Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1074973	08/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Prithipal S Sethi, Md, Inc	3133 W March Lane Ste 1040, Stockton, CA	

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, specimen slides, observation and interviews it was determined that the laboratory failed to provide test requisitions that solicited required patient information (refer to D5305); failed to follow written policies and procedures for the labeling of nongynecologic slide preparations and specimen acceptability (refer to D5311); failed to establish written policies and procedures for two laboratory test processes (refer to D5403); failed to follow manufacturer's instructions for required maintenance for cytocentrifuge (refer to D5429); failed to establish written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish 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); failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); and failed to ensure test reports indicated the name and address of the laboratory where the test was performed (refer to D5805).
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, lack of laboratory records and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to assess the competency of Technical Supervisors. The laboratory failed to provide documentation of a competency assessment for one of one Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for one of one Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director /Technical Supervisor.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (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. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (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 policies and procedures, laboratory records and interviews with the Laboratory Director/Technical Supervisor and Lab Assistant the laboratory failed to ensure that a nongynecologic cytology test requisition was provided to physicians to solicit the required patient information for 331 of 331 consecutive nongynecologic cytology specimens from December 1, 2021 to April 12, 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide a nongynecologic cytology test requisition that solicited the required patient information for 331 of 331 consecutive nongynecologic cytology specimens from December 1, 2022 to April 12, 2022. Required information includes: -The name and address or other suitable identifiers of the authorized person requesting the test -The patient's name or unique patient identifier -The sex and age or date of birth of the patient -The test(s) to be performed -The source of the specimen -The date of specimen collection -Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results Specimens include: -U-7214 to U-7544 2. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor who stated that

	"patient demographic/face sheets" were used in lieu of a test requisition. 3. During an interview on August 9, 2022 at 2:00 PM these findings were confirmed by Lab Assistant who stated that the medical assistants printed "patient demographic/face sheets" and recorded information on the bottom of those.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, cytology slide preparations, observation and interview with the Lab Assistant the laboratory failed to follow written policies and procedures for specimen labeling. The laboratory failed to label ten of 284 cytology slide preparations with the patient name from January 2022 to April 2022. Findings include: 1. The laboratory failed to follow the procedure URINE CYTOLOGY PROCEDURE which stated: -"3.) Slides are properly labeled with two unique patient identifiers: requisition number and patient name." 2. The Survey Team reviewed 284 cytology slide preparations from January 2022 to April 2022. The laboratory failed to label ten of 284 cytology slide preparations with the patient name. Slide preparations include: -U-7290 Slide labeled with patient first name, last initial. and accession number. -U-7320 Slide labeled with patient last name and accession number. -U-7321 Slide labeled with patient last name and accession number. -U-7323 Slide labeled with patient first name, last initial and accession number. -U-7359 Slide labeled with patient last name and accession number. -U-7361 Slide labeled with patient last name and accession number. -U-7367 Slide labeled with patient last name and accession number. -U-7444 Slide labeled with patient last name and accession number. -U-7455 Slide labeled with patient last name and accession number. -U-7496 Slide labeled with patient first name, last initial and accession number. 3. During an interview on August 9, 2022 at 2:00 PM Lab Assistant stated that it is the laboratory's practice to label each slide with accession number, patient first initial and last name. B. Based on review of laboratory policies and procedures, observation and interview with the Lab Assistant the laboratory failed to follow written policies and procedures for specimen acceptability. The laboratory failed to verify the date of birth for one of one nongynecologic cytology specimen during specimen receipt and processing on August 9, 2022. Findings include: 1. The laboratory failed to follow the procedure URINE CYTOLOGY PROCEDURE which stated: -"1.) Urine is collected in vials which have at least 2 unique patient identifiers including patient name and date of birth." 2. The laboratory failed to follow the procedure GROSS EXAMINATION PRACTICES which stated: -"Surgical Pathology and Cytopathology Specimens must be submitted to the gross examination Area in an appropriately labeled, clean container...unacceptable specimens will be re-labeled with verification of the surgeon." 3. During observation of specimen receipt and processing on August 9, 2022 at 2:00 PM the Survey Team identified one of one nongynecologic cytology specimen with a discrepancy between the date of birth on the specimen container and the date of birth on the "patient demographic/face sheet". Lab Assistant proceeded to process the specimen then stain the cytology slide preparation. Specimen includes:

