Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 48D2179122	**(X3) Date Survey Completed** 03/20/2023
Name of Provider or Supplier Us Vi Territorial Public Health Laboratory	**Street Address, City, State** 3500 Estate Richmond, Christiansted, VI	
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) New York CLIA Branch Location federal surveyor conducted an announced CLIA recertification survey at US VI Territory Public health Laboratory on March 20, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiencies were found during the announced routine CLIA recertification survey performed on March 20, 2023.
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 the review of the quality assessment records, review of laboratory records, and interview with the laboratory director and technical supervisor (TS#2), the laboratory failed to establish a quality assessment (QA) policy that monitored post analytic record reviews from 2021 to 2023. Findings Include: 1. On the day of survey, March 20, 2023 at 12:00 am, a review of the laboratory's QA procedure revealed, the procedure lacked provision to assure documents were reviewed and signed on a periodic basis from March 2021 to March 2023. 2. Review of the Panther Maintenance records at 12:10 pm revealed the December 2021, April 2022 thru February 2023 records were not signed for review. 3. Review of the Panther Calibration records at 12:40 pm revealed the February 25, 2022, August 01, 2022, and February 28, 2023 records were not signed for review. 4. The LD and TS#2 confirmed the findings above on March 20, 2023 at 02:20 pm.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)

	The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) records and review interview with the laboratory director (LD) and technical supervisor (TS#2), the laboratory director failed to ensure that the CAP PT documents were signed for review for PT events performed in 2021 and 2022. Findings Include: 1. On the day of survey, March 20, 2023 at 9:30 am, review of the CAP PT records revealed, the LD did not sign the PT evaluation page for PT events performed in 2021 and 2022. 2. A sampling of the following CAP PT events were not signed at 9:40 am: - 2021 SARS Events 1 and 2. - 2022 CT/NG Events 1, 2 and 3. 3. The LD and TS#2 confirmed the findings above on March 20, 2023 at 02:20 pm.