Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0664386	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
North Carolina Baptist Hospital Pathology Lab	Medical Center Boulevard, Winston-Salem, NC	

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, microscopic review of specimen slides and interviews the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors and Cytotechnologists (refer to D5209); failed to follow two written policies and procedures (refer to D5401); failed to follow 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), adenocarcinoma, or malignant neoplasms with available histopathology (refer to D5623); failed to establish and follow written policies and procedures to review prior gynecologic cases and identify cases with a more significant lesion (refer to D5625); failed to establish and follow written policies and procedures for an annual statistical evaluation of the required laboratory statistics (refer to D5629); failed to establish and follow written policies and procedures to reassess a maximum workload limit at least every six months for the Cytotechnologists (refer to D5637); and failed to establish written policies and procedures to ensure workload limits for the Cytotechnologists would be prorated when examining slides in less than an eight-hour work day (refer to D5641).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, lack of competency assessment records and interview the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of six of six Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for six of six Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 3. During an interview on April 10, 2024 at 12:00 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation. B. Based on review of laboratory policies and procedures, competency assessment records and interviews the laboratory failed to follow written policies and procedures to assess the competency of seven of seven Cytotechnologists in 2022. Findings include: 1. The laboratory failed to follow the procedure PERSONNEL FILE, CONTINUING EDUCATION, TRAINING AND COMPETENCY, which stated: "For new hires competency assessment will be performed semiannually (first assessment within seven months from initiation of testing) and second assessment no later than 12 months from the start of testing during the first year, and annually thereafter." 2. The Survey Team requested and the laboratory failed to provide competency assessment records for seven of seven Cytotechnologists in 2022. Cytotechnologists include: -Cytology Manager -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C -Cytotechnologist D -Cytotechnologist E -Cytotechnologist F 3. During an interview on April 9, 2024 at 1: 40 PM, the Cytology Manager stated "I was a little late doing them." 4. During an interview on April 10, 2024 at 12:00 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation.
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 57 laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow two written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure ADDENDUM OR AMENDMENT TO A SIGNED-OUT CASE IN AP BEAKER PROCEDURE, which stated: "In the Correction History Component, enter ".amend" to insert the amended smart phrase that will indicate to the person getting a new report what has been

