Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0912847	04/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Villa Ana Aguas Buenas Iii	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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clnico Villa Ana III on April 28, 2026. 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 ending on April 28, 2026.
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 review of Quality Assessment (QA) records (years 2024-2025) and laboratory testing personnel (TP) interview on April 28, 2026, at 9:17 a.m., the laboratory failed to monitor and evaluate the required General Systems QA for three (3) of six (6) indicators during the year 2025. The findings include: 1. On April 28, 2026, at 9:17 a.m., the QA records were requested. 2. On April 28, 2026, at 9:20 a.m., review of the laboratory QA records showed that the laboratory last evaluated patient confidentiality, complaint investigations, and communications in December 2024. 3. On April 28, 2026, at 10:12 a.m., review of the 2025 QA records showed no documentation that the laboratory monitored or evaluated patient confidentiality, complaint investigations, and communications during the year 2025. 4. During interview on April 28, 2026, at 10:30 a.m., the TP stated that the laboratory had established an annual frequency to monitor and evaluate the General Systems QA and confirmed that the laboratory did not monitor and evaluate patient confidentiality, complaint investigations, and communications during the year 2025.

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 review of Quality Assessment (QA) records (years 2024-2025) and laboratory testing personnel (TP) interview on April 28, 2026, at 10:14 a.m., the laboratory failed to monitor and evaluate the required Preanalytical Systems QA during the year 2025. The findings include: 1. On April 28, 2026, at 9:17 a.m., the QA records were requested. 2. On April 28, 2026, at 9:23 a.m., review of the laboratory QA records showed that the laboratory last evaluated test requests and specimen submission, handling, and referral in June 2024. 3. On April 28, 2026, at 10:14 a.m., review of the 2025 QA records shows no documentation that the laboratory monitored or evaluated test requests and specimen submission, handling, and referral during the year 2025. 4. During interview on April 28, 2026, at 10:30 a.m., the TP stated that the laboratory had established an annual frequency to monitor and evaluate the Preanalytical Systems QA and confirmed that the laboratory did not monitor and evaluate the Preanalytical Systems QA during the year 2025.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on the lack of comparison test results records on white blood cells (WBC) (year 2025), and interview with the laboratory testing personnel (TP) on April 28, 2026, at 10:25 a.m., the laboratory failed to evaluate, twice a year, the relationship of the WBC differential results between the manual method and the Cell Dyn Emerald system. The laboratory processed and reported 5,616 Complete Blood Count (CBC) patient specimens during the year 2025. The findings include: 1. The laboratory performed WBC differential results by two methods: manual examination and the Cell Dyn Emerald system. 2. On April 28, 2026, at 10:25 a.m., the WBC comparison evaluation records were requested. No evaluation records were available for the year 2025. 3. The laboratory processed and reported 5,616 CBC patient specimens during the year 2025. 4. During interview on April 26,2026, at 10:30 a.m., the TP confirmed that the laboratory did not evaluate, twice a year, the relationship of the WBC differential results between the manual method and the Cell Dyn Emerald system.
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 review of Quality Assessment (QA) records (years 2024-2025) and laboratory testing personnel (TP) interview on April 28, 2026, at 10:22 a.m., the laboratory failed to monitor and evaluate the required Postanalytic Systems QA during the year 2025. The findings include: 1. On April 28, 2026, at 9:17 a.m., the QA records were requested. 2. On April 28, 2026, at 9:30 a.m., review of the laboratory QA records showed that the laboratory last evaluated patient test reports and turnaround time (TAT) in December 2024. 3. On April 28, 2026, at 10:25 a.m., review of the 2025 QA records showed no documentation that the laboratory monitored or evaluated patient test reports and TAT during the year 2025. 4. During interview on April 28, 2026, at 10:30 a.m., the TP stated that the laboratory had established an annual frequency to monitor and evaluate the Postanalytic Systems QA and confirmed that the laboratory did not monitor and evaluate patient test reports and TAT during year 2025.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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: Based on review of QA records (year 2024- 2025), WBC comparison records (year 2025), and interview with the laboratory testing personnel (TP) on April 28, 2026, at 12:30 p.m., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory's QA and WBC differential comparison evaluation. Refer to D5291, D5391, D5775 and D5891.