Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1025073	09/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Norman Regional Hospital	3300 Healthplex Parkway, Norman, OK	

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 lack of proficiency testing (PT) enrollment records and interview it was determined that the laboratory failed to enroll in an 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 lack of cytology PT enrollment records and interview it was determined that the laboratory failed to enroll in a HHS-approved cytology PT program for

	gynecologic examination for 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in an approved cytology PT program for 2019 and 2020. 2. During an interview at 9:00 AM on September 7, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
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 and interviews it was determined the laboratory failed to establish written policies and procedures for the transportation of gynecologic cytology slides (refer to D5311); failed to establish written policies and procedures for laboratory test process (refer to D5403); failed to ensure that three laboratory procedures were signed as approved by the Laboratory Director prior to use (refer to D5407); failed to establish written policies and procedures to compare gynecologic cytology cases with a diagnosis of HSIL or malignancy with the histopathology diagnosis (refer to D5623); failed to establish written policies and procedures for the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy (refer to D5625); failed to establish written policies and procedures for an annual statistical evaluation of six of six required laboratory statistics, and failed to ensure the laboratory documented the six required annual statistics (refer to D5629); and failed to establish written policies and procedures to ensure unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures it was determined that the laboratory failed to establish written policies and procedures for the transportation of cytology slides from Facility B (CLIA #37D0469942) to Facility A (CLIA #37D1025073). Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the documentation of the conditions required for the transportation of cytology slides from Facility B to Facility A.
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 six laboratory policies and procedures and interview it was determined that the laboratory failed to establish 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 process for gynecologic cytology PT enrollment and participation of personnel that perform gynecologic cytology testing. 2. During an interview at 9:00 AM on September 7, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to ensure that three of six written policies and procedures were approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to approve, sign and date three of six laboratory procedures in the cytology manual. Procedures include: - Addendum and Amendments - Cytology Specimens - Accessioning and Reporting - Dispatching Couriers for Pick-ups 2. During a telephone interview at 3:45 PM on September 7, 2021, the Laboratory DirectorTechnical Supervisor #1 confirmed these findings.
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 and lack of laboratory records it was determined that the laboratory failed to establish written policies and procedures to compare clinical information with the gynecologic cytology reports and to compare gynecologic cytology cases with a diagnosis of HSIL or malignancy with available histopathology reports for 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to compare clinical information with gynecologic cytology reports and to compare HSIL or malignant gynecologic cytology cases with available histopathology reports. 2. The Survey Team requested and the laboratory failed to provide records of a comparison of each HSIL or malignant gynecologic cytology case with histopathology reports for 2019, 2020 and to the date of the survey in 2021.
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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that 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 for 2019, 2020 and to the date of the survey in 2021. 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. 2. The Survey Team requested and the laboratory failed to provide records of a search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy in 2019, 2020 and to the date of the survey in 2021. 3. During a telephone interview at 3:45 PM on September 7, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics and failed to document six of six required annual statistics for 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six required statistics. 2. The Survey Team requested and the laboratory failed to provide six of six required annual statistics for 2019 and 2020. 3. During a telephone interview at 4:15 PM on September 8, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
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 it was determined that the laboratory failed to establish written policies and procedures to ensure unsatisfactory gynecologic 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 gynecologic specimens were identified and reported as unsatisfactory. 2. During a telephone interview at 4:15 PM on September 8, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
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 review of laboratory policies and procedures, laboratory records and interviews it was determined that 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 PT enrollment for a gynecologic cytology program in 2019 and 2020 (refer to D6088); failed to ensure that written policies and procedures for quality assessment programs were established (refer to D6094); and failed to ensure that written policies and procedures were established to evaluate the competency of three of three Technical Supervisors who performed microscopic evaluations and reporting of gynecologic results for 2019, 2020 and to the date of the survey in 2021 (refer to D6103).
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 PT enrollment records and interview it was determined that the Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2019 and 2020. Findings include: 1. The Laboratory Director failed to ensure that the laboratory enrolled in an HHS-approved PT program for 2019 and 2020. 2. During an interview at 9:00 AM on September 7, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established for analytic and postanalytic quality assessment programs. Cross refer to D5623, D5625 and D5629 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for analytic and postanalytic quality assessment programs. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic and postanalytic quality assessment activities for 2019, 2020 and to the date of the survey in 2021. 3. During a telephone interview at 3:45 PM on September 7, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure that written policies and procedures were established to evaluate the competency of three of three Technical Supervisors who performed microscopic evaluations and reporting of gynecologic cytology results for 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for three of three Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor #1 -Technical Supervisor #2 -Technical Supervisor #3 3. During a telephone interview at 3:45 PM on September 7, 2021, Laboratory Director/Technical Supervisor #1 confirmed these findings.
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.