Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2033989	01/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Services For Jefferson Regional Mc	1600 West 40th Avenue, Pine Bluff, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on interviews it was determined that the laboratory failed to retain all cytology slide preparations for at least five years from November 2016 to the date of the survey in 2020. Findings include: 1. During an interview on January 29, 2020 at 10:45 AM the Cytotechnologist stated that Diff Quick stained slides prepared during bronchoscopic fine needle aspiration procedures were discarded into the Sharps box in the bronchoscopy suite if they were interpreted as bloody, scant or nondiagnostic by the Cytotechnologist. a. These slides were not retained as part of the specimen case. 2. During an interview on January 29, 2020 at 11:48 AM the Cytotechnologist stated "I put stars on the diagnostic ones so I know which ones to keep. For bronchs a bunch of them get thrown away because a bunch of them are nothing." The Cytotechnologist stated that Diff Quick stained slide preparations were also discarded in Sharps boxes on thyroid fine needle aspirations prior to 2017 if they were interpreted as bloody, scant or nondiagnostic by the Cytotechnologist during rapid onsite evaluations. 3. During an interview on January 29, 2020 at 1:00 PM the Cytotechnologist stated that slides were also held back in a box and were only forwarded to the Technical Supervisors if they asked for more. If the Technical Supervisors did not request the held back slides they were discarded. a. The Laboratory Director/Technical Supervisor A stated that they would need to instruct the radiologists to refrain from giving them so much material and added "This is not all Cytotechnologist's fault."

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, observation and interviews it was determined that the laboratory failed to establish written policies and procedures to assess the competency of two of two Technical Supervisors (refer to D5209); failed to ensure that 33 of 33 written laboratory procedures were approved, signed, and dated by the Laboratory Director prior to use (refer to D5407); failed to ensure that all reagents and solutions were labeled to indicate content (refer to D5415); failed to ensure that reagents and solutions were used before the expiration dates (refer to D5417); failed to test Diff Quick staining materials and Papanicolaou staining materials for intended reactivity to ensure predictable staining characteristics (refer to D5473); failed to follow written policies and procedures to establish individual workload limits for one of one Cytotechnologist and two of two Technical Supervisors and to reassess the workload limits at least every six months (refer to D5633 and D5637); failed to ensure that one of one Cytotechnologist did not exceed the prorated workload limit of 12.5 slides per hour (refer to D5641); failed to establish written policies and procedures to ensure that the laboratory maintained records of the number of hours spent examining slides (refer to D5645); and failed to ensure that two of two Technical Supervisors reviewed all nongynecologic preparations (refer to D5653). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
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 and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure optimal integrity of a patient specimen to include all slide preparations from the time of collection or receipt of the specimen through completion of testing and reporting of results from November 2016 to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure optimal integrity of a patient specimen to include all slide preparations from the time of collection or receipt of the specimen through completion of testing and reporting of results. 2. During an interview on January 29, 2020 at 10:45 AM the Cytotechnologist stated that Diff Quick stained slides prepared during bronchoscopic fine needle aspiration procedures were discarded into the Sharps box in the bronchoscopy suite if they were interpreted as bloody, scant or nondiagnostic by the Cytotechnologist. These slides were not retained as part of the