	Accession number: U-7868 Date of birth written on specimen container: 3-28-02 Date of birth typed on "patient demographic/face sheet": 03/28/2000 4. During an interview on August 9, 2022 at 2:00 PM these findings were confirmed by Lab Assistant who stated: -"If the physician who saw this patient was here today, I would ask him to verify the birthdate. Since the month and the day are the same, it's ok."
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory quality assessment records, observation and interview with the Lab Assistant the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems. The laboratory failed to document preanalytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5305 and D5311 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the preanalytic laboratory systems. 2. The Survey Team requested and the laboratory failed to provide documentation of preanalytic laboratory quality assessment activities in 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to have an ongoing mechanism to ensure that cytology test requisitions were provided that solicited the required patient information. (Refer to D5305) b. The laboratory failed to have an ongoing mechanism to monitor, assess and correct problems identified with slide labeling and specimen acceptability. (Refer to D5311) 3. During an interview on August 8, 2022 at 2:00 PM these findings were confirmed by Lab Assistant.
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 eight laboratory policies and procedures, laboratory records and interviews with the Laboratory Director/Technical Supervisor and Lab Assistant the laboratory failed to establish written policies and procedures for two laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how cytology test results were reported in the patient record. a. The Survey Team reviewed 284 "patient demographic /face sheets" from December 2021 to April 2022. A "0" was recorded on the bottom of each "patient demographic/face sheet". There were no signatures or initials. b. During an interview on August 8, 2022 at 2:00 PM these findings were confirmed by Lab Assistant who stated: -"The zero means that it's Negative. (Laboratory Director /Technical Supervisor) writes that on there for his secretary to type." -"The signed reports are sent to me through secure email. I convert them to a PDF then release them to the charts." c. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that time frames were established for cytology test results. a. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of manufacturer's instructions, lack of laboratory maintenance records and interview with the Lab Assistant the laboratory failed to ensure that the required preventive maintenance for one of one cytocentrifuge used for cytology testing was performed as specified by the manufacturer in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The 7620 CYTOPRO CYTOCENTRIFUGE USER'S MANUAL stated: -Page 37: "A Check Rotor Seals. Seals must be inspected frequently for cracks or signs of deterioration. Replace seals yearly, or whenever they show any signs of wear." -Page 38: "The rotor should be sterilized periodically or whenever you observe or suspect a spill." 2. The Survey Team requested and the laboratory failed to provide preventive maintenance records for one of one cytocentrifuge used for cytology testing for 2020, 2021 and to the date of the survey in 2022. Centrifuge includes: -Wescor 7620 Cytopro Cytocentrifuge 3. During an interview on August 9, 2022 at 2:00 PM these findings were confirmed by Lab Assistant who stated "The cytospin sometimes leaks and I wipe down the bottom of the bowl with a disinfecting wipe but I don't document it." When asked if technical support was contacted to investigate the cause of the leak Lab Assistant replied "No."
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 statistical records and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. The laboratory failed to document one of three required nongynecologic statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. Statistics include: -The total number of cytology cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide one of three required nongynecologic annual statistics for 2020 and 2021. Statistics include: -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established for the Technical Supervisors who performed primary screening of nongynecologic cytology specimen slides. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established individual maximum workload limits for the Technical Supervisors who performed primary screening of nongynecologic cytology specimen slides. 2. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish 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 nongynecologic cytology specimen slides. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisors' workload limits would be reassessed at least every six months and adjusted when necessary. 2. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (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, lack of prorated workload limit records and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. The laboratory failed to provide documentation of a prorated workload limit for one of one Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Technical Supervisors when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide records of a prorated workload limit for one of one Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Technical Supervisors examined per 24-hour period and the number of hours spent examining slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Technical Supervisors examined per 24-hour period and the number of hours spent examining slides per 24-hour period. 2. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director /Technical Supervisor.
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 phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of nongynecologic cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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, cytology slide preparations and corresponding final test reports and phone interview with the Laboratory Director /Technical Supervisor the laboratory failed to establish written policies and

	procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report 16 of 16 nongynecologic cytology slide preparations from January 20, 2022 to March 20, 2022 as unsatisfactory. 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. 2. The laboratory failed to identify and report 16 of 16 nongynecologic cytology slide preparations from January 20, 2022 to March 20, 2022 as unsatisfactory. Nongynecologic cytology slide preparations include: -U-7241 -U-7245 -U-7246 -U-7247 -U-7262 -U-7307 -U-7330 -U-7359 -U-7361 -U-7362 -U-7363 -U-7364 -U-7373 -U-7381 -U-7426 -U-7431 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor. On August 19, 2022 Laboratory Director/Technical Supervisor submitted written confirmation of the review to CMS and confirmed the Survey Team findings.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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, lack of laboratory quality assessment records and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5403, D5429, D5629 and D5657 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 2.

	The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating cytology test results reported in the patient record. (Refer to D5403 and D5657) b. The laboratory failed to document a system for monitoring and evaluating equipment maintenance. (Refer to D5429) c. The laboratory failed to document a system for monitoring and evaluating annual statistics. (Refer to D5629) 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 phone interview with the Laboratory Director/Technical Supervisor 290 of 290 final cytology test reports from January 20, 2022 to May 5, 2020 failed to indicate the name and address of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 290 consecutive final cytology test reports from January 20, 2022 to May 5, 2022. Two hundred ninety of 290 final cytology test reports failed to indicate the name and address of the laboratory where the test was performed. Reports include: -U-7214 to U-7506 2. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of policies and procedures, final cytology test reports and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to follow written policies and procedures to ensure that patient test results were released within an established time frame. Findings include: 1. The laboratory failed to follow the procedure MICROSCOPIC EXAMINATION PRACTICES which stated: -"Every effort is made to release Pathology Reports as quickly as is possible limited by good patient care." 2. The Survey Team reviewed thirteen consecutive final test reports from March 31, 2022. The report dates were 17 days later than the collection dates for six of thirteen cases. The report dates were 35 days later than the collection dates for seven of thirteen cases. Cases include: -U-7494 Collection date: March 31, 2022

