Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0321540	10/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	11751 Interchange Drive, Louisville, KY	

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 review of the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) gynecologic cytology proficiency test (PT) program instructions, gynecologic cytology PT participation records and interview the laboratory failed to meet the specified requirements for the annual gynecologic cytology PT examination in 2023 and 2024. The laboratory failed to administer the annual gynecologic cytology PT as required by the PT program's instructions in 2023 and 2024 (refer to D2015).
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two

years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on review of annual CAP gynecologic cytology PT program instructions, annual gynecologic cytology PT participation records and interview the laboratory failed to administer the PT examination as required by the CAP PT laboratory proctor instructions in 2023 and 2024. Findings include: 1. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS PAP PT PROCTOR PACKET INSTRUCTIONS which stated: "Fax the result form immediately after the examinee is done." a. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULTS FORMS, PAP PT SLIDESET VERIFICATION AND ATTESTATION FORMS and COMMUNICATION RESULT REPORTS (FAX REPORTS) for eight examinees in 2023. The laboratory failed to immediately (defined as within 30 minutes) fax the GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULTS FORMS for six of eight examinees. Examinees and record documentation includes: Cytotechnologist A Kit #37035388 Slideset #33983 Ten slides Test date: 09/12/2023 Start time: 09:40 AM Stop time: 10:50 AM Fax confirmation date and time: 12:01 PM Cytotechnologist C Kit #37035391 Slideset #33981 Ten slides Test date: 09/13/2023 Start time: 03:45 PM Stop time: 04:51 PM Fax confirmation date and time: 05:24 PM Cytotechnologist D Kit #37239874 Slideset #33981 Ten slides Test date: 09/12/2023 Start time: 09:08 AM Stop time: 10:18 AM Fax confirmation date and time: 10:53 AM Cytotechnologist G Kit #37035389 Slideset #33983 Ten slides Test date: 09/12/2023 Start time: 03:00 PM Stop time: 04:00 PM Fax confirmation date and time: 05:48 PM Technical Supervisor B Kit #36204436 Slideset #33983 Ten slides Test date: 09/13/2023 Start time: 03:02 PM Stop time: 03:30 PM Fax confirmation date and time: 04:29 PM Laboratory Director Kit #36204435 Slideset #33983 Ten slides Test date: 09/14/2023 Start time: 02:00 PM Stop time: 03:00 PM Fax confirmation date and time: 03:35 PM b. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULTS FORMS, PAP PT SLIDESET VERIFICATION AND ATTESTATION FORMS and COMMUNICATION RESULT REPORTS (FAX REPORTS) for eight examinees in 2024. The laboratory failed to immediately (defined as within 30 minutes) fax the GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULTS FORMS for six of eight examinees. Examinees and record documentation includes: Cytotechnologist A Kit #37649983 Slideset #34044 Ten slides Test date: 09/24/2024 Start time: 09:10 AM Stop time: 10:50 AM Fax confirmation date and time: 11:37 AM Cytotechnologist B Kit #37649985 Slideset #34042 Ten slides Test date: 09/26/2024 Start time: 09:37 AM Stop time: 10:01 AM Fax confirmation date and time: 10:47 AM Cytotechnologist C Kit #37649986 Slideset #34042 Ten slides Test date: 09/25/2024 Start time: 11:03 AM Stop time: 12:21 PM Fax confirmation date and time: 04:11 PM Cytotechnologist D Kit #37649988 Slideset #34042 Ten slides Test date: 09/24/2024 Start time: 09:46 AM Stop time: 10:56 AM Fax confirmation date and time: 11:37 AM * This time was after the time (11:35 AM) Cytotechnologist E began the test on the same slideset Cytotechnologist E Kit #37649987 Slideset #34042 Ten slides Test date: 09/24/2024 Start time: 11:35 AM Stop time: 01:10 PM Fax confirmation date and time: 02:19 PM Laboratory Director Kit #37649982 Slideset #34044 Ten slides Test date: 09/24/2024 Start time: 11:30 AM Stop time: 12:40 PM Fax confirmation date and time: 02:23 PM 2. During an interview on October 21, 2024 at 3:55 PM, the AP Director of Quality Management confirmed the records titled GYNECOLOGIC CYTOLOGY PAP PT INDIVIDUAL RESULTS FORM were not

	faxed immediately after each examinee completed the PT test. The AP Director of Quality Management, who also served at the PT Proctor, stated "it is not always possible to do it right away because I may be on a call or something."
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: Based on review of laboratory policies and procedures, statistical records and interviews the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of six of six required laboratory statistics. The laboratory failed to maintain statistical records for two of six statistics in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of two of six required statistics. Statistics include: -The number of gynecologic cytology cases; -The number of gynecologic cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). a. The laboratory failed to establish written policies and procedures to detail how a program would be established and followed to evaluate the two required statistics specifically for only the cases evaluated and reported from the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide the two of six annual statistics for 2023. 3. During an interview on October 21, 2024 at 11:30 AM, the AP Director of Quality Management confirmed that the statistics provided at the start of the survey titled GREAT LAKES GYNECOLOGIC (GYN) CYTOLOGY QUALITY METRIC BY SCREEN LOCATION which were printed prior to the survey on October 19, 2024 at 08:59 AM, included cases that were sent out to be reported by pathologists at another location. 4. During an interview on October 22, 2024 at 1:40 PM, the AP Director of Quality Management stated the laboratory was still working to retrieve and provide the statistics to reflect only the cases that were reported from this facility.
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.