	patient's specimen case through specimen testing and reporting of results. 3. During an interview on January 29, 2020 at 11:48 AM the Cytotechnologist stated that Diff Quick stained slide preparations were also discarded in Sharps boxes on thyroid fine needle aspirations prior to 2017 if they were interpreted as bloody, scant or nondiagnostic by the Cytotechnologist during rapid onsite evaluations. 4. During an interview on January 29, 2020 at 1:00 PM the Cytotechnologist stated that slides were also held back in a box and only forwarded to the Technical Supervisors if they asked for more. If the Technical Supervisors did not request the held back slides they were discarded. 5. These findings were confirmed by the Cytotechnologist and the Laboratory Director/Technical Supervisor A on January 29, 2020 at 1:00 PM.
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 review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to assess the competency of two of two Technical Supervisors. 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 two of two Technical Supervisors. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for the Laboratory Director/Technical Supervisor A who performed microscopic evaluations in 2018, 2019 and to the date of the survey in 2020 and for Technical Supervisor B who performed microscopic evaluations from July 2019 to the date of the survey in 2020. 3. During interviews on January 27, 2020 at 10:13 AM and 3:15 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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 33 laboratory policies and procedures and interview it was determined that the laboratory failed to establish one written policy and procedure. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the process of staining gynecologic specimens with the manual Papanicolaou stain line. 2. During an interview on January 29, 2020 at 10:45 AM these findings were confirmed by the Cytotechnologist.
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 33 laboratory policies and procedures and interview it was determined that the laboratory failed to ensure that 33 of 33 written policies and procedures were approved, signed and dated by the Laboratory Director prior to the initial dates of use. Findings include: 1. The Survey Team reviewed 33 procedures from the GYN CYTOLOGY STANDARD OF PROCEDURE MANUAL. The Laboratory Director failed to approve, sign and date 33 of 33 laboratory procedures prior to the initial dates of use. Procedures include: 1. GYNECOLOGIC CYTOLOGY: CERVICOVAGINAL SMEAR - THINPREP MANUAL REVIEW 2. PAPANICOLAOU STAINING AND COVERSLIPPING PROCEDURES FOR THINPREP PAPS 3. PROCEDURE FOR EVALUATING PAPANICOLAOU STAIN QUALITY - THINPREPS 4. PROCEDURE FOR REPROCESSING UNSATISFACTORY THINPREP PAPS 5. GYNECOLOGIC CYTOLOGY REPORTING POLICY: THE BETHESDA SYSTEM 2004 6. REJECTION OF GYN CYTOLOGY SPECIMENS 7. UNIDENTIFIED SPECIMENS 8. HIERARCHAL SYSTEM OF CASE REVIEW, 10% QC NEGATIVE CASE REVIEW AND NEGATIVE CASE REVIEW WITH ABNORMAL HISTORY (HIGH RISK) 9. FIVE YEAR PRIOR NEGATIVE REVIEW FOLLOWING CURRENT HGSIL/CA 10. CYTOLOGY - HISTOLOGY - SPECIAL STUDIES CORRELATION 11. COMMUNICATION OF SIGNIFICANT AND UNEXPECTED CYTOLOGY DIAGNOSIS 12. WORKLOAD LIMIT POLICY 13. AMENDED REPORTS 14. ANNUAL STATISTICAL EVALUATION POLICY 15. WORKFLOW: CYTOLOGY AND WORKFLOW: ACCESSIONING A NEW CASE IN POWERPATH 16. RECORD AND SLIDE MAINTENANCE POLICY - GYN CYTOLOGY 17. SLIDE SEND OUT POLICY 18. LABELING PROCEDURE FOR REAGENTS 19. MICROSCOPE MAINTENANCE (REGULAR) 20. CYTOPATHOLOGY QUALITY ASSURANCE POLICY 21. CYTOLOGY SPECIMEN COLLECTION, SUBMISSION AND TEST ORDERING ACCURACY STANDARD 22. TIMELINESS OF RESULT REPORTING STANDARD 23. ACCURACY OF REPORTED RESULTS 24. EFFICIENT STORAGE AND RETRIEVAL OF SLIDES AND REPORTS 25. CYTOPREPARATORY AND TESTING METHOD STANDARD 26. DIAGNOSTIC PROFICIENCY OF CYTOTECHNOLOGIST 27. EFFECTIVENESS OF PERSONNEL POLICIES AND PROCEDURES 28. EMPLOYEE PERFORMANCE EVALUATION 29.

