Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2052330	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pathologists Bio-Medical Laboratories, Pllc	2460 N Interstate Highway 35-E, Ste 230, Waxahachie, TX	

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
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, lack of morphology certification records and interview with the Quality Manager the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test in 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 one Technical Supervisor who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Technical Supervisor B 3. During an interview on August 22, 2023 at 1:30 PM these findings were confirmed by Quality Manager.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (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)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, statistical records and interview with the Quality Manager the laboratory failed to follow written policies and procedures for the evaluation and comparison of one of three nongynecologic cytology statistics. The laboratory failed to document one of three required annual nongynecologic statistics in 2021 and 2022. Findings include: 1. The laboratory failed to follow the policy QUALITY MANAGEMENT PROGRAM which stated: - "Statistical records are maintained, and evaluated at least annually, that include the number of cytopathologic specimens, the type/sources of specimens, and cases by diagnostic category." 2. The Survey Team requested and the laboratory failed to provide records of one of three required annual nongynecologic statistics in 2021 and 2022. Statistic includes: -Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory 3. During an interview on August 22, 2023 at 9:05 AM these findings were confirmed by Quality Manager. B. Based on review of laboratory policies and procedures, lack of statistical records and interview with the Quality Manager the laboratory failed to follow written policies and procedures for the evaluation and comparison of six of six gynecologic cytology statistics. The laboratory failed to document six of six required annual gynecologic statistics in 2021 and 2022. Findings include: 1. The laboratory failed to follow the policy QUALITY MANAGEMENT PROGRAM which stated: -"For gynecologic cytopathology cases, statistical records are maintained of the number of cases of the following cytopathology results. 1. Diagnostic category (including unsatisfactory cases), by preparation type 2. Significant cytologic/histologic discrepancies (as defined by laboratory policy) 3. Total number of negative cases rescreened before sign-out 4. Cases for which the rescreen resulted in reclassification as premalignant or malignant 5. Cases for which histopathology results are available to compare with malignant or high-grade squamous epithelial (HSIL) cytopathology results" 2. The Survey Team requested and the laboratory failed to provide records of six of six required annual gynecologic statistics in 2021 and 2022. Statistics include: -Number of cytology cases examined -Number of specimens processed by specimen type -Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) -Number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison -Number of gynecologic cases where cytology and histology are discrepant -Number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms 3. During an interview on August 22, 2023 at 9:05 AM these findings were confirmed by Quality Manager.
D5655	CYTOLOGY

	CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on August 22, 2023 at 8:45 AM these findings were confirmed by Laboratory Director /Technical Supervisor A.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on August 22, 2023 at 8:45 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final cytology test reports and interview with the Quality Manager 24 of 24 final cytology test reports from December 2021 to June 2022 failed to

	indicate the address of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 24 final cytology test reports from December 2021 to June 2022. Twenty-four of 24 final cytology test reports failed to indicate the address of the laboratory where the test was performed. 2021 test reports include: -PG21-16871 -PG21-16872 -PG21-16890 -PG21-16900 -PG21-16908 -PG21-16921 -PG21-16943 -PG21-16946 -PG21-16962 -PG21-16969 -PG21-16987 -PG21-16996 -PG21-17004 -PG21-17015 2022 test reports include: -PG22-1089 -PG22-1111 -PG22-1883 -PG22-2691 -PG22-2678 -PG22-2677 -PG22-2694 -PG22-2749 -PG22-2774 -PG22-3215 2. During an interview on August 22, 2023 at 11:00 AM these findings were confirmed by the Quality Manager.
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.