

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0669618	(X3) Date Survey Completed 07/13/2023
Name of Provider or Supplier Lab Clinico Clets Inst Of Health Labs	Street Address, City, State Edificio Casa De Salud, San Juan, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based review of laboratory procedures, lack of microscopic examination quality control (QC) records and interview with the laboratory director (LD), General supervisor (GS), and testing personnel (TP), the laboratory failed to establish microscopic examination procedures to include QC procedures for 4 out of 8 tests performed by the laboratory from July 13, 2021 to July 13, 2023. Findings Include: 1. On the day of survey, July 13, 2023, review of laboratory testing procedures revealed, the following 4 out of 8 tests performed by the laboratory from July 13, 2021 to July 13, 2023 did not include procedures for QC: - Potassium Hydroxide (KOH)</p>

Microscopic Examination. - Wet Preparation Microscopic Examination. - Darkfield Microscopy. - Clue Cell Preparation Microscopic Examination. 2. The laboratory was unable to provide QC documentation for the reference collection of photographs reviewed each day of patient testing for KOH, wet mount, darkfield and clue cell microscopic examinations performed from July 13, 2021 to July 13, 2023. 3. The LD and TS confirmed the findings above on July 13, 2023 around 11:40 am.