	Report date: April 17, 2022 -U-7495 Collection date: March 31, 2022 Report date: April 17, 2022 -U-7496 Collection date: March 31, 2022 Report date: April 17, 2022 -U-7497 Collection date: March 31, 2022 Report date: April 17, 2022 -U-7498 Collection date: March 31, 2022 Report date: April 17, 2022 -U-7499 Collection date: March 31, 2022 Report date: April 17, 2022 -U-7500 Collection date: March 31, 2022 Report date: May 5, 2022 -U-7501 Collection date: March 31, 2022 Report date: May 5, 2022 -U-7502 Collection date: March 31, 2022 Report date: May 5, 2022 -U-7503 Collection date: March 31, 2022 Report date: May 5, 2022 -U-7504 Collection date: March 31, 2022 Report date: May 5, 2022 -U-7505 Collection date: March 31, 2022 Report date: May 5, 2022 -U-7506 Collection date: March 31, 2022 Report date: May 5, 2022 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor. When asked if another Technical Supervisor covered when Laboratory Director/Technical Supervisor was away, Laboratory Director/Technical Supervisor replied "No, the specimens are held for my return" and also stated: -"The specimens are collected and they wait until they have enough to batch." -"Cytology is a minute part of my practice. I come in on days that I have nothing else to do because Cytology is incredibly boring."
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory quality assessment records and phone interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic cytology systems. The laboratory failed to document postanalytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5805 and D5815 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the postanalytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of postanalytic quality assessment activities during 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating final test reports for required elements. (Refer to D5805) b. The laboratory failed to document a system for monitoring and correcting problems when delays in testing occur. (Refer to D5815) 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 interview 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 quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur (refer to D6094); and failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of personnel performing cytology duties (refer to D6103).
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, lack of laboratory quality assessment records, cytology specimen slides and phone interview with the Laboratory Director/Technical Supervisor the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5391, D5791 and D5891 Findings include: 1. The Survey Team requested and the Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program for all phases of cytology testing. (Refer to D5391, D5791 and D5891) 2. The Survey Team requested and the Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2020, 2021 and to the date of the survey in 2022. 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 and phone interview with the Laboratory Director/Technical Supervisor the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of Technical Supervisors, Lab Assistants and Secretaries who conducted preanalytic, analytic and postanalytic phases of cytology testing. Cross refer to D5209. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of Lab Assistants who conduct preanalytic and postanalytic phases of

	cytology testing. a. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for one of one Lab Assistant in 2020, 2021 and to the date of the survey in 2022. Lab Assistant includes: -Lab Assistant 2. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor, and maintain the competency of Secretaries who conduct postanalytic phases of testing. a. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for one of one Secretary in 2020, 2021 and to the date of the survey in 2022. Secretary includes: -Secretary 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 microscopic review of 284 negative nongynecologic cases/285 slides and the corresponding final test reports from January 2022 through April 2022 and confirmation by Technical Supervisor on August 19, 2022 the Technical Supervisor failed to verify the accuracy of sixteen nongynecologic cytology tests. 1. U-7241 01/20 /2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 2. U-7245 01/20/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 3. U-7246 01/20/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 4. U-7247 01/20/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 5. U-7262 01/21/2022 Voided urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 6. U-7307 02/10/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 7. U-7330 03/16/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to acellularity and obscuring blood TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 8. U-7359 03/16/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 9. U-7361 03/16/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to acellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 10. U-7362 03/16/2022 Voided urine

	LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 11. U-7363 03/16 /2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to acellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 12. U-7364 03/16/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 13. U-7373 03/16/2022 Voided urine LABORATORY DIAGNOSIS: Negative, scattered neutrophils SURVEY TEAM DIAGNOSIS: Unsatisfactory due to acellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 14. U-7381 03/20/2022 Voided urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 15. U-7426 03/20/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular 16. U-7431 03/20/2022 Voided urine LABORATORY DIAGNOSIS: Negative, limited due to scant cellularity SURVEY TEAM DIAGNOSIS: Unsatisfactory due to acellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory, Scantly Cellular
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 limit records and phone interview with the Laboratory Director/Technical Supervisor it was determined that the Technical Supervisor failed to establish an individual workload limit and failed to reassess workload limits at least every six months for one of one Technical Supervisor performing primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Technical Supervisor who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. (Refer to D5633) Technical Supervisor includes: -Technical Supervisor 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisor who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. (Refer to D5637) Technical Supervisor includes: -Technical Supervisor 3. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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 polices and procedures, lack of laboratory workload records and phone interview with the Laboratory Director/Technical Supervisor 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 in 2020, 2021 and to the date of the survey in 2022. 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 in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 2. During a phone interview on August 8, 2022 at 3:04 PM these findings were confirmed by Laboratory Director/Technical Supervisor.
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.