	changed." a. The Survey Team reviewed five corrected final test reports from December 2023 and January 2024. Two of five corrected final test reports failed to indicate the report was a corrected final test report. Refer to D5821 2. The laboratory failed to follow the procedure PERSONNEL FILE, CONTINUING EDUCATION, TRAINING AND COMPETENCY, which stated: "For new hires competency assessment will be performed semiannually (first assessment within seven months from initiation of testing) and second assessment no later than 12 months from the start of testing during the first year, and annually thereafter." a. The Survey Team requested and the laboratory failed to provide competency assessment records for two of three Staff in 2022. Staff includes: -Staff A -Staff B b. During an interview on April 9, 2024 at 1:40 PM, the Cytology Manager stated "I was a little late doing them." 3. During an interview on April 10, 2024 at 12:00 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation.
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 the laboratory failed to follow 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 HSIL, adenocarcinoma, or malignant neoplasms with available histopathology. The laboratory failed to determine the cause of discrepancy between gynecologic cytology cases with a diagnosis of HSIL or malignancy and the histopathology diagnosis for one of eight cases in 2023. Findings include: 1. The laboratory failed to follow the procedure CYTO-HISTO CORRELATION STUDIES & CLINICAL FOLLOW-UP, which stated: "Discrepant cases are reviewed by the cytology lab manager or designated senior cytotechnologist and sent, with corresponding biopsies, to the cytology fellow for further review. If no errors are found, documentation thereof will be maintained in a correlation binder." 2. The Survey Team reviewed an untitled document that listed all HSIL and malignant cytology cases and the results of follow-up histopathology for 2023. a. The Survey Team identified eight cytology cases with discrepant histopathology diagnoses. b. The Survey Team reviewed laboratory records titled GYNECOLOGICAL CYTO/HISTO CORRELATION used to document the cause of discrepancy between gynecologic cytology cases with a diagnosis of HSIL or malignancy and the histopathology diagnosis. The laboratory failed to document the cause of discrepancy for one of eight cases in 2023. Case includes: -WFG23-2940 3. During an interview on April 10, 2024 at 12:00 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation.
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 interview the laboratory failed to establish and follow written policies and procedures to ensure the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy was performed. The laboratory failed to document the search for prior negative gynecologic specimens for 87 of 95 HSIL or malignant specimens from 2023. The laboratory failed to identify one of 30 HSIL or malignant specimens as having prior negative specimens, and failed to identify two of 23 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 to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. a. The procedure 5-YEAR RETROSPECTIVE NEGATIVE REVIEW OF CURRENT HGSIL/CANCER failed to describe how the search of current HSIL and malignant specimens would be documented if there were no prior negative specimens. 2. The Survey Team requested and the laboratory failed to provide records of the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. The laboratory failed to document the search for prior negative gynecologic specimens for 87 of 95 HSIL or malignant specimens from 2023. Specimens include: -WFG23-00085 -WFG23-00161 -WFG23-00238 -WFG23-00249 -WFG23-00415 -WFG23-00579 -WFG23-00599 -WFG23-00634 -WFG23-00738 -WFG23-00770 -WFG23-00789 -WFG23-00965 -WFG23-01107 -WFG23-01280 -WFG23-01562 -WFG23-01677 -WFG23-01705 -WFG23-02006 -WFG23-02056 -WFG23-02110 -WFG23-02366 -WFG23-02674 -WFG23-02746 -WFG23-03430 -WFG23-03490 -WFG23-04096 -WFG23-04137 -WFG23-04381 -WFG23-04783 -WFG23-04832 -WFG23-05663 -WFG23-06067 -WFG23-06221 -WFG23-06432 -WFG23-06804 -WFG23-07337 -WFG23-07429 -WFG23-07558 -WFG23-07588 -WFG23-07672 -WFG23-07714 -WFG23-08024 -WFG23-08032 -WFG23-08206 -WFG23-08628 -WFG23-08681 -WFG23-08805 -WFG23-09227 -WFG23-09539 -WFG23-09759 -WFG23-09949 -WFG23-10462 -WFG23-10654 -WFG23-10882 -WFG23-10901 -WFG23-11056 -WFG23-11911 -WFG23-12036 -WFG23-12082 -WFG23-12092 -WFG23-12222 -WFG23-12311 -WFG23-12876 -WFG23-13556 -WFG23-13597 -WFG23-13699 -WFG23-13832 -WFG23-13876 -WFG23-13935 -WFG23-14393 -WFG23-14430 -WFG23-14755 -WFG23-15163 -WFG23-15177 -WFG23-15202 -WFG23-15401 -WFG23-15436 -WFG23-15498 -WFG23-16078 -WFG23-11767 -WFG23-16314 -WFG23-16477 -WFG23-16527 -WFG23-16594 -WFG23-16656 -WFG23-16740 -WFG23-16790 a. The Survey Team reviewed a sample of 30 HSIL or malignant specimens from 2023 and identified one of the 30 HSIL or malignant

