Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2018622	10/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Urology Center, Pc	3700 Joseph Siewick Dr Ste 300, Fairfax, VA	

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
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 interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor who performed microscopic evaluation of cytology specimens 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 a written policy or procedure to assess the competency of the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the Laboratory Director/Technical Supervisor for 2017, 2018 and to the date of the survey. 3. During an interview on October 22, 2019 at 11:45 AM the Laboratory Director/Technical Supervisor 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, laboratory records and

	interview it was determined that the laboratory failed to follow written policies and procedures to ensure workload limits were reassessed at least every six months for the Laboratory Director/Technical Supervisor in 2017, 2018, and to the date of the survey in 2019. Findings include: 1. The laboratory failed to follow the written procedure titled PATHOLOGIST'S WORKLOAD LIMITS which stated "The pathologist's tracking data will be reviewed and initialed twice annually by the Medical Director." 2. The Survey Team requested and the laboratory failed to provide a record of any workload limit review that was initialed twice annually. a. Laboratory records titled ESTABLISHED WORKLOAD LIMITS did not include a reassessment for the Laboratory Director/Technical Supervisor in 2017, 2018 and to the date of the survey in 2019. 3. During an interview on October 22, 2019 at 11:45 AM the Laboratory Director/Technical Supervisor 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 review of laboratory policies and procedures, laboratory records, specimen slides 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 written policies and procedures were established to identify needs for remedial training or continuing education to improve upon diagnostic skills of the Laboratory Director/Technical Supervisor (refer to D6103). 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.
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, nongynecologic specimen slides and interview it was determined that the Laboratory Director/Technical Supervisor failed to establish policies and procedures to evaluate the competency and training needs for the Laboratory Director/Technical Supervisor who performed microscopic evaluations of nongynecologic cytology during the years 2017, 2018 and to the date of the survey in 2019. The Laboratory Director/Technical Supervisor failed to identify training needs to microscopically identify two of three high grade or malignant urothelial lesions in March 2019. Cross refer to D5209 1. The Survey Team reviewed statistical records of 30 cases reported by the Laboratory

	Director/Technical Supervisor in March of 2019. a. The records reflected one of 30 cases was evaluated and reported by the Laboratory Director/Technical Supervisor as being "Suspicious" for a high grade urothelial lesion or malignancy. 2. The Survey Team microscopically evaluated and identified two additional cases as "Suspicious" for a high grade urothelial lesion or malignancy in March 2019. Cases include: - USC19-0134-1538 -USC19-0134-1621 a. The Laboratory Director/Technical Supervisor confirmed these microscopic interpretations on October 23, 2019. b. The Laboratory Director/Technical Supervisor failed to identify two of the three cases during March 2019 as being "Suspicious" for a high grade urothelial lesion or malignancy.
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 nongynecologic specimen slides and corresponding final test reports it was determined that the Technical Supervisor failed to verify the accuracy of two nongynecologic test reports (refer to D6115) and failed to reassess the workload limits at least every six months (refer to D6130). The cumulative effect of these practices resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart.
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 347 negative nongynecologic cases/slides from June 2018 to October 2019 and confirmation by the Laboratory Director/Technical Supervisor on 10/23/2019 it was determined that the Laboratory Director/Technical Supervisor failed to verify the accuracy of two nongynecologic cytology reports. 1. USC19-0134-1538 3/6/19 ThinPrep Urine LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM DIAGNOSIS: High Grade Urothelial Carcinoma LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: High Grade Urothelial Carcinoma, retrospectively 2. USC19-0134-1621 3/12/19 ThinPrep Urine LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM DIAGNOSIS: High Grade Urothelial Carcinoma LABORATORY DIRECTOR /TECHNICAL SUPERVISOR DIAGNOSIS: High Grade Urothelial Carcinoma, retrospectively
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 policies and procedures, laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor failed to reassess the workload limits at least every six months and make adjustments when necessary in 2017, 2018 and to the date of the survey in 2019. Cross refer to D5637
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.