Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482320	01/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Services Of Texarkana	1002 Texas Blvd Suite 500, Texarkana, TX	

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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation, review of laboratory records and interview it was determined that the laboratory failed to ensure adequate ventilation of the cytology laboratory. Findings include: 1. During the course of the survey the Survey Team detected a strong chemical odor in the laboratory. 2. On 01/06/2020 the Survey Team observed the cytology preparation technician using open containers of xylene and permount to coverslip cytology slide preparations with no equipment to properly ventilate the area. 3. On 01/06/2020 the Survey Team observed cytology slides being stained on the Sakura automated stainer machine. a. The laboratory "SAFETY MANUAL" stated that the Sakura automated stainer machine activated charcoal filter used to remove hazardous fumes, which are generated from the reagents in the staining unit, is to be "changed every three months." b. The survey team requested the Sakura automated stainer machine records indicating the changing of the charcoal filter. c. During an interview on 01/06/2020 at 2:30 PM the histotechnician stated that there "were no records to indicate the filter had been changed" in 2018, 2019 or to the date of the survey in 2020. 4. During an interview on 01/08/2020 at 9:15 AM the Laboratory Director/Technical Supervisor confirmed these findings.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

	This STANDARD is not met as evidenced by: Based on interview and review of laboratory records it was determined that the laboratory failed to observe the safety procedures established to ensure protection from chemical fume hazards. Cross Refer to D3001 Findings Include: 1. During an interview on 01/07/2020 at 10:15 AM the histotechnician stated that "the laboratory performed xylene and formaldehyde vapor exposure badge tests." a. The laboratory procedure titled 'FORMALDEHYDE PRECAUTIONS' stated when "Occupational Safety and Health Administration (OSHA) permissible exposure limits , 0.75 parts per million (ppm) during an 8 hour period, and short term exposure limits, 2.0 ppm in a 15 minute period, are exceeded, monitoring will be conducted at a 6 month and annual basis." b. The Survey Team reviewed the formaldehyde vapor exposure badge test results from 2018 for the histotechnician. Formaldehyde test badge results for the histotechnician from 07/22/2018 indicated a 15 minute period result of 2.2 ppm. This result exceeded the permissible exposure limit for formaldehyde of 2.0 ppm. c. The Survey Team reviewed the xylene vapor exposure badge test results from 2018 for the histotechnician. Xylene test badge results for the histotechnician from 07/06/2018 indicated a 15 minute period result of "> 300 ppm". This result exceeded the permissible exposure limit for xylene (National Institute for Occupational Health and Safety 15 minute permissible exposure limit for xylene is 150 ppm). 2. The Survey Team requested xylene and formaldehyde vapor badge test results subsequent to the 2018 results. a. During an interview on 01/07/2020 at 3:15 PM the Laboratory Director /Technical Supervisor stated "there was no testing performed following the 2018 testing period."
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, laboratory records, specimen slides and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the number of slides prepared was accurately reported. The laboratory failed to document the number of specimen slides for three of three random gynecologic specimens diagnosed as unsatisfactory for diagnosis between June 17, 2019 and July 3, 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the total number of slides prepared was accurately documented for each specimen. 2. The Survey Team reviewed three of three gynecologic final test reports with a diagnosis of unsatisfactory for interpretation and the corresponding slides between June 17, 2019 and July 3, 2019. The Survey Team observed that the final reports provided by the laboratory failed to document the actual number of slides prepared. Case reports include: -19-003432-PP Final Report: NUMBER OF SLIDES: 1 Actual Number of slides: 2 -19-003393-PP Final Report: NUMBER OF SLIDES: 1 Actual Number of slides: 2 -19-003793-PP Final Report: NUMBER OF SLIDES: 1 Actual Number of slides: 2 3. During and interview on 01/08/2020 at 9:15 AM the Laboratory Director/Technical Supervisor confirmed these findings.

D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and review of gynecologic specimen slides it was determined that the laboratory failed to follow written policies and procedures to identify more significant lesions on prior negative specimens from new specimens with High-Grade Intraepithelial Lesions (HSIL). The laboratory failed to identify two of twelve prior negative specimens as having a more significant lesion than initially reported. Findings include: 1. The laboratory failed to follow the procedure "QC REVIEW OF PRIOR NEGATIVE CASES", which stated: "Each patient diagnosed with a new high grade intraepithelial lesion or cancer has all negative gynecologic slides received by the laboratory within the previous 5 years reviewed if available in the laboratory. Documentation of the fact that the review occurred is made using the form entitled QA Review of Prior Negative Cases. Specific discrepancies are documented on this form and it is signed by all reviewers." 2. The Survey Team reviewed twelve prior negative specimens from nine new HSIL's from October 2016 through November 2019. a. The Laboratory Director/Technical Supervisor confirmed on 01/18/2020 that the laboratory did not identify two of twelve prior negative specimens as having a more significant lesion than was originally reported. Prior Negative Cases Include: -18-5607-PP -17-4493-PP
D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (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)(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. 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 for a program to evaluate the case reviews of Cytotechnologist #1 and Cytotechnologist #2 against the laboratory's overall statistical values 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 or procedures for a program to evaluate the case reviews of Cytotechnologist #1 and Cytotechnologist #2 against the laboratory's overall statistical values. 2. The Survey Team requested and the laboratory failed to provide records for comparative reviews to evaluate the case

	reviews of Cytotechnologist #1 and Cytotechnologist #2 against the laboratory's overall statistical values. 3. During an interview on 01/07/2020 at 3:15 PM the Laboratory Director/Technical Supervisor confirmed these findings.
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 observation, review of laboratory policies and procedures, laboratory records, review of gynecologic specimen slides and interviews it was determined that the Laboratory Director 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 D3001, D3011, D5203, D5625, D5631
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 333 routine negative gynecologic cytology cases /335 slides from June to July 2019 and confirmation by the Laboratory Director /Technical Supervisor on 01/07/2020 it was determined that the Laboratory Director /Technical Supervisor failed to verify the accuracy of two gynecologic cytology reports. 1. 19-003300-PP 06/07/19 ThinPrep - Vaginal Cervical Endocervical LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory; scant cellularity LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory; scant 2. 19-003339-PP 06/11/19 ThinPrep - Vaginal Cervical Endocervical LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory; scant cellularity LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory; scant
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.