Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0250964	11/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Palmetto Adult And Children's Urology, Pa	2890 Tricom Street, North Charleston, SC	

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
D0000	A focus survey was completed on November 3, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: Cytology-42 C.F.R. 493-1221 Laboratory Director-42 C.F.R. 493.1441
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, cytology specimen slide preparations, and interviews the laboratory failed to follow written policies and procedures to document the competency of the Technical Supervisor (refer to D5209); failed to refer nongynecologic cytology tests to a CLIA-certified laboratory (refer to D5315); failed to establish written policies and procedures for three laboratory test processes (refer to D5403); failed to test staining materials for intended reactivity of the Papanicolaou stain (refer to D5473); failed to follow written policies and procedures for an annual statistical comparison of three of three required nongynecologic statistics (refer to D5629); failed to follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); and failed to ensure cytology specimen slides were retrieveable upon request (refer to D5663).
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233

	The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview with Staff A, the laboratory failed to establish written policies and procedures for the documentation of complaints and problems reported to the laboratory for 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for investigating and documenting complaints and problems reported to the laboratory. 2. The Survey Team requested and the laboratory failed to provide documentation of complaints and problems reported to the laboratory. 3. During an interview on September 11, 2023 at 3:37 PM, Staff A confirmed these findings.
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, competency assessment records and interview with Staff A, the laboratory failed to follow written policies and procedures to assess the competency of one of one Technical Supervisor in 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the procedure TECHNICAL SUPERVISOR COMPETENCY ASSESSMENT POLICY, which stated: "Competency of the Technical Supervisor must be assessed annually." 2. The Survey Team requested and the laboratory failed to provide competency records for the one of one Technical Supervisor in 2022 and January 2023 to the date of the survey in 2023. Technical Supervisor includes: - Laboratory Director/Technical Supervisor A 3. During an interview on September 12, 2023 at 4:32 PM, the Survey Team requested the competency assessment records for Laboratory Director/Technical Supervisor A. Staff A stated: "I only have 2021."
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on interviews and review of nongynecologic final test reports, the Laboratory Director/Technical Supervisor A failed to refer 106 nongynecologic cytology tests to a CLIA-certified laboratory from May 12, 2023 to October 17, 2023. Findings include: 1. During an interview on September 11, 2023 at 10:10 AM, the Practice Administrator stated: "The slides are not screened onsite at Facility A." "Specimens

	are sent to Facility B to be processed." "The slides are then sent to the Laboratory Director/Technical Supervisor A at Facility C to be read." 2. During a phone interview on September 11, 2023 at 10:50 AM, the Laboratory Director/Technical Supervisor A stated: "I do not screen on site at Facility A." "The slides are screened at Facility C." "I haven't screened on-site at Facility A since March 2020." 3. During an interview on September 11, 2023 at 12:14 PM, when asked if there is a CLIA certificate for Facility C, the Practice Administrator stated: "There is no CLIA certificate for the Laboratory Director/Technical Supervisor A at Facility C." "Laboratory Director /Technical Supervisor A is working under our CLIA number." 