Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 17D1019093	**(X3) Date Survey Completed** 05/17/2023
Name of Provider or Supplier Labcorp Kansas, Inc - Cyto Founders' Circle	**Street Address, City, State** 1947 N Founders Circle, Wichita, KS	
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**
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slides and interviews the laboratory failed to follow written policies and procedures to ensure specimen slides were labeled with a unique patient identifier (refer to D5203); failed to establish written policies and procedures to define effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process (refer to D5617); failed to establish written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and stain them separately from other nongynecologic specimens and filter or change the stains following staining (refer to D5619); failed to establish written policies and procedures to ensure the laboratory identified cases with a more significant lesion during the review of all negative gynecologic specimens received within the previous 5 years, for each patient with a current high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm, and failed to identify three of 29 prior negative gynecologic cases as having a more significant lesion than originally reported (refer to D5625); failed to document the rescreen results for 29 of 29 previous negative cases on current cases with a diagnosis of HSIL or malignancy (refer to D5627); failed to establish written policies and procedures for an annual statistical evaluation of six of six required gynecologic laboratory statistics, and failed to document six of six required gynecologic laboratory statistics (refer to D5629); and failed to establish written policies and procedures to ensure that a Technical Supervisor confirmed gynecologic slide preparations interpreted to exhibit reactive or reparative changes (refer to D5649).

D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, specimen slides and interviews the laboratory failed to follow written policies and procedures to ensure specimen slides were labeled with a unique patient identifier. The laboratory failed to ensure that 40 of 40 consecutive specimen slides from April 2023 were labeled with a unique patient identifier. Findings include: 1. The laboratory failed to follow the procedure LP-01 GYN CYTOLOGY (PAP TEST) LABORATORY PROCEDURES, which stated: "ix. Label ThinPrep slide with specimen accession number and patient's ID on the frosted end of the slide using a xylene resistant marker." 2. The Survey Team reviewed specimen slides for 40 consecutive patient specimens from April 2023. Forty of 40 specimen slides failed to be labeled with a unique patient identifier. Specimen slides include: Accession number Specimen slide -23-GY-2519 2519 -23-GY-2520 2520 -23-GY-2521 2521 -23-GY-2522 2522 -23-GY-2523 2523 -23-GY-2524 2524 -23-GY-2525 2525 -23-GY-2526 2526 -23-GY-2527 2527 -23-GY-2528 2528 -23-GY-2529 2529 -23-GY-2530 2530 -23-GY-2531 2531 -23-GY-2532 2532 -23-GY-2533 2533 -23-GY-2534 2534 -23-GY-2535 2535 -23-GY-2536 2536 -23-GY-2537 2537 -23-GY-2538 2538 -23-GY-2539 2539 -23-GY-2540 2540 -23-GY-2541 2541 -23-GY-2542 2542 -23-GY-2543 2543 -23-GY-2544 2544 -23-GY-2545 2545 -23-GY-2546 2546 -23-GY-2547 2547 -23-GY-2548 2548 -23-GY-2549 2549 -23-GY-2550 2550 -23-GY-2551 2551 -23-GY-2552 2552 -23-GY-2553 2553 -23-GY-2554 2554 -23-GY-2555 2555 -23-GY-2556 2556 -23-GY-2557 2557 -23-GY-2558 2558 3. During an interview on May 16, 2023 at 1:15 PM, Staff A stated that the complete accession number was not written on the frosted end of the specimen slide with a xylene resistant marker during processing. 4. During an interview on May 16, 2023 at 2:25 PM, these findings were confirmed with the Quality Manager, Laboratory Manager and Cytotechnologist A. 5. During an interview on May 17, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 74 laboratory policies and procedures, interviews and review of laboratory records the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure LP-01 GYN CYTOLOGY (PAP TEST) LABORATORY PROCEDURES, which stated: "iii. Either weekly or after 820 slides, whichever comes first, replace all solutions and