	PROFICIENCY TESTING CYTOLOGY 30. CENTRIFUGE/CYTOSPIN SPEED CHECK AND QC 31. DAILY QC SPECIMEN PREP/STAIN 32. CORRECTION OF LABORATORY RECORDS 33. LABORATORY ASC/SIL RATIO STATISTICAL RECORDS - OUTLIERS 2. During an interview on January 27, 2020 at 11:09 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A. The Laboratory Director/Technical Supervisor A provided them to the Survey Team and stated "I figured that honesty is the best policy. I signed these today. I know that they were already supposed to be signed. I know that it's a deficiency."
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview it was determined that the laboratory failed to ensure that 14 of 14 reagents and solutions were labeled to indicate content. Findings include: 1. During observation of the cytology processing area on January 28, 2020 at 11:20 AM the Survey Team identified 14 of 14 staining dishes from the Papanicolaou manual stain line were not labeled to indicate content. 2. During an interview on January 29, 2020 at 1:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B and Cytotechnologist.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview, it was determined that the laboratory failed to ensure that three reagents and solutions were not used after their expiration dates. Findings include: 1. During an observation of the cytology processing area on January 28, 2020 at 11:20 AM the Survey Team identified: a. One bottle of HEMA-DIFF #3 THIAZINE which had an expiration date of August 2019 b. One jar of HEMA-DIFF #2 XANTHENE which had an expiration date of March 2018 c. One jar of HEMA-DIFF #3 THIAZINE which had an expiration date of March 2018. 2. During an interview on January 28, 2020 at 11:30 AM these findings were confirmed by the Cytotechnologist. The Cytotechnologist confirmed that these stains were currently being used on fine needle aspiration procedures and stated "I need to throw that out then. Those jars will need to be emptied, cleaned out and relabeled."
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: A. Based on review of laboratory records and interviews it was determined that the laboratory failed to test Diff Quick staining materials for intended reactivity to ensure predictable staining characteristics for each day of use in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide Diff Quick stain assessment records for 2018, 2019 and to the date of the survey in 2020. 2. During an interview on January 27, 2020 at 3:15 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, and Cytotechnologist. B. Based on review of laboratory records and interviews it was determined that the laboratory failed to test Papanicolaou staining materials from the manual stain process for intended reactivity to ensure predictable staining characteristics for each day of use in 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide Papanicolaou stain assessment records for the manual stain process for 2019 and to the date of the survey in 2020. 2. During an interview on January 27, 2020 at 3:15 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, and Cytotechnologist.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor A for two of two Technical Supervisors and one of one Cytotechnologist. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD LIMIT POLICY which stated: "3. Pathologists who screen previously unscreened gynecologic slides and non-gynecologic slides (including FNA direct smears) must adhere to and document the above workload limit... " "9. Workload limits will be set for individuals examining slides on other than an 8 hour workday basis." "10. As part of the laboratory's ongoing quality assurance program, the laboratory director and cytology general supervisor will set individual limits for each cytotechnologist based on his/her performance." 2. The Survey Team requested and the laboratory failed to provide documentation that a maximum workload limit was established for the Laboratory Director/Technical Supervisor A and Cytotechnologist in 2018, 2019 and to the date of the survey in 2020 and for Technical Supervisor B for 2019 and to the date of the survey in 2020. 3. During an interview on January 27, 2020 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, and Laboratory Manager confirmed these findings.

D5635	CYTOLOGY CFR(s): 493.1274(d)(1)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section. 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 failed to establish written policies and procedures to use evaluations of the individual Cytotechnologist's performance when assessing the workload limit for one of one Cytotechnologist in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the workload limit for the Cytotechnologist was based on individual capabilities using evaluations of the following: a. A review of ten-percent of the cases interpreted as negative b. A comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides 2. The Survey Team requested and the laboratory failed to provide established individual workload limits for one of one Cytotechnologist. 3. During an interview on January 27, 2020 at 3:15 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, and the Laboratory Manager.
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: A. Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that the workload limit for one of one Cytotechnologist was reassessed at least every six months and adjusted when necessary. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD LIMIT POLICY which stated: "10. ...the laboratory director and cytology general supervisor will set individual limits for each cytotechnologist based on his/her performance. This performance review will occur at least every six months." 2. The Survey Team requested and the laboratory failed to provide documentation that the workload limit for one of one Cytotechnologist had been reassessed at least every six months in 2018, 2019 and to the date of the survey in 2020. 3. During an interview on January 27, 2020 at 3:15 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, and Laboratory Manager. B. Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for two of two Technical Supervisors was

	reassessed at least every six months and adjusted when necessary. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the workload limit for two of two Technical supervisors was reassessed at least every six months and adjusted when necessary. 2. The Survey Team requested and the laboratory failed to provide documentation that the workload limit for the Laboratory Director/Technical Supervisor A had been reassessed at least every six months in 2018, 2019, and to the date of the survey in 2020, and for Technical Supervisor B in 2019 and to the date of the survey in 2020. 3. During an interview on January 27, 2020 at 3:15 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, and Laboratory Manager.
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 laboratory records it was determined that the laboratory failed to follow written policies and procedures to ensure that one of one Cytotechnologist did not exceed the prorated workload limit of 12.5 slides per hour when examining slides in less than an 8-hour workday during 31 of 218 days in 2018 and nine of 218 days in 2019. Findings include: 1. The policy WORKLOAD LIMIT POLICY stated: "9. The number of slides that may be examined will be prorated by allowing no more than an average of 12.5 slides per available slide examination hours." 2. The Survey Team reviewed "Cytotechnologist Daily Workload" logs from 2018 and 2019. One of one Cytotechnologist exceeded the prorated workload limit of 12.5 slides per hour during 31 of 218 days in 2018 and 10 of 218 days in 2019. 2018 days include: -February 7 Number screened: 5 Number allowed: 4 -March 12 Number screened: 5 Number allowed: 4 -March 16 Number screened: 7 Number allowed: 6 -April 2 Number screened: 7 Number allowed: 6 -April 5 Number screened: 12 Number allowed: 10 -April 13 Number screened: 18 Number allowed: 17 -May 2 Number screened: 9 Number allowed: 7 -May 21 Number screened: 7 Number allowed: 5 -June 11 Number screened: 13 Number allowed: 12 -July 10 Number screened: 6 Number allowed: 4 -July 12 Number screened: 6 Number allowed: 4 -July 13 Number screened: 8 Number allowed: 6 -August 1 Number screened: 9 Number allowed: 6 -August 6 Number screened: 14 Number allowed: 13 -August 21 Number screened: 4 Number allowed: 3 -August 22 Number screened: 5 Number allowed: 4 -September 4 Number screened: 8 Number allowed: 6 -September 25 Number screened: 3 Number allowed: 2 -October 11 Number screened: 3 Number allowed: 2 -October 16 Number screened: 3 Number allowed: 2 -October 22 Number screened: 5 Number allowed: 4 -November 1 Number screened: 8 Number allowed: 6 -November 5 Number screened: 9 Number allowed: 6 -November 7 Number screened: 5 Number allowed: 4 -November 9 Number screened: 3 Number allowed: 2 -November 19 Number screened: 5 Number allowed: 4 -November 26 Number screened: 3 Number allowed: 2 -December 4 Number

