Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2154476	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Vivid Pathology Pa	123 Baptist Way, Pensacola, FL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the lack of cytology proficiency testing (PT) enrollment records and interviews the laboratory failed to enroll in a CMS-approved cytology PT program for gynecologic examination (refer to D2001).
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews the laboratory failed to enroll in a CMS-approved cytology PT program for gynecologic examination

	for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in a CMS-approved cytology PT program for 2022 and 2023. 2. During an interview on April 8, 2024 at 8:45 AM, when asked if the laboratory had enrolled or was currently enrolled in a CMS-approved cytology PT program the Laboratory Director/Technical Supervisor A and Vice President (VP) of Quality Assurance replied "no." 3. During an interview on April 8, 2024 at 11:00 AM, the VP of Quality Assurance and Cytology Supervisor inquired as to the process of enrolling the laboratory in a cytology PT program, confirmed the laboratory had not been enrolled prior to the survey, and stated they would begin the enrollment process.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish and follow safety procedures to ensure protection from physical, chemical and electrical hazards. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure protection from physical, chemical and electrical hazards. 2. During an interview on April 8, 2024 at 8:45 AM, when asked if the laboratory had written safety procedures to ensure protection from physical, chemical and electrical hazards that were specific to the laboratory being surveyed, the Laboratory Director/Technical Supervisor A and VP of Quality Assurance replied "no." 3. During an interview on April 8, 2024 at 3:45 PM, the VP of Quality Assurance confirmed the written policies and procedures in MEDIA LAB did not reflect the safety policies and procedures of the laboratory being surveyed. The VP of Quality Assurance stated that they were creating a new manual in MEDIA LAB and would include the safety policies and procedures that were specific to the location of the laboratory being surveyed.
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 laboratory policies and procedures provided by the laboratory in MEDIALAB and interview the laboratory procedure manual failed to include 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 laboratory's enrollment in a gynecologic cytology PT program and how the laboratory personnel participated in a gynecologic cytology PT program. 2. During an interview on April 8, 2024 at 4:00 PM, the VP of Quality Assurance and Cytology Supervisor confirmed the written policy titled GEN 1-7 PROFICIENCY TESTING did not reflect the laboratory's current gynecologic cytoloy PT enrollment and participation practices.
D5623	CYTOLOGY CFR(s): 493.1274(c)(2) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the VP of Quality Assurance the laboratory failed to establish written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL) or other malignant neoplasms with available histopathology. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures of the laboratory's process to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasms with the histopathology report and determine the cause of any discrepancies. a. The policy provided by the laboratory titled GYN CORRELATION detailed the process for the correlation program at another laboratory (FACILITY B-CLIA #10D0962657). b. The records provided by the laboratory titled CYTOPATHOLOGY GYN CORRELATION LOG included cases evaluated and reported from multiple locations and was completed by staff at FACILITY B. 2. During an interview on April 8, 2024 at 10:50 AM, the VP of Quality Assurance stated that FACILITY B was responsible for performing the requirements of the cytology comparative program and confirmed the laboratory did not have written policies or procedures to reflect the current process.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3)

	(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, microscopic review of specimen slides and interviews the laboratory failed to establish written policies and procedures for a program to review all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm. The laboratory failed to document the search for prior negatives on current HSIL or malignant specimens from 2023 and January 1, 2024 to the date of the survey in 2024, and failed to identify one of seven prior negative specimens as having a more significant lesion. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures of the laboratory's process to review all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory, for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm. a. The policy provided by the laboratory titled HGSIL 5 YEAR NEGATIVE RETROSPECTIVE REVIEW detailed the process for the review program at FACILITY B. b. The records provided by the laboratory titled 5 YEAR NEGATIVE RETROSPECTIVE REVIEW LOG included cases evaluated and reported from multiple locations and was completed by staff at FACILITY B. c. During an interview on April 8, 2024 at 10:50 AM, the VP of Quality Assurance stated FACILITY B was responsible for performing the requirements of the cytology review program and confirmed the laboratory did not have written policies or procedures to reflect the current process. 2. The Survey Team requested and the laboratory failed to provide documentation of the search for prior negative gynecologic specimens received within the previous 5 years for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, in 2023 and January 1, 2024 to the date of the survey in 2024. a. During an interview on April 8, 2024 at 10:50 AM, the Cytology Supervisor stated the laboratory's "5-year gyn pull list only prints cases if there was a prior cytology" and confirmed there was no documentation that every patient with a current HSIL, adenocarcinoma, or other malignant neoplasm was searched for prior normal or negative cases. b. Laboratory statistical records titled ANNUAL STATS GYN BY DX 2023 documented 69 HSIL, adenocarcinoma, or other malignant neoplasms reported by the laboratory in 2023. The laboratory failed to establish and follow a process to document the search for prior negatives on the 69 HSIL, adenocarcinoma, or other malignant neoplasms in 2023. c. Laboratory statistical records titled ANNUAL STATS GYN-# BY DX-2024 GYN documented nine HSIL, adenocarcinoma, or other malignant neoplasms reported by the laboratory January through March 2024. The laboratory failed to establish and follow a process to document the search for prior negatives on the nine HSIL, adenocarcinoma, or other malignant neoplasms in 2024. 3. The Survey Team identified and Technical Supervisor A confirmed on April 17, 2024 the laboratory failed to identify one of seven prior negative gynecologic cases as having a more significant lesion than was originally reported. Case includes: -CG21-12374

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 the lack of gynecologic cytology PT enrollment records and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure that the laboratory enrolled in an annual CMS-approved gynecologic cytology PT program for 2022 and 2023 (refer to D6088).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of gynecologic cytology PT enrollment records and interviews the Laboratory Director failed to ensure the laboratory enrolled in an annual CMS-approved gynecologic cytology PT program for 2022 and 2023. Findings include: 1. The Laboratory Director failed to ensure the laboratory enrolled in a CMS-approved PT program for 2022 and 2023. Refer to D2001
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 157 negative gynecologic cytology cases/161 slides and the corresponding final cytology test reports from January through March 2024 and confirmation by Technical Supervisor A on April 17, 2024, the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. CG24-4939 03/12/2024 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative For Intraepithelial Lesion Or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR A DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. CG24-4852 03/11/2024 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative For Intraepithelial Lesion Or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for evaluation; scant, bloody TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory for evaluation
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.