Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0205041	10/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Center For Urologic Care Of Berks Cnty	1320 Broadcasting Road, Suite 200, Wyomissing, PA	

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, laboratory records and interviews it was determined that the laboratory failed to ensure written policies and procedures were approved, signed and dated by the Laboratory Director (refer to D5407); failed to establish policies and procedures for the annual evaluation and comparison of three of three laboratory statistics (refer to D5629); failed to establish and reassess a workload limit for six of six Technical Supervisors (refer to D5633, D5637); failed to follow written policies and procedures to ensure that the laboratory would maintain records of the total number of hours spent examining slides (refer to D5645); and failed to establish written policies and procedures to ensure that unsatisfactory cytology slide preparations 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.
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 21 laboratory policies and procedures and interview it was determined that the laboratory failed to ensure that 21 of 21 written procedures were approved, signed and dated by the Laboratory Director prior to the start of the survey on October 28, 2019. Findings include: 1. The Laboratory Director failed to sign and date 21 laboratory procedures prior to the date of the survey. Procedures include: - ACCESSIONING ACCURACY REVIEW - COMMUNICATIONS - PERSONNEL COMPETENCY - COMPLAINT INVESTIGATIONS - EQUIPMENT, REAGENTS, SUPPLIES - GENERAL QUALITY ASSURANCE PLAN - HOW TO SCREEN A SLIDE - LABELING OF CYTOLOGY SLIDES - EQUIPMENT MAINTENANCE - PAPANICOLAOU STAINING - PATHOLOGISTS STATISTICS - PATIENT CONFIDENTIALITY POLICIES - TESTS RESULTS - PROCEDURE MANUALS - REPORTING OF TEST RESULTS - SAFETY QC - SPECIMEN IDENTIFICATION AND INTEGRITY - DAILY CONTROL SLIDES - SPECIMEN SUBMISSION AND HANDLING - CYTOLOGY PROCESSING (THINPREP) - WORKLOAD LIMIT FOR CYTOLOGY SCREENING 2. During an interview on October 30, 2019 at 9:30 AM the Chief Operating Officer 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 review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish a written policy and procedure and maintain statistics for an annual evaluation of three required statistics for nongynecologic cases during the years 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual evaluation of the following three required annual statistics: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. The Survey Team requested and the laboratory failed to provide documentation of the three annual nongynecologic statistics during the years 2017 and 2018. 3. During an interview on October 29, 2019 at 11:15 AM the Chief Operating Officer confirmed these findings.
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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum individual workload limit was established for six of six Technical Supervisors when performing primary evaluation of cytology specimen slide preparations in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide, written policies and procedures to ensure that a maximum individual workload limit was established by the Technical Supervisor for the six of six Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of an established individual workload limit for six of six Technical Supervisors for 2017, 2018 and to the date of the survey in 2019. Technical Supervisors include: -Technical Supervisor #1 -Technical Supervisor #2 -Technical Supervisor #3 -Technical Supervisor #4 -Technical Supervisor #5 -Technical Supervisor #6 3. During an interview on October 29, 2019 at 3:10 PM the Chief Operating Officer confirmed these findings.
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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for six of six Technical Supervisors were reassessed at least every six months during the years 2017 and 2018, and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy and procedure for the reassessment of workload limits at least every six months for six of six Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit for six of six Technical Supervisors during the years 2017 and 2018 and to the date of the survey in 2019. Technical Supervisors include: -Technical Supervisor #1 -Technical Supervisor #2 -Technical Supervisor #3 -Technical Supervisor #4 -Technical Supervisor #5 -Technical Supervisor #6 3. During an interview on October 30, 2019 at 9:30 AM the Chief Operating Officer confirmed these findings.
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 follow policies and procedures. The laboratory did not maintain records of the total number of hours spent examining slides in each 24-hour period for six of six Technical Supervisors in August, September and to the date of the survey in October 2019. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD LIMIT FOR NON-GYNECOLOGICAL CYTOLOGY SCREENING which stated "A workload log will be kept for each work period detailing the number of hours spent examining cytology slides and the total number of slides examined." 2. The Survey Team reviewed the CYTOLOGY WORKLOAD LOG for August, September and to the date of the survey in October, 2019. The CYTOLOGY WORKLOAD LOG included slides examined by the six Technical Supervisors. Thirty eight of 38 days had no record of the time spent examining slides. Technical Supervisors with no record of time spent examining slides include: -Technical Supervisor #1 -August 6, 2019 -September 6, 2019 -September 13, 2019 -October 1, 2019 -Technical Supervisor #2 -August 7, 2019 -August 14, 2019 -August 21, 2019 -August 28, 2019 -September 25, 2019 -October 2, 2019 -October 9, 2019 -October 16, 2019 -October 24, 2019 -Technical Supervisor #3 -August 2, 2019 -August 22, 2019 -September 10, 2019 -September 19, 2019 -September 24, 2019 -October 3, 2019 -October 10, 2019 -October 17, 2019 -Technical Supervisor #4 -August 9, 2019 -September 17, 2019 -September 26, 2019 -October 4, 2019 -October 11, 2019 -Technical Supervisor #5 -August 29, 2019 -September 4, 2019 -September 11, 2019 -September 18, 2019 -October 15, 2019 -October 23, 2019 -Technical Supervisor #6 -August 30, 2019 -September 5, 2019 -September 12, 2019 -October 8, 2019 -October 22, 2019 -October 25, 2019 3. During an interview on October 29, 2019 at 9:40 AM the Chief Operating Officer 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 review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic 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. 2. During an interview on October 29, 2019 at 3:10 PM the Chief Operating Officer confirmed that the laboratory did not have a policy and procedure specifying the criteria for an unsatisfactory nongynecologic slide.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance and oversight with applicable regulations (refer to D6079). 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 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 D5407, D5629, D5633, D5637, D5645 and D5655
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 procedures, lack of laboratory records and interview it was determined that the Technical Supervisor failed to establish and reassess individual workloads limits for six of six Technical Supervisors.during the years 2017 and 2018 and to the date of the survey in 2019. 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 procedures, laboratory records and interview it was determined that six of six Technical Supervisors failed to document the number of hours spent examining slides during each 24-hour period in August, September and to the date of the survey in October 2019. Cross refer to D5645
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.