	screened: 3 Number allowed: 2 -December 6 Number screened: 3 Number allowed: 2 - December 17 Number screened: 8 Number allowed: 4 -December 19 Number screened: 3 Number allowed: 2 2019 days include: -February 15 Number screened: 6 Number allowed: 4 -February 22 Number screened: 8 Number allowed: 7 -March 6 Number screened: 7 Number allowed: 6 -March 27 Number screened: 9 Number allowed: 6 -May 17 Number screened: 22 Number allowed: 21 -June 5 Number screened: 5 Number allowed: 4 -July 26 Number screened: 14 Number allowed: 13 - September 23 Number screened: 19 Number allowed: 17 -December 3 Number screened: 7 Number allowed: 6
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure the laboratory would maintain records of the number of hours spent examining slides for two of two Technical Supervisors and one of one Cytotechnologist. Cross refer to D6133 and D6167 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory would maintain records of the number of hours spent examining slides for two of two Technical Supervisors and one of one Cytotechnologist. 2. During an interview on January 29, 2020 at 12:21 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor A and Technical Supervisor B.
D5653	CYTOLOGY CFR(s): 493.1274(e)(3) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. 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 follow written policies and procedures to ensure that all nongynecologic preparations were reviewed by two of two Technical Supervisors from November 2016 to the date of the survey in 2020. Findings include: 1. The Survey Team reviewed the procedure CYTOLOGY 10% RE-SCREEN POLICY which stated: "In the Pathology Department of Jefferson Regional Medical Center, all cytological cases including all positive and negative non-gynecological cases, and all gynecological cases are re-evaluated by the pathologists." 2. During an interview on January 29, 2020 at 10:45 AM the Cytotechnologist stated that Diff

	Quick stained slides prepared during bronchoscopic fine needle aspiration procedures were discarded into the Sharps box in the bronchoscopy suite if they were interpreted as bloody, scant or nondiagnostic by the Cytotechnologist. These slides were not brought back to the laboratory, accessioned with the case and referred to the Technical Supervisors for evaluation. 3. During an interview on January 29, 2020 at 11:48 AM the Cytotechnologist stated "I put stars on the diagnostic ones so I know which ones to keep. For bronchs a bunch of them get thrown away because a bunch of them are nothing." The Cytotechnologist stated that Diff Quick stained slide preparations were also discarded in Sharps boxes on thyroid fine needle aspirations prior to 2017 if they were interpreted as bloody, scant or nondiagnostic by the Cytotechnologist during rapid onsite evaluations. 4. During an interview on January 29, 2020 at 1:00 PM the Cytotechnologist stated that nongynecologic slides were also held back in a box and were only forwarded to the Technical Supervisors if they asked for more. If the Technical Supervisors did not request the held back nongynecologic slides they were discarded. 5. These findings were confirmed by the Cytotechnologist and the Laboratory Director/Technical Supervisor A on January 29, 2020 at 1:00 PM.
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, observation 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 fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that testing systems developed and used for cytology provided quality laboratory services for all aspects of gynecologic and nongynecologic cytology test performance (refer to D6082); failed to ensure that one of one Cytotechnologist performed test methods as required for accurate and reliable results (refer to D6087); failed to ensure that reports of test results included accurate numbers and types of slides prepared during fine needle aspiration procedures (refer to D6098); failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of two of two Technical Supervisors performing cytology test procedures (refer to D6103); failed to ensure that an approved procedure manual was available to all personnel (refer to D6106); and failed to specify in writing the duties of the Cytotechnologist during fine needle aspiration procedures to include the handling of specimen slides from preparation through the reporting of patient test results (refer to D6107). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, observation and interviews it was determined that the Laboratory Director/Technical Supervisor A failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5407, D5415, D5417, D5633, D5635, D5637, D5641, D5645 and D5653
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, observation and interviews it was determined that the Laboratory Director failed to ensure that testing systems developed and used for cytology provided quality laboratory services for all aspects of gynecologic and nongynecologic cytology test performance. Cross refer to D5415, D5417, D5473 and D5653
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures, laboratory records, observations and interviews it was determined that the Laboratory Director failed to ensure that one of one Cytotechnologist performed test methods as required for accurate and reliable results. Cross refer to D5203, D5415, D5417 and D5653
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews it was determined that the Laboratory Director failed to ensure that reports of test results included accurate numbers and types of slides prepared during fine needle aspiration procedures from November 2016 to the date of the survey in 2020. Cross refer to D3043, D5203 and D5653
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, laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor A failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of two of two Technical Supervisors performing cytology test procedures. Cross refer to D5209
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 review of laboratory policies and procedures and interview it was determined that the Laboratory Director/Technical Supervisor A failed to ensure that an approved procedure manual was available to all personnel. Cross refer to D5407
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures and interviews it was determined that the Laboratory Director failed to specify in writing the duties of the

