Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0699484	09/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Norman Regional Porter	901 N Porter Ave, 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 the lack of cytology proficiency testing (PT) enrollment records and interview it was determined that the laboratory failed to enroll in an approved 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 the lack of cytology PT enrollment records and interviews it was determined that the laboratory failed to enroll in an 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 on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology/Histology Supervisor. 3. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
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, slide preparations and interviews it was determined the laboratory failed to establish 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 for the collection, labeling, storage and preservation, and transportation of nongynecologic specimens (refer to D5311); failed to establish written policies and procedures for five laboratory test processes (refer to D5403); failed to establish written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination (refer to D5619); failed to establish written policies and procedures to ensure unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report cytology test results (refer to D5657); and failed to ensure final test reports indicated the correct name of the laboratory where the test was performed (refer to D5805).
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 it was determined that the laboratory failed to establish written policies and procedures to ensure specimen slides were labeled with a unique patient identifier. The laboratory failed to ensure that five of six patient specimens from January and February 2021 had specimen slides labeled with a unique patient identifier. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure specimen slides were labeled with a unique patient identifier. 2. The Survey Team reviewed specimen slides from six cases from January and February 2021 that had an additional slide preparation made. The additional prepared specimen slide for five of the six cases failed to have a unique patient identifier. Cases include: P21-81 Identifier on additional slide: 21-81 P21-88 Identifier on additional slide: 21-88 P21-261 Identifier on additional slide: 21-261

	P21-294 Identifier on additional slide: 21-294 P21-438 Identifier on additional slide: 21-438 3. During an interview on September 8, 2021 at 11:45 AM, these findings were confirmed with the Administrative Laboratory Director, Laboratory Manager and Pathology/Histology Supervisor. 4. During an interview on September 9, 2021 at 9:00 AM, the Survey Team requested a procedure detailing how slides were to be labeled. The Pathology/Histology Supervisor stated "I'm pretty sure I don't have that."
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 and interview it was determined that the laboratory failed to establish written policies and procedures for the collection, labeling, storage and preservation, and transportation of nongynecologic specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the collection, labeling, storage and preservation, and transportation of nongynecologic specimens. 2. During an interview on September 8, 2021 at 11:05 AM, these findings were confirmed with the Pathology/Histology Supervisor.
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 thirteen laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure H & E MANUAL STAIN - FROZEN SECTIONS which stated: "H&E stain, HE stain or hematoxylin and eosin stain, is a popular staining method in histology. It is the most widely used stain in medical diagnosis; for example when a pathologist looks at a biopsy of a suspected cancer, the histological section is likely to be stained with H&E and termed H&E section, H+E section, or HE section. It is also used for staining cytology slides from endo bronchial (EBUS) procedures and thyroid adequacy procedures." "the 1st case of the day will be used to QC H&E stain" a. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the hematoxylin and eosin (H&E) stain used for the immediate assessment of nongynecologic cytology slides was assessed each day of use in 2020 and to the date of the survey in 2021. b. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology/Histology Supervisor.

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 thirteen laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures for five laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for enrolling and participating in an HHS-approved cytology PT program. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for accessioning nongynecologic specimens into the laboratory information system (LIS). 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for the entering and reporting of cytology test results into the LIS. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to test staining materials for intended reactivity of the nongynecologic Diff Quick stain for each day of use. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the storage and retention requirements for gynecologic cytology slides. a. During an interview on September 7, 2021 at 9:55 AM, the Administrative Laboratory Director stated that gynecologic slides were stored at Facility B (CLIA #37D0469942). 6. During an interview on September 7, 2021 at 1: 50 PM, these findings were confirmed with the Pathology/Histology Supervisor. 7. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on the lack of laboratory records and interviews it was determined that the laboratory failed to test staining materials for intended reactivity of the Diff Quick stain and Hematoxylin and Eosin (H&E) stain for each day of use in 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Diff Quick stain used for the immediate assessment of nongynecologic cytology slides was assessed each day of use in 2020 and to the date of the survey in 2021. 2. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the H&E stain used for the immediate assessment of nongynecologic cytology slides was assessed each day of use in 2020 and to the date of the survey in 2021. 3. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology/Histology Supervisor. 4. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. 2. The Survey Team requested and the laboratory failed to provide records documenting that stains were filtered or changed following staining of specimens with a high potential for cross-contamination. 3. During an interview on September 8, 2021 at 11:45 AM, these findings were confirmed with the Pathology/Histology Supervisor.
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 interviews it was determined that the laboratory failed to establish written policies and procedures for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. 2. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology/Histology Supervisor. 3. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
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 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 high grade squamous intraepithelial lesion (HSIL) or malignancy was performed. 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 malignancy reported by the laboratory. 2. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed by Technical Supervisor C. Technical Supervisor C stated that the search and review of prior negative specimens was performed by Facility B.
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 interviews it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of six of six required laboratory statistics. The laboratory failed to document the 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 of six required statistics. 2. The Survey Team requested and the laboratory failed to provide the six required annual statistics for 2019 and 2020. 3. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology /Histology Supervisor. 4. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
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 interviews it was determined that the laboratory failed to establish written policies and procedures to ensure unsatisfactory gynecologic and 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 include criteria to ensure unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to include criteria to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 3. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology/Histology Supervisor. 4. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
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 interviews it was determined that the laboratory failed to establish written policies and procedures for

