Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658176	(X3) Date Survey Completed 10/01/2019
Name of Provider or Supplier Path Lab ,Inc	**Street Address, City, State** Torre San Cristobal Suite 407-A, Coto Laurel, 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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on written protocols, direct observation, vapor analysis records review and histotecnologist # 3 interview on October 1, 2019 at 9:50 AM, it was determined that the laboratory failed to follow written protocol to ensure its ventilation system properly removes vapors and fumes for the type of testing done in the laboratory since June 23, 2017. The findings include: 1. The written protocol for the laboratory ventilation system establishes to performed every three months inspections and checked the velocity tests; velocity test that should be maintained at minimal 3,500 ppm. 2. On October 1, 2019 at 9:50 AM, it was observed that the laboratory did not have records for inspection and for the velocity tests for the Hood located at the gross dictation station since January 2018. 3. The histotecnologist # 3 confirmed on October 1, 2019 at 9:50 AM, that the laboratory did not have available the certification of the inspection nor the velocity test of this hood since January 2018. 4. The written protocol for the vapor and fumes analysis did not specify the frequency to be performed the analysis. 5. The vapor analysis records showed that the laboratory did not perform the laboratory vapor analysis for more than two years. The records showed that the laboratory performed vapor analysis on June 23, 2017 and on September 27, 2019.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

	This STANDARD is not met as evidenced by: Based on facility records review and laboratory manager interview on October 1, 2019 at 9:00 AM, it was determined that the laboratory failed to be in compliance with the State laboratory requirements. The findings include: 1. On October 1, 2019 at 9:00 AM, the facility records showed that the laboratory's Biomedical Generator Number was due since August 4, 2019. 2. The laboratory manager confirmed that the laboratory's Biomedical Generator Number in record was expired since August 4, 2019.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Oncore manufacturer's instructions, preventive maintenance record of the Oncore immunohistochemiclal staining system, immunohistochemical stains quality control records and interview with the histotechnologist #2 on October 1, 2019 at 10: 10 AM, it was determined that the laboratory failed to meet the analytic requirements for Histopathology (Immunohistochemiclal stains). Refer to D 5429 (The laboratory failed to follow manufacturer's instructions for the preventive maintenance of the Oncore system January 2, 2018 to September 24 2019). Refer to D 5601 (The laboratory failed to check the negative reactivity each time of use the following immunohistochemical stains from January 2, 2018 to September 24 2019: HP, Panck, Panck Plus, Mammaglobin, GCDFP-15 and GATA-3).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on Oncore manufacturer's instructions, preventive maintenance record of the Oncore immunohistochemiclal staining system and interview with the histotechnologist #2 on October 1, 2019 at 10:10 AM, it was determined that the laboratory failed to follow manufacturer's instructions for the preventive maintenance of the Oncore system January 2, 2018 to September 24 2019. The findings include: 1. The laboratory performs immunohistochemical stains by the Oncore system. 2. The Oncore manufacturer instructed the laboratory to perform the following preventive maintenance: chambers cleaning daily, module cleaning daily, remove residual DAB weekly, wash stations weekly, disinfect & waste weekly, deep clean chambers monthly, disinfect quarterly and semiannual tube cleaning. 3. On October 1, 2019 at 10:10 AM, the preventive maintenance record of the Oncore immunohistochemiclal system showed that the laboratory did not document the preventive maintenance as required by the manufacturer from January 2, 2018 to September 24, 2019. 4. The

	histotechnologist #2 confirmed on October 1, 2019 at 10:10 AM, that the laboratory did not document the preventive maintenance as required by the manufacturer but she stated that the laboratory performed the preventive maintenance as the manufacturer required. 5. The laboratory processed 2,587 cases by the Oncore system from January 2, 2018 to December 31, 2018.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the immunohistochemical stains quality control records and interview with the histotechnologist #2 on October 1, 2019 at 10:10 AM, it was determined that the laboratory failed to check the negative reactivity each time of use the following immunohistochemical stains from January 2, 2018 to September 24 2019: HP, Panck, Panck Plus, Mammaglobin, GCDFP-15 and GATA-3. The findings include: 1. The laboratory perform immunohistochemical stains by the Oncore system. 2. On October 1, 2019 at 10:10 AM, it review of the immunohistochemical stains quality control records from January 2, 2018 to September 24 2019 showed that that the laboratory did not check the negative reactivity each time of use the following immunohistochemical stains from January 2, 2018 to September 24 2019: HP, Panck, Panck Plus, Mammaglobin, GCDFP-15 and GATA-3. 3. The histotechnologist #2 confirmed on October 1, 2019 at 10:10 AM, that the laboratory did not check the negative reactivity each time of use the immunohistochemical stains. She stated that the laboratory checked the positive reactivity of the those stains each time of use. 4. The laboratory processed 2,587 cases for immunohistochemical stains from January 2, 2018 to December 31, 2018.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on facility records, written protocols, direct observation, vapor analysis records review, Oncore manufacturer's instructions, preventive maintenance record of the Oncore immunohistochemiclal staining system, immunohistochemical stains quality control records, interview with the laboratory manager, histotechnologist #2 and histotecnologist # 3 on October 1, 2019 at 10:10 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to comply with the laboratory facility administration and the analytical system requirements. Refer to D

	6079 (The laboratory director failed to comply with his responsibilities for the facility administration requirements). Refer to D 6093 (The laboratory director failed to comply with the requirements for Histopathology (Immunohistochemiclal stains).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on facility records, written protocols, direct observation, vapor analysis records review, interview with the laboratory manager and histotecnologist # 3 on October 1, 2019 at 9:50 AM, it was determined that the laboratory director failed to comply with his responsibilities for the facility administration requirements. Refer to D 3001 (The laboratory failed to follow written protocol to ensure its ventilation system properly removes vapors and fumes for the type of testing done in the laboratory since June 23, 2017). Refer to D 3009 (The laboratory failed to be in compliance with the State laboratory requirements).
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 Oncore manufacturer's instructions, preventive maintenance record of the Oncore immunohistochemiclal staining system, immunohistochemical stains quality control records and interview with the histotechnologist #2 on October 1, 2019 at 10: 10 AM, it was determined that the laboratory it was determined that the laboratory director failed to comply with the requirements for Histopathology (Immunohistochemiclal stains). Refer to D 5028.