4. During an interview on October 30, 2023 at 9:13 AM, when asked if the Laboratory Director/Technical Supervisor A is screening at Facility C, the Practice Administrator stated: "Laboratory Director/Supervisor A previews the cases at Facility C and comes down to Facility A on the weekend to screen and sign out." 5. During an interview on October 30, 2023 at 11:51 AM, when asked if the Laboratory Director is screening at Facility C, Staff A stated: "Laboratory Director/Technical Supervisor A is screening at Facility C and comes down every other weekend to screen them again and sign them out." 6. During an interview on November 1, 2023, Staff A provided a list of 106 nongynecologic cytology tests with corresponding report dates referred to Facility C from May 12, 2023 to October 17, 2023. Cytology tests and report dates include: -UH3211344 05/18 /23 -UH3211345 05/18/23 -UH3211346 05/17/23 -UH3211474 05/18/23 - UH3211635 05/18/23 -UH3211636 05/18/23 -UH3211637 05/15/23 -UH3211922 05 /21/23 -UH3212056 05/21/23 -UH3212164 05/21/23 -UH3212165 05/21/23 - UH3212166 05/21/23 -UH3212167 05/21/23 -UH3212333 05/21/23 -UH3212459 05 /21/23 -UH3212769 05/28/23 -UH3212868 05/30/23 -UH3212869 05/30/23 - UH3213158 05/30/23 -UH3213159 05/30/23 -UH3213412 06/19/23 -UH3214105 06 /19/23 -UH3214106 06/19/23 -UH3214107 06/19/23 -UH3214199 06/19/23 - UH3214355 06/19/23 -UH3214356 06/19/23 -UH3214966 06/25/23 -UH3215072 06 /25/23 -UH3216392 06/30/23 -UH3216923 07/13/23 -UH3217303 07/25/23 - UH3217304 07/25/23 -UH3217533 07/25/23 -UH3217671 07/25/23 -UH3217672 07 /25/23 -UH3217673 07/25/23 -UH3217674 07/25/23 -UH3218355 07/31/23 - UH3218356 07/31/23 -UH3218357 07/31/23 -UH3218645 08/07/23 -UH3218863 08 /07/23 -UH3218864 08/07/23 -UH3218865 08/07/23 -UH3218866 08/07/23 - UH3218867 08/07/23 -UH3218868 08/07/23 -UH3218869 08/07/23 -UH3218993 08 /07/23 -UH3218994 08/07/23 -UH3219095 08/07/23 -UH3219096 08/07/23 - UH3219214 08/14/23 -UH3219302 08/09/23 -UH3219303 08/14/23 -UH3219304 08 /14/23 -UH3219409 08/14/23 -UH3219410 08/14/23 -UH3219411 08/14/23 - UH3219507 08/14/23 -UH3219508 08/14/23 -UH3219509 08/14/23 -UH3219740 08 /15/23 -UH3219741 08/15/23 -UH3219915 08/15/23 -UH3219916 08/15/23 - UH3220170 08/20/23 -UH3220171 08/20/23 -UH3220172 08/20/23 -UH3220671 08 /27/23 -UH3220786 08/27/23 -UH3220787 08/27/23 -UH3220888 08/27/23 - UH3221259 09/04/23 -UH3221589 09/04/23 -UH3222662 09/25/23 -UH3222663 09 /25/23 -UH3222952 09/25/23 -UH3223263 09/25/23 -UH3223478 09/27/23 - UH3223479 09/27/23 -UH3223692 10/08/23 -UH3223693 10/03/23 -UH3223873 10 /08/23 -UH3223874 10/05/23 -UH3223996 10/05/23 -UH3224137 10/08/23 - UH3224348 10/15/23 -UH3224349 10/09/23 -UH3224647 10/15/23 -UH3224785 10 /15/23 -UH3224786 10/15/23 -UH3224966 10/17/23 -UH3225032 10/16/23 - UH3225033 10/17/23 -UH3225180 10/17/23 -UH3225283 10/17/23 -UH3225411 10 /17/23 -UH3225412 10/17/23 -UH3225515 10/17/23 -UH3225516 10/17/23 - UH3225517 10/17/23 -UH3225776 10/17/23 -UH3225777 10/17/23 -UH3225778 10 /17/23
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 14 laboratory policies and procedures and interview with Staff A, the laboratory failed to establish written policies and procedures for three laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process of transporting specimens from Facility A to Facility B for processing. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for reporting final nongynecologic cytology test results in the laboratory's information system. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process of filing and storing cytology specimen slides. a. Cytology specimen slides were being stored at Facility C. b. There was no record or policy of what was being stored at Facility C. 4. During an interview on September 12, 2023 at 4:32 PM, Staff A confirmed these findings.
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 14 laboratory policies and procedures and interview with Staff A, the laboratory failed to ensure that one of 14 written procedures was approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date one of 14 laboratory procedures. Procedure includes: - SPECIMEN COLLECTION OF PATHOLOGY SAMPLES 2. During an interview on September 12, 2023 at 4:32 PM, Staff A confirmed these findings.