	the system of narrative descriptive nomenclature used by the laboratory to report gynecologic and 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 gynecologic and nongynecologic cytology test results. 2. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology/Histology Supervisor. 3. During an interview on September 7, 2021 at 4:00 PM, Technical Supervisor C stated that the laboratory used The Bethesda System for Reporting Gynecologic Cytology and The Bethesda System for Reporting Thyroid Cytopathology.
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 test reports and interview it was determined that 35 of 35 final test reports from January 2021 and July through September 2021 failed to indicate the correct name of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 35 final test reports from January 2021 and July through September 2021. Thirty-five of 35 final test reports failed to indicate the correct name of the laboratory where the test was performed. Reports include: - P21-1 - P21-2 - P21-3 - P21-4 - P21-5 - P21-11 - P21-12 - P21-14 - P21-15 - P21-16 - P21-18 - P21-20 - NR21-523 - NR21-539 - NR21-541 - NR21-635 - NR21-636 - NR21-637 - NR21-638 - NR21-639 - NR21-640 - NR21-641 - NR21-642 - NR21-644 - NR21-645 - NR21-646 - NR21-647 - NR21-648 - NR21-704 - NR21-705 - NR21-706 - NR21-707 - NR21-708 - NR21-709 - NR21-710 2. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Laboratory Manager.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the postanalytic phases of cytology testing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an

	ongoing mechanism to monitor, assess and correct problems identified in the postanalytic phases of testing. 2. The Survey Team requested and the laboratory failed to provide documentation of any postanalytic quality assessment activities or problems. 3. The Survey Team reviewed 35 final test reports from January 2021 and July through September 2021. Thirty-five of 35 final test reports indicated the incorrect CLIA number where the test was performed and failed to indicate the correct name of the laboratory where the test was performed. Reports include: - P21-1 - P21-2 - P21-3 - P21-4 - P21-5 - P21-11 - P21-12 - P21-14 - P21-15 - P21-16 - P21-18 - P21-20 - NR21-523 - NR21-539 - NR21-541 - NR21-635 - NR21-636 - NR21-637 - NR21-638 - NR21-639 - NR21-640 - NR21-641 - NR21-642 - NR21-644 - NR21-645 - NR21-646 - NR21-647 - NR21-648 - NR21-704 - NR21-705 - NR21-706 - NR21-707 - NR21-708 - NR21-709 - NR21-710 a. During an interview on September 7, 2021 at 9:35 AM, the Administrative Laboratory Director stated "We have been having issues with that." b. During an interview on September 7, 2021 at 1:50 PM, the Laboratory Manager stated the CLIA number on the final test reports was for Facility C (37D1040474) and not the laboratory being surveyed. 4. The Survey Team identified one random nongynecologic final test report that documented the incorrect number of slide preparations for the case. Report includes: N21-555 Final Test Report: 1 ThinPrep slide Actual Glass Slides: 1 ThinPrep slide, 1 cell block slide 5. During an interview on September 7, 2021 at 2:30 PM, these findings were confirmed with the Pathology/Histology Supervisor. 6. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
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 that the laboratory enrolled in an annual gynecologic cytology PT program for 2019 and 2020 (refer to D6088); failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur (refer to D6093); and failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of personnel performing cytology testing (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. Cross refer to D2001 Findings include: 1. The Laboratory Director failed to ensure that the laboratory enrolled in an HHS-approved PT program for 2019 and 2020.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 interviews it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross refer to D5473, D5623, D5625, D5629 Findings include: 1. The Laboratory Director failed to ensure the laboratory tested staining materials for intended reactivity of the Diff Quick stain and H&E stain used for the immediate assessment of nongynecologic slides. 2. The Laboratory Director failed to ensure written policies and procedures were established for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. 3. The Laboratory Director failed to ensure written policies and procedures were established 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. 4. The Laboratory Director failed to ensure written policies and procedures were established for an annual statistical evaluation of six of six required laboratory statistics, and failed to ensure the laboratory documented the six required annual statistics.
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, laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5891 Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic phases of testing.
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 interviews it was determined that the Laboratory Director failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of personnel performing cytology testing. 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. a. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for four of four Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of Staff performing slide preparation and staining of nongynecologic specimens for rapid assessment. a. The Survey Team requested and the laboratory failed to provide competency assessment records for three of three Staff performing nongynecologic slide preparation and staining for 2019, 2020 and to the date of the survey in 2021. Staff includes: - Pathology/Histology Supervisor - Staff A - Staff B 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of Staff performing nongynecologic specimen accessioning. a. The Survey Team requested and the laboratory failed to provide competency assessment records for four of four Staff performing nongynecologic specimen accessioning for 2019, 2020 and to the date of the survey in 2021. Staff includes: - Pathology/Histology Supervisor - Staff A - Staff B - Staff C 4. During an interview on September 7, 2021 at 1:50 PM, these findings were confirmed with the Pathology/Histology Supervisor. 5. During an interview on September 7, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C.
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 305 random negative gynecologic cases/311 slides and the corresponding final test reports from January through May 2021 it was determined that the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. P21-214 01/21/2021 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS: 2. P21-441 02/08/2021 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS:

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.