Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1085608	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
White River Medical Center	1710 Harrison Street, Batesville, AR	

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 the lack of laboratory policies and procedures, record review, observation and interviews it was determined the laboratory failed to establish written policies and procedures to ensure positive identification of patient specimens (refer to D5203); failed to establish written policies and procedures to assess the competency of seven of seven Technical Supervisors (refer to D5209); failed to establish written policies and procedures to describe how nongynecologic specimens were collected, labeled, stored, preserved and transported (refer to D5311); failed to have a procedures manual available to personnel (refer to D5401); failed to establish written policies and procedures for any laboratory test processes (refer to D5403); failed to test staining materials for intended reactivity (refer to D5473); failed to establish written policies and procedures for the evaluation and comparison of three of three required nongynecologic statistics (refer to D5629); failed to establish written policies and procedures to ensure unsatisfactory nongynecologic 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 nongynecologic cytology test results (refer to D5657); and failed to establish written policies and procedures to ensure corrected reports indicated the basis for the correction on the report (refer to D5659).
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 the lack of laboratory policies and procedures, observation and interview it was determined the laboratory failed to establish written policies and procedures to ensure positive patient identification during all phases of nongynecologic specimen testing. The laboratory failed to label two of two specimen slides with a unique identifier during nongynecologic testing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure positive patient identification during all phases of nongynecologic testing. 2. The Survey Team observed incomplete patient identifier accession numbers on 26 of 26 glass specimen slides associated with two specimens on 06/16/2021. Specimens include: Accession #: # Written on Specimen Slides: -WM21-177 177 -WM21-179 179 3. During an interview on 02/15/2022 at 3:00 PM, the Laboratory Director /Technical Supervisor A confirmed these findings.
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: Based on the lack 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 assess the competency of Technical Supervisors. The laboratory failed to assess the competency of seven of seven Technical Supervisors in 2021 and to the date of the survey in 2022. Findings include: 1. 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 Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for seven of seven Technical Supervisors in 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director /Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E - Technical Supervisor F - Technical Supervisor G 3. During an interview on 02/14/2022 at 11:30 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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 the lack 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. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for packing and shipment of nongynecologic cytology specimens to Facility B for processing and preliminary diagnostic review and for the receipt of prepared specimen slides from Facility B. 3. During an interview on 02/15 /2022 at 10:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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 the lack of written policies and procedures and interview it was determined that the laboratory failed to have a procedures manual available to laboratory personnel during 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedures manual for all cytology tests and examinations performed at the laboratory. 2. During an interview on 02/14/2022 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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 the lack of written policies and procedures and interview it was determined that the laboratory failed to establish any written policies and procedures for any phase of testing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the receipt of specimens and the accessioning into the laboratory information system (LIS). 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the processing and staining of specimens requiring an intraoperative consultation. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology intraoperative consultations. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process of microscopic examination of cytology tests. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the data entry and reporting of cytology test results in the laboratory information system (LIS). 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology interlaboratory consultations with an outside laboratory. 7. During an interview on 02/15/2022 at 9:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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 interview it was determined that the laboratory failed to test staining materials for intended reactivity of the Diff Quick stain and rapid Hematoxylin and Eosin (H&E) stain for each day of use in 2021 and to the date of the survey in 2022. 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 2021 and to the date of the survey in 2022. 2. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the rapid H&E stain used for the immediate assessment of nongynecologic cytology slides was assessed each day of use in 2021 and to the date of the survey in 2022. 3. During an interview on 02/16/2022 at 9:00 AM, the Laboratory Director/Technical Supervisor A 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 the lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for the annual evaluation and comparison of three of three nongynecologic laboratory statistics for 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the annual statistical evaluation and comparison of three of three required nongynecologic laboratory statistics. 2. During an interview on 02/15/2022 at 9:30 AM, the Laboratory Director/Technical Supervisor A 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 the lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure unsatisfactory 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 ensure that unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory for evaluation. 2. During an interview on 02/15/2022 at 9: 30 AM, the Laboratory Director/Technical Supervisor A confirmed these findings
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 the lack of laboratory policies and procedures and interview 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 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 nongynecologic cytology test results. 2. During an interview on 02 /15/2022 at 9:30 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to ensure that corrected reports indicated the basis for the correction on the report. 2. During an interview on 02/15/2022 at 9:30 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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 the lack of laboratory policies and procedures, lack of laboratory records, observation and interview 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 analytic phases of cytology testing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define a quality assessment program to monitor, assess and correct problems in the analytic phases of cytology testing. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities or problems. 3. 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 with the quality assessment of the Diff Quick stain and the rapid H&E stain used for nongynecologic slide preparations. 4. During an interview on 02/15/2022 at 9:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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 the lack 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 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. During an interview on 02/15/2022 at 9:00 AM, the Laboratory Director /Technical Supervisor A 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 the lack of written laboratory policies and procedures, laboratory records, cytology slide preparations 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 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); failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094); and failed to ensure that an approved written procedures manual was available to all personnel (refer to D6106).
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 the lack of laboratory policies and procedures, review of laboratory records and interview 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. The Laboratory Director failed to establish and maintain a programs to identify failures in quality as they occurred in 2021 and to the date of the survey in 2022. Cross refer to D5473 and D5629 Findings include: 1. The Laboratory Director failed to provide written policies and procedures of an established quality control program to assure the quality of cytology testing. 2. The Laboratory Director failed to to provide records of an established quality control program to identify failures in

	quality of cytology testing. 3. The Laboratory Director failed to ensure a quality control program was established to test staining materials for intended reactivity of the Diff Quick stain and rapid H&E stain. (See D5473) 4. The Laboratory Director failed to ensure a quality control program was established to evaluate and compare nongynecologic laboratory statistics. (See D5629) 5. During an interview on 02/15 /2022 at 10:00 AM, the Laboratory Director/Technical Supervisor A 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 the lack of laboratory policies and procedures, lack of laboratory records, review of specimen slides and interview it was determined that the Laboratory Director failed to ensure quality assessment programs were established in the general laboratory, preanalytic, analytic and postanalytic phases of testing. The Laboratory Director failed to establish and maintain a program to identify failures in quality as they occurred in 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies, procedures and records of an established quality assessment program and failed to identify failures in quality as they occur in 2021 and to the date of the survey in 2022. 2. During an interview on 02/15/2022 at 10:00 AM, the Laboratory Director /Technical Supervisor A confirmed these findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures and interview it was determined that the Laboratory Director/Technical Supervisor A failed to ensure that an approved, written procedures manual was available to all personnel. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide a written and approved procedures manual. 2. During an interview on 02/14/2022 at 11:00 AM, the Laboratory Director/Technical Supervisor A 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.