

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0995859	(X3) Date Survey Completed 12/05/2018
Name of Provider or Supplier Centro De Patologia Avanzada De Pr	Street Address, City, State Ext Hermanas Davila Calle 8 Bloque I32, Bayamon, 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 review of the monthly peer review for histology and non-gynecologic cases records (years 2017 and 2018), annual tests records (year 2018) and interview with the laboratory director on December 5, 2018 at 11:45 AM, it was determined that the laboratory flailed to perform the monthly evaluation of the peer review of histology and non gynecologic cases from March 2018 to November 2018. The findings included: 1. On December 5, 2018 at 11:45 AM, the peer review for histology and non-gynecologic cases records showed that the laboratory did not perform the</p>

monthly evaluation from March 2018 to November 2018. 2. The laboratory director confirmed on December 5, 2018 at 11:45 AM, that the that the laboratory did not perform the monthly evaluation of the peer review from March 2018 to November 2018. 3. The annual tests records (year 2018) showed that the laboratory processed the following cases from March 2018 to November 2018: 15,142 histology cases and 728 non gynecologic cases.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on written procedures flotation bath temperature requirement, flotation bath # 1 temperature records (year 2018) and laboratory histotechnologist interview on December 5, 2018 at 9:30 AM, it was determined that the laboratory failed to follow written instructions when monitoring the temperature of the flotation bath # 1, uses in the processed of the tissue blocks from January 9, 2018 to December 4, 2018. The findings include: 1. The written procedures showed that the flotation bath temperature requirement is a temperature range from 42 C to 55 C. 2. The flotation bath # 1 temperature records showed that the temperatures of this bath was out the lower temperature limit from January 9, 2018 to December 4, 2018. The monitoring of the temperature showed a range from 40 C to 41 C and corrective action were not documented. 3. The histotechnologist confirmed on December 5, 2018 at 9:30 AM, that the temperatures of the flotation bath # 1 showed a range from 40 C to 41 C from January 9, 2018 to December 4, 2018. 4. The laboratory used this flotation bath in the processed of 19, 611 tissue blocks from January 9, 2018 to December 4, 2018.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 the monthly peer review for histology and non-gynecologic cases records (years 2017 and 2018), annual tests records (year 2018) , written procedures flotation bath temperature requirement, flotation bath # 1 temperature records (year 2018), interview with the laboratory histotechnologist and with the laboratory director on December 5, 2018 at 11:45 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements from January 9, 2018 to December 4, 2018. Refer to D 5403. (The laboratory director on December 5, 2018 at 11:45 AM, it was determined that the laboratory flailed to perform the monthly evaluation of the peer review of histology and non gynecologic cases from

March 2018 to November 2018). Refer to D 5413. (The laboratory failed to follow written instructions when monitoring the temperature of the flotation bath # 1, uses in the processed of the tissue blocks from January 9, 2018 to December 4, 2018).