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: Based on the lack of laboratory records and interview with Staff A, the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used for nongynecologic cytology specimen slides for each day of use from June 1, 2022 to September 11, 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide laboratory records documenting that the characteristics of the Papanicolaou stain used for nongynecologic cytology slide preparations were assessed each day of use from June 1, 2022 to September 11, 2023. 2. During an interview on September 12, 2023 at 4:32 PM, Staff A 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, lack of statistical records and interview with Staff A, the laboratory failed to follow written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. The laboratory failed to document three of three required annual nongynecologic statistics for 2021 and 2022. Findings include: 1. The laboratory failed to follow the policy QUALITY ASSURANCE PROGRAM which stated: "An annual statistical report will be performed including the number of urine cytology cases examined (the only cytology specimen submitted by this office), and the number of cases reported by diagnosis (including unsatisfactory)." 2. The Survey Team requested and the laboratory failed to provide records of the three required annual statistics for 2021 and 2022. Statistics include: -Number of nongynecologic cytology cases examined. -Number of nongynecologic specimens processed by specimen type. -Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory. 3. During an interview on September 11, 2023 at 3:37 PM, Staff A 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 workload establishment records and interview with Staff A, the laboratory failed to follow written policies and procedures to ensure individual maximum workload limits were established for the Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides. The laboratory failed to provide individual maximum workload limits for one of one Technical Supervisor in 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy titled CYTOLOGY WORKLOAD LIMITS signed on December 14, 2018 which stated: "This policy is intended to establish workload limits and guidelines. No individual will screen more than 100 slides in a 24 hour period. The prorated number of cytology slides for the Laboratory Director/Technical Supervisor A is 25 slides in 24 hours at PACU." 2. The Survey Team requested and the laboratory failed to provide individual maximum workload limits for one of one Technical Supervisor in 2021, 2022 and January 2023 to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor A 3. During an interview on September 12, 2023 at 4:32 PM, Staff A 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 reassessed workload limit records and interview with Staff A, the laboratory failed to follow written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for the Technical Supervisor. The laboratory failed to provide reassessed maximum workload limits for one of one Technical Supervisor in 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy titled QUALITY ASSURANCE PROGRAM which stated: "A 6 month cytology workload assessment will be performed and documented." 2. The Survey Team requested and the laboratory failed to provide reassessed maximum workload limits for one of one Technical Supervisor in 2021, 2022 and January 2023 to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor A 3. During an interview on September 12, 2023 at 4:32 PM, Staff A 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 with Staff A, the laboratory failed to follow written policies and procedures to ensure that the laboratory maintained records for the total number of cytology specimen slides the Laboratory Director/Technical Supervisor A examined and the number of hours spent examining those slides in a 24-hour period from May 17, 2023 to the date of the survey on September 11, 2023. Findings include: 1. The laboratory failed to follow written policies and procedures titled CYTOLOGY WORKLOAD LIMITS which stated: "The screener/pathologist will be responsible for recording the time spent and number of slides screened each day slides are read." 2. The Survey Team reviewed laboratory records titled PRIMARY SCREENING RECORD from May 17, 2023 to the date of the survey on September 11, 2023. The records failed to document the total number of cytology specimen slides examined and the hours spent examining those slides in each 24-hour period for 17 out of 17 dates. Dates include: -05/17/23 -05/18/23 -05/21/23 -05/28/23 -05/30/23 -06/19/23 -06/25/23 -07/11/23 -07/13/23 -07/25/23 -07/31/23 -08/07/23 -08/09/23 -08/14/23 -08/15/23 -08/20/23 -08/27/23 3. During an interview on September 12, 2023 at 4:32 PM, Staff A confirmed these findings.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory workload establishment records and interview with Staff A, the laboratory failed to follow written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisor in 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy titled CYTOLOGY WORKLOAD LIMITS which stated: "PRINCIPLE: This policy is intended to establish workload limits and guidelines." "SCOPE: This policy applies to all persons screening cytology slides." 2. The Survey Team requested and the laboratory failed to provide records of individual maximum workload limits for one of one Technical Supervisor in 2021, 2022 and January 2023 to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director /Technical Supervisor A 3. During an interview on September 23, 2023 at 4:32 PM, Staff A confirmed these findings.
