

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0862228	(X3) Date Survey Completed 08/24/2022
Name of Provider or Supplier Laboratorio Clets Ponce	Street Address, City, State 1er Piso Antiguo Edificio Del Hospital Regional, Ponce, 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) New York CLIA Branch Location federal surveyors conducted an announced CLIA recertification survey at Laboratorio EST/VIH/SIDA Ponce on August 24, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiency was found during the announced routine CLIA recertification survey performed on August 24, 2022.
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the he ASI Rapid Plasma Reagin (RPR) Card Test kit for syphilis quality control (QC) records, review of the quality assessment (QA) records and interview with the laboratory director (LD), the LD failed to maintain, review and sign QA and RPR QC documents from 2021 to 2022. Findings Include: 1. On the day of survey, 08/24/2022 review of the RPR QC records and QA records revealed, The LD did not sign the yearly QA records and monthly RPR QC records when reviewed from 2021 to 2022. 2. The LD confirmed on 08/24/2022 around 11:00 am, they reviewed the QA and QC records periodically but did not sign and date the document when the review was performed.</p>