Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0868940	01/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Urologic Care Sc	22285 N Pepper Rd, Lake Barrington, IL	

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
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, observation and interview the laboratory failed to follow written policies and procedures to ensure positive patient identification of patient specimens during nongynecologic specimen processing. Findings include: 1. The laboratory failed to follow the procedure SPECIMEN ACCESSIONING AND HANDLING, which stated: "Cytology specimen accession numbers begin with the prefix "C" followed by the last two digits of the year, i.e. 2006, "06", a dash and then the next sequential numerical number." "This accession number is written on the requisition and on the specimen container." "Write the accession number on a 50ml centrifuge tube." 2. The laboratory failed to follow the procedure COLLECTION AND PREPARATION OF NON-GYNECOLOGICAL SPECIMENS, which stated: "Number requisition and specimen container with next available accession number." "Number centrifuge tube with accession number and pour 50 ml or total volume of specimen in centrifuge tube." 3. During an observation of nongynecologic specimen processing on January 14, 2025 at 9:00 AM, Staff B failed to write C and the year on the specimen containers and centrifuge tubes for five of five specimens. Specimens include: Accession number Number on container/tube: -C25-49 49 -C25-50 50 -C25-51 51 -C25-52 52 -C25-53 53 4. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.

D5305	TEST REQUEST CFR(s): 493.1241(c) (c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of laboratory test requisitions and interview the laboratory failed to ensure test requisitions solicited the sex of the patient for 20 of 20 test requisitions from November 2024. Findings include: 1. The Survey Team reviewed 20 consecutive test requisitions from November 2024. Twenty of 20 test requisitions failed to solicit the sex of the patient. Test requisitions include: -C24-1340 -C24-1341 -C24-1342 -C24-1343 -C24-1344 -C24-1345 -C24-1346 -C24-1347 -C24-1348 -C24-1349 -C24-1350 -C24-1351 -C24-1352 -C24-1353 -C24-1354 -C24-1355 -C24-1356 -C24-1357 -C24-1358 -C24-1359 2. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 22 laboratory policies and procedures, interviews and laboratory records the laboratory failed to follow two written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure PREVENTING CROSS CONTAMINATION OF CYTOLOGY AND TISSUE, which stated: "All stains and solutions are covered when not in use, and changed or filtered as needed to remove any sediment or cellular debris, and after known malignant or highly cellular cases are stained. In addition stains will be changed weekly." a. During an interview on January 14, 2025 at 9:00 AM, the Cytotechnologist stated all stains and solutions were changed weekly. b. The Survey Team reviewed records titled CYTOLOGY STAIINING DAILY LOG from January 1, 2024 through January 10, 2025. The laboratory failed to change the stains and solutions for 23 of 53 weeks. Weeks include: -01/01/24 through 01/05/24 -01/29/24 through 02/02/24 -02/05/24 through 02

	/09/24 -02/19/24 through 02/23/24 -02/26/24 through 03/01/24 -03/04/24 through 03 /08/24 -03/25/24 through 03/29/24 -04/08/24 through 04/12/24 -04/15/24 through 04 /19/24 -05/06/24 through 05/10/24 -05/20/24 through 05/24/24 -06/10/24 through 06 /14/24 -07/01/24 through 07/05/24 -07/22/24 through 07/26/24 -08/19/24 through 08 /23/24 -09/02/24 through 09/06/24 -09/30/24 through 10/04/24 -10/14/24 through 10 /18/24 -11/04/24 through 11/08/24 -11/25/24 through 11/29/24 -12/02/24 through 12 /06/24 -12/16/24 through 12/20/24 -12/30/24 through 01/03/25 2. The laboratory failed to follow the procedure CYTOCENTRIFUGE MAINTENANCE IN CYTOLOGY, which stated: "Monthly Maintenance Lubricate center piece (head bearings) and locking ball bearing of the cytospin and the centrifuge used lithium grease sparingly so that it does not get on the inside of the bowl liner during centrifuging. Trunnion lubrication on the Thermo IEC CL30 Centrifuge. This operation is necessary to allow the buckets to swing freely. Clean the trunnions with a dry wipe (as well as the part of the bucket that rotates on the trunnions). Then, put a very small quantity of grease on the curved face of the trunnion. Do not apply too much grease because it will eventually coat the bowl liner of the centrifuge as centrifugal force pulls the grease from the trunnions. If the centrifuge is having imbalance problems, try this operation before calling for service." "Log monthly maintenance by initialing the CYTOSPIN 2 / CENTRIFUGE MAINTENANCE LOG." a. During an interview on January 14, 2025 at 9:00 AM, the Cytotechnologist stated the Shandon Cytospin 4 was lubricated quarterly and documented on the laboratory record titled INSTRUMENT RECORD for the Shandon Cytospin 4. The Cytotechnologist further stated the monthly maintenance performed and documented on the laboratory record titled CYTOSPIN 2 / CENTRIFUGE MAINTENANCE LOG did not include lubricating the Cytospin. b. During an interview on January 14, 2025 at 9:00 AM, the Cytotechnologist stated the Thermo IEC CL30 Centrifuge was lubricated quarterly and documented on the laboratory record titled INSTRUMENT RECORD for the Thermo IEC CL30 Centrifuge. The Cytotechnologist further stated the monthly maintenance performed and documented on the laboratory record titled CYTOSPIN 2 / CENTRIFUGE MAINTENANCE LOG did not include lubricating the Centrifuge. 3. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 22 laboratory policies and procedures, observation and interviews the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how cytology spray fixative would be removed from specimen slides prior to staining. 2. During an observation of nongynecologic specimen processing (specimens C25-49 through C25-53) on January 14, 2025 at 9:00 AM, the Cytotechnologist sprayed Leica Surgipath Cytology fixative on the specimen slides after removing the specimen slides from the Shandon Cytospin 4. After the specimen slides were dry the Cytotechnologist rinsed the specimen slides in water and proceeded to stain the specimen slides with the Papanicolaou stain. a. The procedure PAPANICOLAOU STAINING failed to include an alcohol step to remove the fixative coating from the specimen slides prior to staining. 3. During an interview on January 14, 2025 at 9:25 AM, the Cytotechnologist confirmed there was no step to remove the fixative coating from the specimen slides prior to staining. a. The laboratory's failure to remove the fixative coating interfered with the stain's ability to stain the cells. 4. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 22 laboratory policies and procedures and interview the laboratory failed to ensure three of 22 written policies and procedures were approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date three of 22 laboratory policies and procedures to indicate approval. Procedures include: -DOWNTIME PROCEDURE IN THE EVENT OF EQUIPMENT FAILURE -CYTOLOGY/SURGICAL REPORTS - COMMUNICATION WITH PHYSICIANS AND LABORATORY 2. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (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 workload limit records

	and interview the laboratory failed to follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of cytology specimens. The Technical Supervisor failed to establish an individual maximum workload limit for one of one Technical Supervisors who performed primary screening in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY WORKLOAD SURVEILLANCE POLICY, which stated: "The number of slides examined by each pathologist engaged in the evaluation of cytology preparations will be no more than 100 slides in a 24-hour period." 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for one of one Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisor includes: -Technical Supervisor B 3. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (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 workload limit reassessment records and interview 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 Supervisors who performed primary screening of cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for one of one Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY WORKLOAD SURVEILLANCE POLICY, which stated: "Workload limits for individuals will be reviewed and approved on a biannual basis. Approval will be recorded on the CYTOLOGY TOTALS AND PATHOLOGY WORKLOAD RECORDING log." 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit for one of one Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisor includes: -Technical Supervisor B 3. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, workload records and interviews the laboratory failed to follow written policies and procedures to ensure workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD SURVEILLANCE POLICY, which stated: "Screening time will be recorded on the CYTOLOGY TOTALS AND PATHOLOGY WORKLOAD RECORDING log." 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for one of one Technical Supervisors in an effort to prorate the maximum number of slides that could be evaluated. Refer to D5633, D5637, D5647, D6130 3. The Survey Team requested and the laboratory failed to provide documentation of the number of hours one of one Technical Supervisors spent examining slides per 24-hour period in an effort to prorate the maximum number of slides that could be evaluated. Refer to D5645, D6133