D5663	CYTOLOGY CFR(s): 493.1274(f)(4) (f) Record and slide retention. (f)(4) All slides must be retrievable upon request.

	This STANDARD is not met as evidenced by: Based on interview and review of laboratory records, the laboratory failed to ensure cytology specimen slides from November 1, 2019 through December 31, 2019 were retrievable upon request. Findings include: 1. The Survey Team requested and the laboratory failed to provide cytology specimen slides for November 1, 2019 through December 31, 2019. 2. During an interview on November 1, 2023 at 11:34 AM, the Survey Team requested from Staff A all cytology specimen slides and corresponding laboratory records from November 1, 2019 through December 31, 2019. Staff A stated: "These are the ones we couldn't find." "I can get you a copy of the final reports." 3. During an interview on November 1, 2023 at 12:10 PM, Staff A provided copies of the corresponding laboratory records for eight missing cytology specimen slides from November 1, 2019 through December 31, 2019. Cytology specimen slides include: -UH9833715 -UH9834215 -UH9835113 -UH9835114 -UH9836245 -UH9836540 -UH9838624 -UH9839060
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, cytology specimen slide preparations and interview with Staff A, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems with diagnostic interpretation errors in nongynecologic cytology testing. The laboratory failed to identify and document failures of the cytology analytic systems in 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy QUALITY MANAGEMENT PROGRAM IN SURGICAL PATHOLOGY/CYTOLOGY which stated: "Random Reviews. Ten (10) cases of surgical pathology/cytology will be submitted for review twice yearly by a second pathologist." a. The Survey Team requested and the laboratory failed to provide laboratory records documenting the random review of cytology cases for 2021, 2022 and January 2023 to the date of the survey. b. During an interview on September 12, 2023 at 4:32 PM, Staff A confirmed these findings. 2. The laboratory failed to monitor and assess the accuracy of reporting nongynecologic cytology tests. (refer to D6115)
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of final cytology test reports and interviews, 134 of 134 final cytology test reports from January 1, 2023 to September 4, 2023 failed to accurately indicate the address of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 134 final cytology test reports from January 1, 2023 to September 4, 2023. One hundred thirty-four of 134 final cytology test reports failed to indicate the address of the laboratory where the test was performed. Test reports include: -UH2234086 -UH2234207 -UH2234208 -UH2234352 -UH2234353 -UH2234354 -UH3200586 -UH3200587 -UH3200736 -UH3200914 -UH3201060 -UH3201061 -UH3201197 -UH3201300 -UH3201574 -UH3201575 -UH3201576 -UH3201815 -UH3202081 -UH3202082 -UH3202083 -UH3202324 -UH3202325 -UH3202326 -UH3202327 -UH3202328 -UH3202467 -UH3202580 -UH3202892 -UH3202893 -UH3202894 -UH3202895 -UH3202896 -UH3203291 -UH3204063 -UH3204341 -UH3204560 -UH3204561 -UH3204946 -UH3205426 -UH3205709 -UH3205710 -UH3206082 -UH3206809 -UH3207298 -UH3208296 -UH3208541 -UH3208542 -UH3208658 -UH3208660 -UH3208894 -UH3209131 -UH3209132 -UH3209234 -UH3210376 -UH3210377 -UH3210497 -UH3210635 -UH3211344 -UH3211345 -UH3211346 -UH3211474 -UH3211635 -UH3211636 -UH3211637 -UH3211922 -UH3212056 -UH3212164 -UH3212165 -UH3212166 -UH3212167 -UH3212333 -UH3212459 -UH3212769 -UH3212868 -UH3212869 -UH3213158 -UH3213159 -UH3213412 -UH3214105 -UH3214106 -UH3214107 -UH3214199 -UH3214355 -UH3214356 -UH3214966 -UH3215072 -UH3216392 -UH3216923 -UH3217303 -UH3217304 -UH3217533 -UH3217671 -UH3217672 -UH3217673 -UH3217674 -UH3218355 -UH3218356 -UH3218357 -UH3218645 -UH3218863 -UH3218864 -UH3218865 -UH3218866 -UH3218867 -UH3218868 -UH3218869 -UH3218993 -UH3218994 -UH3219095 -UH3219096 -UH3219214 -UH3219302 -UH3219303 -UH3219304 -UH3219409 -UH3219410 -UH3219411 -UH3219507 -UH3219508 -UH3219509 -UH3219740 -UH3219741 -UH3219915 -UH3219916 -UH3220170 -UH3220171 -UH3220172 -UH3220671 -UH3220786 -UH3220787 -UH3220888 -UH3221259 -UH3221589 2. During an interview on September 11, 2023 at 10:10 AM, the Practice Administrator confirmed that the address on the final cytology test reports indicated the address of Facility A. 3. During a phone interview on September 11, 2023 at 10:50 AM, the Laboratory Director/Technical Supervisor A stated: "I haven't screened any slides at Facility A since March 2020." When asked where the cases from Facility A are signed out, the Laboratory Director/Technical Supervisor A stated: "At Facility C." 4. During an interview on September 12, 2023 at 4:32 PM, Staff A 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, cytology specimen slide preparations and interviews, 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 that quality control programs were established and followed to assure the quality of laboratory services

