Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658324	08/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio De Patologia	Escuela De Medicina Rio Piedras, 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
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 vapors check records review and general supervisor of the histology area interview on August 9, 2018 at 9:50 AM, it was determined that the laboratory failed to perform the vapors check in one out of three histotechnologists since July 2017. The findings include: 1. The vapors check records showed that the laboratory did not perform the vapors check in one out of three histotechnologists since July 2017. 2. The general supervisor of the histology area confirmed on August 9, 2018 at 9:50 AM, that the laboratory did not perform the vapors check of the new histotechnologist who was hired in July 2017.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files and interview with the laboratory supervisor on August 9, 2018 at 12:05 PM, it was determined that the laboratory did not follow their written policy for personnel competence's. The findings include: a. The laboratory supervisor stated that the personnel competence must be done every year. b. The laboratory personnel files were reviewed on August 9, 2018 at 12:05 P.M. c. The

	laboratory did not perform the following personnel competence's since year 2017: a. Supervisor - GS 4 b. Clinical Consultant- CC 1 c. Technical Supervisor - TS 1 d. Technical Supervisor - TS 3 e. Testing personnel- TP 1 f. Testing personnel - TP 7 g. Histotechnologist - # 227 h. Histotechnologist- # 3171 i. Histotechnologist - # 14
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on quality assessment (QA) program, QA activities records review and interview with the general supervisor of histopathology specialty on August 9, 2018 at 10:00 AM, it was determined that the laboratory failed to follow written procedures to asses the general laboratory system requirements in the histopathology specialty since January 2018. Refer to D 5209. (The laboratory did not follow their written policy for personnel competence's).
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment (QA) program, QA activities records review and interview with the general supervisor of histopathology specialty on August 9, 2018 at 10:00 AM, it was determined that the laboratory failed to follow written procedures to asses the pre analytic system requirements in the histopathology specialty since January 2018. The findings include: 1. The QA program establish to evaluate every three months the following pre analytic system requirements: immunoperoxidases requisition, special stain requisition, electronic microscopic requisition, tissue sample condition and medical history. 2. On August 9, 2018 at 10:00 AM, QA activities records showed that the histopathology laboratory did not perform the QA assess of the pre-analytic area requirements since January 2018. 3. The general supervisor of histopathology specialty confirmed on August 9, 2018 at 10:00 AM, that the laboratory did not perform the required assessment since January 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on quality assessment (QA) program, QA activities records review and interview with the general supervisor of histopathology specialty on August 9, 2018 at 10:00 AM, it was determined that the laboratory failed to follow written procedures to asses the analytic system requirements in the histopathology specialty since January 2018. The findings include: 1. The QA program establish to evaluate every three months the following comparison of test results to asses the analytic system requirements: comparison of cases by two pathologists (peer review) and comparison of cases referred for consultations. 2. On August 9, 2018 at 10:00 AM, the QA activities records showed that the histopathology laboratory did not perform the QA assess of the analytic area requirements since January 2018. 3. The general supervisor of histopathology specialty confirmed on August 9, 2018 at 10:00 AM, that the laboratory did not perform the required assessment since January 2018.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assessment (QA) program, QA activities records review and interview with the general supervisor of histopathology specialty on August 9, 2018 at 10:00 AM, it was determined that the laboratory failed to follow written procedures to asses the post- analytic system requirements in the histopathology specialty since January 2018. The findings include: 1. The QA program establish to evaluate every three months the turn-around- time (TAT) of the histopathology examinations results reports. 2. On August 9, 2018 at 10:00 AM, the QA activities records showed that the histopathology laboratory did not perform the QA assess of the post-analytic area requirements since January 2018. 3. The general supervisor of histopathology specialty confirmed on August 9, 2018 at 10:00 AM, that the laboratory did not perform the required assessment since January 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 vapors check records, personnel records and files, QA records review and general supervisor of the histology area interview on August 9, 2018 at 9:50 AM, it was determined that the laboratory director failed to fulfill the laboratory director responsibilities. Refer to D 6076 (The laboratory director failed to ensure the ventilation necessary for conducting all phases of the testing process in the histology laboratory). Refer to D 6094 (The laboratory director failed to comply with the QA requirements). Refer to D 6101 (The laboratory director failed to ensure that the general supervisor of the histology specialty met the qualification for this position). Refer to D 6103 (The laboratory director did not perform the annual competence

	evaluations of the Clinical Consultant- CC1, Technical Supervisor - T'S 1 and Technical Supervisor -TS 3).
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 vapors check records review and general supervisor of the histology area interview on August 9, 2018 at 9:50 AM, it was determined that the laboratory director failed to ensure the ventilation necessary for conducting all phases of the testing process in the histology laboratory. Refer to D 3009 (The laboratory failed to perform the vapors check in one out of three histotechnologists since July 2017).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 quality assessment (QA) program, QA activities records review and interview with the general supervisor of histopathology specialty on August 9, 2018 at 10:00 AM, it was determined that the laboratory failed to follow written procedures to asses the QA program requirements in the histopathology specialty since January 2018. Refer to D 5291 (The laboratory failed to follow written protocol to assess the general laboratory system requirements). Refer to D 5391 (The laboratory failed to follow written protocol to assess the pre-analytic system requirements). Refer to D 5791 (The laboratory failed to follow written protocol to assess the analytic system requirements). Refer to D 5891 (The laboratory failed to follow written protocol to assess the post-analytic system requirements).
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

	This STANDARD is not met as evidenced by: Based on personnel records review and interview with the general supervisor of the histopathology specialty on August 9, 2018 at 12:45 PM, , it was determined that the laboratory director failed to ensure that the general supervisor of the histology specialty met the qualification for this position. Refer to D 6141.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory personnel files and interview with the laboratory supervisor, it was determined that the laboratory director did not perform the annual competence evaluations of the following personnel: Clinical Consultant- CC 1 Technical Supervisor - T'S 1 Technical Supervisor -TS 3 Refer to D 5209.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on personnel records review and interview with the general supervisor of the histopathology specialty on August 9, 2018 at 12:45 PM, , it was determined that the general supervisor failed to met the requirements for the position of general supervisor in histopathology specialty since March 2018. Refer to D 6143 (The general supervisor position for the histopathology specialty was filled by a medical technologist since March 2018).
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of

	laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m). This STANDARD is not met as evidenced by: Based on personnel records review and interview with the general supervisor of the histopathology specialty on August 9, 2018 at 12:45 PM, , it was determined that the general supervisor failed to met the qualification for the position of general supervisor in histopathology since March 2018. The finding includes: 1. The general supervisor position in histopathology specialty was filled by a medical technologist since March 2018.