	record in maintenance log book (see Exhibit C)." a. During an interview on May 16, 2023 at 12:50 PM, Staff B stated that gynecologic and nongynecologic specimen slides were stained on the Sakura Tissue-Tek autostainer. Staff B further stated that the number nongynecologic specimen slides stained was not documented on the records titled THINPREP STAIN MAINTENANCE. b. The Survey Team reviewed records titled THINPREP STAIN MAINTENANCE from 2022 through the date of the survey in 2023. The records failed to document the number of nongynecologic specimen slides that were stained on the Sakura Tissue-Tek autostainer. c. During an interview on May 16, 2023 at 2:25 PM, these findings were confirmed with the Quality Manager, Laboratory Manager and Cytotechnologist A. d. During an interview on May 17, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5617	CYTOLOGY CFR(s): 493.1274(b)(2) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures to define effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process. 2. During an interview on May 16, 2023 at 12:50 PM, Staff B stated that gynecologic and nongynecologic specimens were stained on the Sakura Tissue-Tek autostainer. Staff B further stated the stains and solutions were not filtered or replaced between staining gynecologic and nongynecologic specimens. 3. During an interview on May 16, 2023 at 2:25 PM, these findings were confirmed with the Quality Manager, Laboratory Manager and Cytotechnologist A. 4. During an interview on May 17, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5619	CYTOLOGY CFR(s): 493.1274(b)(3) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures to identify nongynecologic specimens with a high potential for cross-contamination and stain them separately from other nongynecologic specimens and filter or change the stains following

	staining. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to identify nongynecologic specimens with a high potential for cross-contamination and stain them separately from other nongynecologic specimens and filter or change the stains following staining. 2. During an interview on May 16, 2023 at 12:50 PM, Staff B stated that the laboratory did not identify nongynecologic specimens with a high potential for cross-contamination and stain them separately. Staff B further stated that all nongynecologic specimens were stained together. 3. During an interview on May 16, 2023 at 2:25 PM, these findings were confirmed with the Quality Manager, Laboratory Manager and Cytotechnologist A. 4. During an interview on May 17, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 and microscopic review of specimen slides the laboratory failed to establish written policies and procedures to ensure the laboratory identified cases with a more significant lesion during the review of all negative gynecologic specimens received within the previous 5 years, for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm. The laboratory failed to identify three of 29 prior negative gynecologic cases from 21 current HSIL's from January 2021 through December 2022, as having a more significant lesion than originally reported. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory identified cases with a more significant lesion during the review of all negative gynecologic specimens received within the previous 5 years, for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm reported by the laboratory. a. The procedure QI-22 RETROSPECTIVE RESCREENS OF GYN (PAP) SPECIMENS failed to describe how the laboratory would identify and document the rescreen results of specimens with a more significant lesion. Refer to D5627. 2. The Survey Team reviewed records titled FIVE YEAR RETRO-REVIEW OF CURRENT HIGH GRADE/CA. The Survey Team reviewed 29 previous negative gynecologic cases from 21 current cases of HSIL from January 2021 through December 2022. a. The Survey Team identified and the Laboratory Director/Technical Supervisor A confirmed on May 17, 2023 that the laboratory failed to identify three of 29 prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative cases include: -20-GY-4927 -20-GY-5416 -19-GY-3494
D5627	CYTOLOGY CFR(s): 493.1274(c)(4)

