

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0955970	(X3) Date Survey Completed 01/05/2018
Name of Provider or Supplier Laboratorio Clinico Los Colobos	Street Address, City, State Los Colobos Cinema Bldg Shopping Cntr, Carolina, 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 on procedures manual, scotch tape testing records, scotch tape patients reports records review and general supervisor interview on January 5, 2018 at 9:30 AM, it was determined that the laboratory failed to have written procedures for the processing, examination and reporting when 5 out of 5 patient's scotch tape smears were examined and reported from July 6, 2017 to November 29, 2017. The findings include: 1. On January 5, 2018 at 9:30 AM, the scotch tape testing records showed that the laboratory examined and reported out of 5 patient's scotch tape smears from</p>

July 6, 2017 to November 29, 2017. 2. On January 5, 2018 at 9:35 AM, the laboratory procedures manual showed that the laboratory did not have available the following written procedures for the examination scotch tape smears: processing, criteria for specimen acceptability and rejection, microscopic examination, including the detection of inadequately prepared slide and reporting patient results since July 6, 2017. 3. The general supervisor confirmed January 5, 2018 at 9:45 AM that the laboratory did not have available the requiere written procedures for the patient's scotch tape smears examination and reports since July 6, 2017. 4. On January 5, 2018 at 9:30 AM, the scotch tape testing records showed that the laboratory examined 5 out of 5 patient's scotch tape smears from July 6, 2017 to November 29, 2017: sample #608844 on July 6, 2017, sample #624008 on October 19, 2017, sample #621187 on September 5, 2017, sample #627550 on November 14, 2017 and sample #630598 on November 29, 2017. 5. On January 5, 2018 at 9:40 AM, the scotch tape patients reports records showed discrepancy in the reports of the 5 out of 5 patient's scotch tape smears from July 6, 2017 to November 29, 2017: a. Sample #608844 reported on July 6, 2017 as Negative, no Enterobius Vermicularis seen. b. Sample #624008 reported on October 19, 2017 as Positive, few E. Vermicularis ova seen. c. Sample #621187 reported on September 5, 2017 as None seen, * none E. vermicularis seen*. d. Sample #627550 reported on November 14, 2017 as negative no Enterobius Vermicularis seen. e. Sample #630598 reported on November 29, 2017 as Positive Enterobius Vermicularis.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on procedures manual, scotch tape testing records, scotch tape patients reports records review and general supervisor interview on January 5, 2018 at 9:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems of the scotch tape smear examination. Refer to D 5403. (The laboratory failed to have written procedures for the processing, examination and reporting when 5 out of 5 patient's scotch tape smears were examined and reported from July 6, 2017 to November 29, 2017).

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on procedures manual, scotch tape testing records, scotch tape patients reports records review and general supervisor interview on January 5, 2018 at 9:30 AM, it was determined that technical consultant failed to ensure compliance with the requirements for analytic systems of the scotch tape smear examination. Refer to D 5403. (The laboratory failed to have written procedures for the processing, examination and reporting when 5 out of 5 patient's scotch tape smears were examined and reported from July 6, 2017 to November 29, 2017).