA requirements. Refer to D5291 , D5391, D5791 and D5891.