Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2159309	12/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatopathology Partners Pc	123 Fox Rd, Second Floor, Knoxville, TN	

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 review of laboratory policies and procedures, record review and interview it was determined that the laboratory failed to establish written policies and procedures to prevent cross-contamination between gynecologic and nongynecologic specimens during staining (refer to D5617); failed to establish written policies and procedures to prevent cross-contamination of nongynecologic specimens having a high potential for cross-contamination during staining (refer to D5619); failed to follow written policies and procedures for an annual statistical evaluation of three of six required statistics for gynecologic specimens in 2016 and 2017 (refer to D5629); failed to establish written policies and procedures for reassessing workload limits for two of two cytotechnologists in 2016, 2017 and to date of the survey in 2018 (refer to D5637); and failed to establish written policies and procedures to ensure that unsatisfactory specimens were identified and reported as unsatisfactory (refer to D5655). 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.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures, lack of quality assessment records and interview, it was determined that Facility A failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the preanalytic system for the years 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the preanalytic cytology system. 2. The Survey Team requested and the laboratory failed to provide documentation of any quality assessment activities or problems. 3. Cytotechnologist #1 stated during an interview with the Survey Team at 3:35 PM on December 11, 2018 that the laboratory did not have a preanalytic quality assessment program.
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 18 laboratory policies and procedures and interview, it was determined that Facility A failed to establish written policies and procedures for the staining of nongynecologic specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the staining of nongynecologic specimens. 2. Cytotechnologist #1 confirmed during an interview with the Survey Team at 8:30 AM on December 12, 2018 that the laboratory did not have a written procedure for the staining of nongynecologic specimens.
D5617	CYTOLOGY CFR(s): 493.1274(b)(2) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, it was determined that Facility A failed to establish written policies and procedures to prevent cross-contamination between gynecologic and nongynecologic specimen slides during the staining process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prevent cross-contamination between gynecologic and nongynecologic specimen slides during staining. 2. Cytotechnologist #1 confirmed during an interview with the Survey Team at 8:30 AM on December 12, 2018 that the laboratory did not have written procedures for preventing cross-contamination between gynecologic and nongynecologic slides.
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 and interview, it was determined that Facility A failed to establish written policies and procedures to prevent cross-contamination between nongynecologic specimen slides with a high potential for cross-contamination. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and staining procedures to prevent cross-contamination of nongynecologic specimens that have a high potential for cross-contamination with other nongynecologic specimens during the Papanicolaou staining process. 2. Cytotechnologist #1 stated during an interview with the Survey Team at 8: 30 AM on December 12, 2018 that all nongynecologic slides were stained together.
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 review of laboratory policies and procedures, review of laboratory

	records and interview, it was determined that the laboratory failed to follow written policies and procedures for an annual statistical evaluation of three of six required statistics for gynecologic specimens in 2016 and 2017. Findings include: 1. The Survey Team reviewed the procedure titled QUALITY ASSURANCE PROGRAM FOR CYTOLOGY which stated: "Statistics: An annual review of the number of: a. The number of gynecologic cases with a diagnosis of HSIL or higher for which histology results were available for comparison; b. The number of gynecologic cases where cytology and histology were discrepant; c. The number of gynecologic cases where a rescreen of a negative specimen resulted in a reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma or other malignant neoplasms." 2. The Survey Team reviewed the Cytology Annual Statistics for 2016 and 2017 and found these documents did not contain the three of six statistics specified in the written procedure. 3. Cytotechnologist #1 confirmed during an interview with the Survey Team at 5:30 PM on December 1 0, 2018 that the laboratory did not follow the laboratory procedure to document three of six required annual statistics.
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: Based on review of laboratory policies and procedures, laboratory records and interview, it was determined that Facility A failed to establish written policies and procedures to ensure that the workload limits for two of two cytotechnologists were reassessed at least every six months and adjusted when necessary in 2017, and to the date of the survey in 2018. 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 cytotechnologists would be reassessed at least every six months and adjusted when necessary. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit for two of two cytotechnologists for 2017 and to the date of the survey in 2018. 3. Technical Supervisor #1 stated during an interview with the Survey Team at 10:40 AM on December 11, 2018 that "We didn't know it had to be done every six months."
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 interview, it was determined that Facility A failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic systems. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an

	ongoing mechanism to monitor and assess the quality of the postanalytic system. 2. The Survey Team requested and the laboratory failed to provide documentation of any quality assessment activities or problems. 3. Cytotechnologist #1 stated during an interview with the Survey Team on December 11, 2018 at 3:35 PM that the laboratory did not have a postanalytic quality assessment program.
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 written laboratory policies and procedures, laboratory records and interviews, it was determined that Facility A 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 and oversight with applicable regulations (refer to D6079); and failed to ensure that quality assessment programs were established (refer to D6094). 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 the review of written policies and procedures, laboratory records and interview, it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of Facility A, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5403, D5629 and D5637
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 written 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 D5391 and D5891.
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 review of 242 negative gynecologic cases from 2018 and confirmation by the Technical Supervisor on December 12, 2018 it was determined that Technical Supervisor failed to verify the accuracy of one gynecologic cytology test result. Case Includes: 1. GYC18-5660 July 6, 2018 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation due to Limited Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Evaluation
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.