	and identify failures in quality as they occur (refer to D6093); failed to ensure quality assessment programs were established and followed to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094); and failed to follow written policies and procedures to assess and monitor the competency of the Technical Supervisor performing nongynecologic cytology testing and failed to follow written policies and procedures to ensure the competency of the Technical Supervisor to accurately report diagnostic interpretations (refer to D6103).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 laboratory policies and procedures, lack of laboratory records and interview with Staff A, the Laboratory Director who also functions as Technical Supervisor A, failed to ensure that quality control programs were established and maintained to assure the quality of nongynecologic cytology testing and identify failures in quality as they occur. The Laboratory Director failed to provide records of an established quality control program in cytology in 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assure the quality of cytology testing and identify failures in quality as they occur. 2. The Survey Team requested and the Laboratory Director failed to provide records of an established quality control program in cytology in 2021, 2022 and January 2023 to the date of the survey in 2023. 3. During an interview on September 12, 2023 at 4:32 PM, Staff A confirmed these findings.
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 laboratory policies and procedures and laboratory records, the Laboratory Director failed to ensure quality assessment programs were followed to assure the quality of laboratory services and identify failures in quality as they occur. Findings include: 1. The Laboratory Director failed to ensure policies and procedures were followed for a quality assessment program for all phases of cytology testing. a. Laboratory policy titled QUALITY ASSURANCE PROGRAM stated: "The daily technical quality of the cases will be reviewed by the pathologist (medical director) and documented on the stain quality screening log." "An annual statistical report will be performed including the number of urine cytology cases examined (the only cytology specimen submitted by this office), the number of cases reported by diagnosis (including unsatisfactory). "A 6 month cytology workload assessment will be performed and documented." b. The laboratory failed to follow the policy titled QUALITY MANAGEMENT PROGRAM IN SURGICAL PATHOLOGY

	/CYTOLOGY. (refer to D5791) 2. The Laboratory Director failed to ensure records of an established quality assessment program were maintained and failed to identify failures in quality as they occurred in 2021, 2022 and January 2023 to the date of the survey in 2023. a. The Laboratory Director failed to ensure documentation of the testing of staining materials for intended reactivity of the Papanicolaou stain. (refer to D5473) b. The Laboratory Director failed to ensure documentation of an established program for an annual statistical evaluation of the required laboratory statistics. (refer to D5629) c. The Laboratory Director failed to ensure documentation of an established program for monitoring the establishment and reassessment of maximum workload limits for the Technical Supervisor. (refer to D5633, D5637, D5647, D6130) d. The Laboratory Director failed to ensure documentation of an established program for monitoring workload records to ensure the total number of slides examined in each 24-hour period and the number of hours the Technical Supervisor spent examining slides in each 24-hour period was documented. (refer to D5645)
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: A. Based on review of laboratory policies and procedures, lack of competency assessment records and interview, the Laboratory Director, who also functions as Technical Supervisor A, failed to ensure written policies and procedures were followed to assess and monitor the competency of the Technical Supervisor who conducted analytic and post analytic phases of cytology testing. The Laboratory Director failed to provide documentation of a competency assessment for one of one Technical Supervisor in 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Laboratory Director failed to ensure the written policy TECHNICAL SUPERVISOR COMPETENCY ASSESSMENT POLICY was followed. The policy stated: "Competency of the Technical Supervisor must be assessed annually." 