	Cytotechnologist during fine needle aspiration procedures to include the handling of specimen slides from preparation through the reporting of patient test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures that identify the duties of the Cytotechnologist during fine needle aspiration procedures to include the handling of specimen slides from preparation through the reporting of patient test results. 2. During an interview on January 29, 2020 at 1:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Cytotechnologist, and Laboratory Manager.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 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 Technical Supervisor A failed to establish policies and procedures for the evaluation of Cytotechnologist competency that included direct observations of specimen handling, processing and testing during fine needle aspiration procedures (refer to D6121); failed to reassess the workload limits at least every six months (refer to D6130); and failed to ensure that two of two Technical Supervisors documented the number of hours spent examining slides during each 24 hour period (refer to D6133). The cumulative effect of these practices resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures for the evaluation of Cytotechnologist competency that included direct observations of specimen handling, processing and testing during fine needle aspiration procedures. Findings include: 1. The Survey Team requested and the laboratory failed to provide policies and procedures for the evaluation of Cytotechnologist competency that included direct observations of specimen handling, processing and testing during fine needle aspiration procedures. 2. During an interview on January 29, 2020 at 1:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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 laboratory records and interview it was determined that Technical Supervisor A failed to establish individual workload limits and to reassess the workload limits at least every six months for two of two Technical Supervisors and one of one Cytotechnologist. Cross refer to D5633 and D5637
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that one of one Technical Supervisor in 2018 and two of two Technical Supervisors in 2019 failed to document the number of hours spent examining slides during each 24-hour period. Findings include: 1. The Survey Team reviewed binders titled CYTOLOGY MONTHLY STATISTICS 2018 and CYTOLOGY MONTHLY STATISTICS 2019 which included workload records for two of two Technical Supervisors. a. Laboratory Director/Technical Supervisor A failed to document the hours spent evaluating slides during seven of eight days in 2018 and two of two days in 2019. 2018 days include: -January 16 -April 10 -May 3 -May 17 -August 31 -December 20 -December 21 2019 days include: -February 12 -August 19 b. Technical Supervisor B failed to document the hours spent evaluating slides during four of four days in 2019. 2019 days include: -August 20 -August 21 -August 22 -August 23 2. During an interview on January 29, 2020 at 12:21 PM these findings were confirmed by the Laboratory Director /Technical Supervisor A and Technical Supervisor B.
D6167	CYTOTECHNOLOGIST RESPONSIBILITIES CFR(s): 493.1485(c) The cytotechnologist is responsible for documenting the number of hours spent examining slides in each 24-hour period. This STANDARD is not met as evidenced by: Based on review of laboratory records it was determined that one of one Cytotechnologist failed to document the number of hours spent examining slides in each 24-hour period during 21 of 21 days in 2019. Findings include: 1. The Survey Team reviewed "Cytotechnologist Daily Workload" logs from 2018 and 2019. One of one Cytotechnologist failed to document the number of hours spent examining slides in each 24-hour period during 21 of 21 days in 2019. 2019 days include: -April 1 -April 2 -April 3 -April 4 -April 5 -April 8 -April 9 -April 10 -April 11 -April 15 -April 16 -April 17 -April 18 -April 19 -April 22 -April 23 -April 24 -April 25 -April 26 -April 29 -April 30

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.