Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658015	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
San Pablo Pathology Group	Torre San Pablo Suite 403, 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	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of 22 laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for gynecologic cytology proficiency testing enrollment and participation of personnel that perform gynecologic cytology testing. 2. During an interview on March 28, 2023 at 2:30 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, morphology certification records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 SYSTEM should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by HOLOGIC or by organizations or individuals designated by HOLOGIC." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification for one of two Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Technical Supervisor A 3. During an interview on March 29, 2023 at 12:30 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of laboratory records, review of laboratory statistical records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used for gynecologic and nongynecologic slide preparations for each day of use in 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used for gynecologic and nongynecologic slide preparations were assessed each day of use in 2022 and to the date of the survey in 2023. 2. The Survey Team reviewed records titled CYTOLOGY MONTHLY REPORT: CT/CSP and CYTOLOGY MONTHLY REPORT: CTE/CSPE for 2022 and 2023. a. The laboratory stained 860 gynecologic slide preparations in 2022 and to the date of the survey in 2023. b. The laboratory stained 3,196 nongynecologic slide preparations in 2022 and to the date of the survey in 2023. 2. During an interview on March 28, 2023 at 3:40 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.

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 policies and procedures and interview the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of Technical Supervisors who conducted analytic and postanalytic phases of cytology testing. The Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the Cytotechnologist who conducted preanalytic, analytic and postanalytic phases of cytology testing. The Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the Histotechnologists who conducted preanalytic phases of cytology testing. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of Technical Supervisors who conducted analytic and postanalytic phases of cytology testing. 2. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of the Cytotechnologist who conducted preanalytic, analytic and postanalytic phases of cytology testing. 3. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of Histotechnologists who conducted preanalytic phases of cytology testing. 4. During an interview on March 28, 2023 at 3: 40 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on microscopic review of 404 negative gynecologic cytology cases/424 slides from July 1, 2022 through March 17, 2023 and confirmation by Technical Supervisor B on March 28, 2023 the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. 22CT617-01 10/13/2022 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy Reactive Cellular Changes Associated with Inflammation (Includes Typical Repair) SURVEY TEAM DIAGNOSIS: High Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR B DIAGNOSIS: High Grade Squamous Intraepithelial Lesion (CIS)
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for

	CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.