2. The Survey Team requested and the Laboratory Director failed to provide documentation of a competency assessment for one of one Technical Supervisor in 2022 and January 2023 to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor A 3. During an interview on September 12, 2023 at 4:32 PM, Staff A confirmed these findings. B. Based on review of laboratory policies and procedures, laboratory records and cytology specimen slide preparations, the Laboratory Director, who also functions as Technical Supervisor A, failed to ensure written policies and procedures were followed to ensure the competency of the Technical Supervisor to accurately report diagnostic interpretations. The Laboratory Director failed to establish policies and procedures to identify the need for remedial training and to improve upon the diagnostic skills of one of one Technical Supervisor from November 1, 2018 to October 17, 2023. Findings include: 1. The Laboratory Director failed to establish policies and procedures to identify the need for remedial training and to improve upon the diagnostic skills of the Technical Supervisor to identify and report the following diagnostic entities: (refer to D6115) -High grade urothelial carcinoma -Suspicious for

	high grade urothelial carcinoma -Unsatisfactory for evaluation -Polyoma virus effect 2. The Laboratory Director failed to identify training needs for the Technical Supervisor to identify lesions that were High Grade Urothelial Carcinoma. The Technical Supervisor failed to accurately identify and report 16 of 16 patient cases that were High Grade Urothelial Carcinoma from November 1, 2018 to October 17, 2023. Cases include: -UH3208659 -UH2214036 -UH2209667 -UH2204798 -UH1230350 -UH1208131 -UH0207083 -UH9824671 -UH9818803 -UH9813041 -UH3220170 -UH3219410 -UH3218994 -UH3205710 -UH2228238 -UH0217300 3. The Laboratory Director failed to identify training needs for the Technical Supervisor to identify lesions that were Suspicious for Malignancy. The Technical Supervisor failed to accurately identify and report 14 of 19 patient cases that were Suspicious for Malignancy from November 1, 2018 to October 17, 2023. Cases include: -UH3222952 -UH3221259 -UH3200586 -UH3201575 -UH2221892 -UH2218858 -UH2200836 -UH0231506 -UH0210275 -UH0200368 -UH9832096 -UH9814417 -UH9808476 -UH8842183 4. The Laboratory Director failed to identify training needs for the Technical Supervisor to identify cases that were Unsatisfactory for Evaluation. The Technical Supervisor failed to accurately identify and report two of two patient cases that were Unsatisfactory for Evaluation from November 1, 2018 to October 17, 2023. Cases include: -UH2201892 -UH1224542 5. The Laboratory Director failed to identify training needs for the Technical Supervisor to identify and report patient cases that contained Polyoma Virus Effect. The Technical Supervisor failed to accurately report eight of eight patient cases that contained Polyoma Virus Effect from November 1, 2018 to October 17, 2023. Cases include: -UH3221589 -UH3214356 -UH2216732 -UH1232266 -UH1220325 -UH0226427 -UH3217303 -UH3209131
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: A. Based on microscopic review of 601 random negative nongynecologic cases/601 slides and the corresponding final cytology test reports from November 1, 2018 through October 17, 2023 and confirmation by the Survey Team Pathologist on November 3, 2023, Technical Supervisor A failed to verify the accuracy of 32 nongynecologic cytology tests. 1. UH3208659 04/10/2023 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 2. UH2214036 05 /19/2022 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 3. UH2209667 04/07/2022 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 4. UH2204798 02/23/2022 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 5. UH1230350 10/17/2021 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 6. UH1208131 03/28/2021 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 7. UH0207083 03

/11/2020 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 8. UH9824671 08/17/2019 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 9. UH9818803 06/22/2019 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 10. UH9813041 04/26/2019 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 11. UH3222952 09/25/2023 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma; High grade squamous dysplasia. 12. UH3221259 09/04/2023 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma, possibly with squamous differentiation. 13. UH3200586 02/02/2023 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 14. UH3201575 02/02 /2023 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 15. UH2221892 08/13/2022 Urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma; Polyoma virus effect. 16. UH2218858 07/18/2022 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 17. UH2200836 01/12/2022 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 18. UH0231506 12/13/2020 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 19. UH0210275 05/05/2020 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 20. UH0200368 01/11 /2020 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 21. UH9832096 10/21/2019 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 22. UH9814417 05/12 /2019 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma; High grade squamous dysplasia. 