	Records of initial examinations and all rescreening results must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews the laboratory failed to document the rescreen results for 29 of 29 previous negative cases from current cases with a diagnosis of HSIL or malignancy from January 2021 through December 2022. Findings include: 1. The Survey Team reviewed records titled FIVE YEAR RETRO-REVIEW OF CURRENT HIGH GRADE/CA from January 2021 through December 2022. The laboratory failed to document the rescreen results for 29 of 29 previous negative cases from current cases with a diagnosis of HSIL or malignancy from January 2021 through December 2022. Cases include: 21-GY-2794 21-GY-9862 20-GY-394 20-GY-2049 20-GY-4927 20-GY-5416 20-GY-6874 20-GY-8270 20-GY-8281 20-GY-9222 20-GY-9924 20-GY-10308 20-GY-14000 19-GY-13 19-GY-1272 19-GY-2661 19-GY-3494 19-GY-5727 19-GY-6470 19-GY-8732 19-GY-9816 19-GY-11938 19-GY-16078 19-GY-17327 19-GY-18145 18-GY-7192 18-GY-10347 18-GY-19260 18-GY-19526 2. During an interview on May 16, 2023 at 2:25 PM, these findings were confirmed with the Quality Manager, Laboratory Manager and Cytotechnologist A. 3. During an interview on May 17, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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, laboratory records and interviews the laboratory failed to establish written policies and procedures for an annual statistical evaluation of six of six required gynecologic laboratory statistics. The laboratory failed to document six of six required gynecologic laboratory statistics for 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six of six required gynecologic statistics. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation; -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; -The number of gynecologic cases where cytology and histology are discrepant; -The 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. 2. The Survey Team requested and the laboratory failed to provide six of six required annual gynecologic laboratory statistics for 2021 and 2022. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation; -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; -The number of gynecologic cases where cytology and histology are discrepant; -The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasms. 3. During an interview on May 16, 2023 at 2:25 PM, these findings were confirmed with the Quality Manager, Laboratory Manager and Cytotechnologist A. 4. During an interview on May 17, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5649	CYTOLOGY CFR(s): 493.1274(e)(1) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities: (e)(1)(i) Squamous cell. (e)(1)(i)(A) Atypical squamous cells of undetermined significance (ASC-US) or cannot exclude HSIL (ASC-H). (e)(1)(i)(B) LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1). (e)(1)(i)(C) HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion. (e)(1)(i)(D) Squamous cell carcinoma. (e)(1)(ii) Glandular Cell (e)(1)(ii)(A) Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular). (e)(1)(ii)(B) Atypical cells favor neoplastic (endocervical or glandular). (e)(1)(ii)(C) Endocervical adenocarcinoma in situ. (e)(1)(ii)(D) Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS. (e)(1)(iii) Other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, final test reports and interviews the laboratory failed to establish written policies and procedures to ensure that a Technical Supervisor confirmed gynecologic slide preparations interpreted to exhibit reactive or reparative changes. The laboratory failed to ensure 20 of 20 gynecologic slide preparations interpreted to exhibit reactive or reparative changes from March through April 2023 were confirmed by a Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure a Technical Supervisor confirmed each gynecologic slide preparation interpreted to exhibit reactive or reparative changes. 2. The Survey Team reviewed 20 final test reports from March through April 2023 that reported "Reactive cellular changes associated with inflammation." Twenty of 20 final test reports were not confirmed by a Technical Supervisor. Test reports include: -23-GY-2140 -23-GY-2151 -23-GY-2204 -23-GY-2315 -23-GY-2322 -23-GY-2346 -23-GY-2359 -23-GY-2384 -23-GY-2398 -23-GY-2418 -23-GY-2421 -23-GY-2423 -23-GY-2428 -23-GY-2430 -23-GY-2439 -23-GY-2465 -23-GY-2466 -23-GY-2469 -23-GY-2476 -23-GY-2482 3. During an interview on May 16, 2023 at 2:25 PM, these

	findings were confirmed with the Quality Manager, Laboratory Manager and Cytotechnologist A. 4. During an interview on May 17, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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, final test reports and gynecologic specimen slides the laboratory failed to follow written policies and procedures to ensure unsatisfactory gynecologic specimen slides were identified and reported as unsatisfactory. The laboratory failed to identify and report one of eight gynecologic specimen slides from March through April 2023 as unsatisfactory. Findings include: 1. The laboratory failed to follow the procedure LP-03 SCREENING PROCEDURE, which stated: "ii. Liquid Base SurePath and ThinPrep paps: Insufficient number of cells on a liquid base specimen is considered to be less than 5000 squamous cells." 2. The laboratory failed to identify and report one of eight gynecologic specimen slides from March through April 2023 as unsatisfactory. Specimen slide includes: -23-GY-2258
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 the microscopic review of 373 negative gynecologic cases/386 slides from March through April 2023 the Technical Supervisor failed to verify the accuracy of three gynecologic cytology tests. 1. 23-GY-2485 04/10/2023 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR A DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 2. 23-GY-2298 04/03/2023 I-TPPT 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 3. 23-GY-2258 03/31/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation Insufficient Cellularity TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory for Interpretation Mostly Inflammatory Cells
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.