	specimens that had one prior negative specimen the laboratory failed to identify. Specimen includes: -WFG23-00599 3. The Survey Team identified and Technical Supervisor A confirmed on April 10, 2024 the laboratory failed to identify two of 23 prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative cases include: -P20-11650 -P20-17584 4. During an interview on April 10, 2024 at 12:00 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation.
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 and interview the laboratory failed to establish written policies and procedures for an annual statistical evaluation of two of six required gynecologic laboratory statistics. 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 gynecologic statistics. Statistics include: -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 2. During an interview on April 10, 2024 at 12:00 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation. B. Based on review of laboratory policies and procedures, laboratory statistical records and interview the laboratory failed to follow written policies and procedures for the evaluation and comparison of two of three nongynecologic cytology statistics. The laboratory failed to document two of three required annual nongynecologic statistics for 2022 and 2023. Findings include: 1. The laboratory failed to follow the procedure STATISTICAL REPORTS POLICY, which stated: "Statistical data is analyzed for the following:" "Number of specimens processed by specimen type" "Volume of patient cases reported by diagnoses, including number or cases reported as unsatisfactory for diagnosis" 2. The Survey Team requested and the laboratory failed to provide records of two of three required annual nongynecologic statistics for 2022 and 2023. Statistics include: -Number of specimens processed by specimen type -Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) 3. During an interview on April 8, 2024 at 4:20 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation.

D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. 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 and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Cytotechnologists. The laboratory failed to ensure the Technical Supervisor reassessed the maximum workload limits at least every six months for seven of seven Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess a maximum workload limit for the Cytotechnologists at least every six months and adjust when necessary. a. The procedure WORKLOAD SURVEILLANCE CYTOTECHNOLOGIST failed to state when the Technical Supervisor would reassess workload limits for the Cytotechnologists. 2. The Survey Team requested workload reassessment records titled CYTOTECHNOLOGIST PRODUCTIVITY EVALUATION AND COMPETENCY ASSESSMENT for 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The laboratory provided workload assessment records for the period of June 2023 through December 31, 2023 for seven of seven Cytotechnologists. The Technical Supervisor failed to reassess the workload limit for the period until March 13, 2024. Cytotechnologists include: -Cytology Manager -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C -Cytotechnologist D -Cytotechnologist E -Cytotechnologist F b. The laboratory failed to provide workload reassessment records for January 2022 through December 2022 and January 2023 through June 2023 for seven of seven Cytotechnologists. Cytotechnologists include: -Cytology Manager -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C -Cytotechnologist D -Cytotechnologist E -Cytotechnologist F c. During an interview on April 9, 2024 at 1:40 PM, the Cytology Manager confirmed workload limits were not reassessed at least every six months in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 3. During an interview on April 10, 2024 at 12:00 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview the laboratory

	failed to establish written policies and procedures to ensure workload limits for the Cytotechnologists would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Cytotechnologists when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. During an interview on April 8, 2024 at 4:20 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. 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 and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the competency of the Technical Supervisors and Cytotechnologists. Refer to D5209 b. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or malignant neoplasms with available histopathology. Refer to D5623 c. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the program to review prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy and identify cases with a more significant lesion. Refer to D5625 d. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the annual statistical evaluation of the required laboratory statistics. Refer to D5629 e. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the reassessment of workload limits at least every six months. Refer to D5637 f. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate corrected final test reports to ensure corrected final test reports indicated the reports were corrected final test reports. Refer to D5821
D5821	TEST REPORT CFR(s): 493.1291(k)

	When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of corrected final test reports and interview the laboratory failed to ensure two of five corrected final test reports indicated the reports were corrected final test reports. Findings include: 1. The Survey Team reviewed five corrected final test reports from December 2023 and January 2024. Two of five corrected final test reports failed to indicate the report was a corrected final test report. Reports include: -WFP23-02595 -WFG24-01156 2. During an interview on April 8, 2024 at 4:20 PM, these findings were confirmed with the Laboratory Director, Cytology Manager and Director of Quality, Safety and Accreditation. The Cytology Manager stated that corrected final test reports were supposed to state "Amended Report" on the corrected final test report.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of workload records and interviews the Technical Supervisor failed to reassess a maximum workload limit at least every six months for seven of seven Cytotechnologists in 2022 and 2023. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a maximum workload limit at least every six months for seven of seven Cytotechnologists in 2022 and 2023. Refer to D5637 Cytotechnologists include: -Cytology Manager -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C -Cytotechnologist D -Cytotechnologist E -Cytotechnologist F
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.