23. UH9808476 03/16/2019 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma. 24. UH8842183 12/21/2018 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma; Polyoma virus effect. 25. UH2201892 01/27/2022 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory. Acellular specimen. 26. UH1224542 08/19/2021 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory. Acellular specimen. 27. UH3221589 09/04/2023 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells; Polyoma virus effect. 28. UH3214356 06/19/2023 Voided urine LABORATORY DIAGNOSIS: Negative for

	malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells; Polyoma virus effect. 29. UH2216732 06/19/2022 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma; Polyoma virus effect. 30. UH1232266 11/01/2021 Urine other LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma; Polyoma virus effect. 31. UH1220325 07/14/2021 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma; Polyoma virus effect. 32. UH0226427 10/20/2020 Voided urine LABORATORY DIAGNOSIS: Negative for malignancy. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma; Polyoma virus effect. B. Based on microscopic review of 47 random non-negative nongynecologic cases/47 slides and the corresponding final cytology test reports from November 1, 2018 through October 17, 2023 and confirmation by the Survey Team Pathologist on November 3, 2023, Technical Supervisor A failed to verify the accuracy of eight nongynecologic cytology tests. 1. UH3220170 08/20/2023 Urine other LABORATORY DIAGNOSIS: Atypical urothelial cells and clusters. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 2. UH3219410 08/14/2023 Voided urine LABORATORY DIAGNOSIS: Rare atypical urothelial cell clusters. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 3. UH3218994 08/07/2023 Urine other LABORATORY DIAGNOSIS: Rare atypical urothelial cells. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 4. UH3205710 03/08/2023 Voided urine LABORATORY DIAGNOSIS: Atypical transitional cells with degenerative changes. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 5. UH2228238 10/25/2022 Voided urine LABORATORY DIAGNOSIS: Atypical urothelial cell clusters. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 6. UH0217300 07/18/2020 Urine other LABORATORY DIAGNOSIS: Rare clusters of mildly atypical transitional cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma. 7. UH3217303 07/25/2023 Voided urine LABORATORY DIAGNOSIS: Rare atypical urothelial cells and rare red blood cells. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma; Polyoma virus effect. 8. UH3209131 04/15/2023 Voided urine LABORATORY DIAGNOSIS: Atypical Urothelial cell clusters. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma; Polyoma virus effect.
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, lack of laboratory workload establishment records and interview with Staff A, Technical Supervisor A failed to establish individual workload limits and to reassess the workload limits at least every six months for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Cross refer to D5633 and D5637 Findings include: 1. The Survey

	Team requested and Technical Supervisor A failed to provide documentation that Technical Supervisor A established a maximum workload limit for one of one Technical Supervisor in 2021, 2022 and January 2023 to the date of the survey in 2023. (refer to D5633) Technical Supervisor includes: -Technical Supervisor A 2. The Survey Team requested and Technical Supervisor A failed to provide records of a workload reassessment at least every six months for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (refer to D5637) Technical Supervisor includes: -Technical Supervisor A 3. During an interview on September 11, 2023 at 3:37 PM, Staff A confirmed these findings.
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 workload records and interview with Staff A, one of one Technical Supervisor performing primary screening of nongynecologic cytology specimen slides failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period from May 17, 2023 to September 11, 2023. Cross refer to D5645 Findings include: 1. The Survey Team requested and the laboratory failed to provide records of the total number of slides screened and the total number of hours one of one Technical Supervisor devoted to screening nongynecologic cytology specimen slides during each 24-hour period from May 17, 2023 to September 11, 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor A 2. During an interview on September 12, 2023 at 4: 32 PM, Staff A confirmed these findings.
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.