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (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, workload records and interviews the laboratory failed to follow written policies and procedures to ensure the laboratory maintained records of the number of hours the Technical Supervisors spent examining slides per 24-hour period. The laboratory failed to maintain records of the number of hours one of one Technical Supervisors spent examining slides in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD SURVEILLANCE POLICY, which stated: "Screening time will be recorded on the CYTOLOGY TOTALS AND PATHOLOGY WORKLOAD RECORDING log." 2. The Survey Team requested and the laboratory failed to provide records of the number of hours one of one Technical Supervisors spent examining slides per 24-hour period in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisor includes: -Technical Supervisor B 3. During an interview on January 14, 2025 at 9:25 AM, the Cytotechnologist stated the Cytotechnologist completed the CYTOLOGY TOTALS AND PATHOLOGY WORKLOAD RECORDING log for Technical Supervisor B and estimated it took Technical Supervisor B six minutes to examine each slide. 4. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d)(4) Records are available to document the workload limit for each individual. (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following:

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interview the laboratory failed to follow written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisors who performed primary screening of cytology specimens from 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY WORKLOAD SURVEILLANCE POLICY, which stated: "The number of slides examined by each pathologist engaged in the evaluation of cytology preparations will be no more than 100 slides in a 24-hour period." "Workload limits for individuals will be reviewed and approved on a biannual basis. Approval will be recorded on the CYTOLOGY TOTALS AND PATHOLOGY WORKLOAD RECORDING log." 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one Technical Supervisors who performed primary screening of cytology specimens in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisor includes: -Technical Supervisor B 3. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (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, nongynecologic cytology slide preparations and corresponding final test reports and confirmation by Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify three of three nongynecologic cytology slide preparations as being unsatisfactory for evaluation from January 2023 through December 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory due to poor technical quality. 2. The laboratory failed to identify and report three of three nongynecologic tests from January 2023 through December 2024 as unsatisfactory for evaluation. These findings were confirmed by Technical Supervisor A on January 15, 2025. Tests include: -C23-1089 -C24-1196 -C24-1360
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, observation 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 be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations (refer to D6079); and failed to ensure quality control and quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094).
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, specimen slides, observation and interviews the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure patient specimens were labeled with a unique patient identifier during all phases of testing. Refer to D5203 2. The Laboratory Director failed to provide direction and oversight to ensure test requisitions solicited the sex of the patient. Refer to D5305 3. The Laboratory Director failed to provide direction and oversight to ensure the laboratory followed two written policies and procedures. Refer to D5401 4. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were established for all laboratory test processes. Refer to D5403 5. The Laboratory Director failed to provide direction and oversight to ensure all written policies and procedures were approved by the Laboratory Director. Refer to D5407 6. The Laboratory Director failed to provide direction and oversight to ensure the Technical Supervisor performing evaluation and reporting of cytology specimens had an established workload limit and failed to ensure criteria were established to reassess workload limits at least every 6 months. Refer to D5633, D5637, D5647, D6130 7. The Laboratory Director failed to provide direction and oversight to ensure the Technical Supervisor performing evaluation and reporting of cytology specimens maintained records of the number of hours the Technical Supervisor spent examining slides per 24-hour period. Refer to D5645, D6133 8. The Laboratory Director failed to provide direction and oversight to ensure unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. Refer to D5655
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	(e)(5) Ensure that the quality control and 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, observation and interviews the Laboratory Director failed to ensure quality control and quality assessment programs were established for an ongoing mechanism to monitor, assess and correct problems identified with the preparation of nongynecologic cytology specimen slides during the microscopic examination of the specimen slides. The Laboratory Director failed to identify poor stain quality for nongynecologic cytology specimen slide preparations from September 2024 through December 2024. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established and followed for an ongoing program to identify, correct and prevent recurrence of stain quality problems for nongynecologic cytology slide preparations. a. The procedure PREVENTING CROSS CONTAMINATION OF CYTOLOGY AND HISTOLOGY stated: "Daily check of the stain quality is completed and monitored for both the Pap stain and the H&E stain; this will be recorded on the PATHOLOGY TECHNICAL STAINING QA log." b. The procedure PAPANICOLAOU STAINING stated: "REPORTING RESULTS/RANGES/INTERPRETATION: Nuclei - Crisp clear blue color Cytoplasm - Superficial cells - orange Intermediate cells - bluish green" 2. The Survey Team observed 18 cases with poor stain quality of the specimen slide preparations that included lack of nuclear detail, lack of cytoplasmic differentiation and inconsistent staining patterns. Cases include: -C24-1162 -C24-1167 -C24-1170 -C24-1177 -C24-1178 -C24-1205 -C24-1220 -C24-1246 -C24-1306 -C24-1319 -C24-1320 -C24-1375 -C24-1415 -C24-1418 -C24-1460 -C24-1472 -C24-1482 -C24-1483 a. The Survey Team reviewed laboratory records titled PATHOLOGY TECHNICAL STAINING QA from September 2024 through December 2024. The records failed to document the identification of any staining problems on the dates the slides were stained. 3. During an observation of nongynecologic specimen processing (specimens C25-49 through C25-53) on January 14, 2025 at 9:00 AM, the Cytotechnologist sprayed Leica Surgipath Cytology fixative on the specimen slides after removing the specimen slides from the Shandon Cytospin 4. After the specimen slides were dry the Cytotechnologist rinsed the specimen slides in water and proceeded to stain the specimen slides with the Papanicolaou stain. The Cytotechnologist failed to remove the fixative coating from the specimen slides prior to staining which interfered with the stains ability to stain the specimen slides. a. During an interview on January 14, 2025 at 9:25 AM, the Cytotechnologist confirmed there was no step to remove the fixative coating from the specimen slides prior to staining. The fixative coating interfered with the stain's ability to stain the cells. 4. During an interview on January 15, 2025 at 9:40 AM, these findings were confirmed with the Laboratory Director /Technical Supervisor A, Technical Supervisor B, Cytotechnologist, Practice Manager and Regulatory Affairs Officer.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys 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 the microscopic review of 391 random negative nongynecologic cytology cases/slides from September 2024 through December 2024 and confirmation by the Technical Supervisor on January 15, 2025 the Technical Supervisor failed to verify the accuracy of three nongynecologic cytology tests. 1. C24-1388 11/12/24 Bladder Wash LABORATORY DIAGNOSIS: Benign Urothelial Cells SURVEY TEAM DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma TECHNICAL SUPERVISOR A DIAGNOSIS: Atypical; Suspicious for High-Grade Urothelial Carcinoma 2. C24-1196 09/27/24 Bladder Wash LABORATORY DIAGNOSIS: Benign Urothelial Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory - Poor Technical Quality TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory - Poor Technical Quality 3. C24-1360 11/05/24 Bladder Wash LABORATORY DIAGNOSIS: Benign Urothelial Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory - Poor Technical Quality TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory - Poor Technical Quality B. Based on the microscopic review of 24 focused non-negative nongynecologic cytology cases/slides from January 2023 through March 2024 and confirmation by the Technical Supervisor on January 15, 2025 the Technical Supervisor failed to verify the accuracy of one nongynecologic cytology test. 1. C23-1089 08/28/23 Bladder Wash LABORATORY DIAGNOSIS: Atypical Urothelial Cells of Undetermined Significance SURVEY TEAM DIAGNOSIS: Unsatisfactory - Poor Technical Quality TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory - Poor Technical Quality
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c)(2) Must establish the workload limit for each individual examining slides; (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 the lack of workload limit records and interview the Technical Supervisor failed to establish and reassess a maximum workload limit for one of one Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor established a maximum workload limit for one of one Technical Supervisors who performed primary cytology slide examinations in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Refer to D5633 and D5647 2. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisors who performed primary cytology slide examinations in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Refer to D5637 and D5647
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) (c)(6) 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 workload records and interviews one of one Technical Supervisors failed to document the number of hours devoted to screening during each 24-hour period in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. One of one Technical Supervisors failed to document the number of hours devoted during each 24-hour period to screening cytology slides in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. 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.