Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0692370	12/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
International Medical Laboratory	15 Corporate Park, Irvine, 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, observation and interviews the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors (refer to D5209); failed to establish written policies and procedures for laboratory test processes (refer to D5311 and D5403); failed to follow manufacturer's instructions for gynecologic cytology specimens when using the RESOLUTION BIOMEDICAL CLEARPREP Pap Test (refer to D5411); failed to establish performance specifications when the laboratory modified RESOLUTION BIOMEDICAL CLEARPREP Pap Tests manufacturer's instructions with an alternate method of processing gynecologic cytology specimens (refer to D5423); failed to establish written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics (refer to D5629); failed to establish and follow written policies and procedures for the establishment and reassessment of individual workload limits (refer to D5633, D5635 and D5637); 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).
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 competency records and interview with Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of Technical Supervisors in 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 the Technical Supervisors who performed cytology testing. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for Technical Supervisors who performed cytology testing in 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on December 5, 2022 via telephone at 4:00 PM the Laboratory Director /Technical Supervisor A confirmed these findings and stated that the laboratory "does not do pathologist evaluations."
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 lack of instructions to clinicians, review of laboratory test requisitions and interview with Staff B the laboratory failed to ensure that an electronic test requisition solicited the required patient information for cytology Pap Test requests. Required patient information was not solicited on eight of eight electronic Pap Test requisitions sampled from September of 2022. Cross refer to D5311 Findings include: 1. The Survey Team requested of Staff A and Staff B and the laboratory failed to provide instructions to clinicians for submitting required patient information on test requisitions for cytology Pap Tests. Refer to D5311 2. During a review of test requisitions provided by Cytotechnologist and sampled from September 2022, eight of eight electronic Pap Test requisitions failed to solicit the following required patient information for cytology Pap Tests: -The source of the specimen -The patient's last menstrual period -Whether the patient had a previous abnormal report, treatment, or biopsy. Test requisition case numbers include: -705732 -705899 -706084 -706206 -706212 -706328 -706757 -706788 3. During an interview with Staff B on December 6, 2022 at 10:50 AM the paper laboratory test requisition provided to the Survey

	Team was not the same test requisition that was submitted electronically by clinicians for Pap Tests.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of final cytology test reports and corresponding laboratory records the laboratory failed to ensure that cytology specimen information was transcribed accurately into the laboratory information system (LIS) for nine of 40 cytology specimens sampled in September 2022. Findings include: 1. The Survey Team compared 40 final cytology test reports with corresponding laboratory records. Nine of 40 final cytology test reports failed to have accurate specimen information transcribed into the LIS. Specimen information includes: Case #705838 Lab Order Requisition Information: LMP 08/15/22 Cytology Test Report Information: LMP not given Case #705846 Lab Order Requisition Information: Name "Calendaria" Cytology Test Report Information: Name "Candelaria" Case #705810 Lab Order Requisition Information: Specimen Received in ThinPrep vial Cytology Test Report Information: Specimen Received in SurePath vial Case #705868 Lab Order Requisition Information: Date of Collection 09/03/22 Cytology Test Report Information: Date of Collection 09/06/22 Case #705803 Lab Order Requisition Information: Specimen Received in SurePath vial Cytology Test Report Information: Specimen Received in ThinPrep vial Case #706038 Lab Order Requisition Information: LMP 11/11/20 Cytology Test Report Information: LMP 11/11/21 Case #706192 Lab Order Requisition Information: Source cervix Cytology Test Report Information: Source none given Case #706552 Lab Order Requisition Information: Name "Martha" Cytology Test Report Information: Name "Marta" Case #706788 Lab Order Requisition Information: Specimen Received in ThinPrep vial Cytology Test Report Information: Specimen Received in SurePath vial
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: Based on review of laboratory policies and procedures and interview with Staff B the laboratory failed to establish written policies and procedures for the collection, labeling, storage, preservation, transportation and referral of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the collection, labeling, transportation and referral of nongynecologic cytology specimens. 2. The Survey Team requested and the

	laboratory failed to provide written policies and procedures for the storage, preservation, and transportation of gynecologic cytology specimens. 3. The cytology procedure COLLECTION AND ORDER ACCURACY stated: -"Specimen requirements for Cytologic Evaluation can be found in Pacific Medical Laboratory Directory of Services and is available to all client clinics and physician's offices. The proper techniques for ordering tests, specimen collection, handling, labeling and transporting to the laboratory are also defined in the Directory of Services." a. The Survey Team requested and the laboratory failed to provide the "Directory of Services." 4. During an interview on December 6, 2022 at 11:00 AM when asked for the laboratory's instructions to complete a test requisition, collect and label gynecologic and nongynecologic cytology specimens, preserve and transport cytology specimens, Staff B stated: -"I don't have that. Why do you want something that tells them how to fill out a form? Here is a requisition...it doesn't need a policy." 5. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 43 laboratory policies and procedures and interview with the Cytotechnologist 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 the laboratory's requirements for microscopic examination of nongynecologic specimens, including the detection of inadequately prepared slides. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's system for entering results in the patient record and reporting nongynecologic cytology results. 3. During an interview on December 6, 2022 at 11: 30 AM these findings were confirmed with the Cytotechnologist.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, observation, review of laboratory records and interviews the laboratory failed to follow manufacturer's instructions to prepare, evaluate and store gynecologic cytology specimens using the RESOLUTION BIOMEDICAL CLEARPREP Pap Test in January 2022 through the date of the survey in 2022. Cross refer to D5413 Findings include: 1. The RESOLUTION BIOMEDICAL CLEARPREP PRODUCT INSERT states: -"8. Using a disposable pipette, transfer sufficient volume of the mixed cell suspension onto a ClearPrep microscope slide to cover the 18 x 22 mm oval." -"ClearPrep Slide. The microscope slide is also an innovative product that is integral to the ClearPrep process." -"LIMITATIONS. -Proper performance requires use of supplies provided or recommended by Resolution Biomedical, Inc. for use with ClearPrep. Product performance may be compromised if other supplies are used." a. Staff C was observed on December 6, 2022 at 10:00 AM, preparing five of five RESOLUTION BIOMEDICAL CLEARPREP Pap Tests without using the RESOLUTION BIOMEDICAL CLEARPREP microscope slides. Case numbers prepared without the RESOLUTION BIOMEDICAL CLEARPREP slides include: -714822 -714855 -714932 -714949 -714952 b. The Survey Team observed RESOLUTION BIOMEDICAL CLEARPREP Pap Tests slides from January to the date of the survey 2022 which were filed and stored in boxes. (i) The RESOLUTION BIOMEDICAL CLEARPREP Pap Tests randomly observed in the boxes were not prepared on RESOLUTION BIOMEDICAL CLEARPREP microscope slides. The accession numbers for the Pap Test slides ranged from #680931 to #714439. The Survey Team was unable to ascertain the exact number of slides in the boxes. (ii) During an interview on December 6, 2022 at 11:15 AM Cytotechnologist confirmed that "probably none were prepared on RESOLUTION BIOMEDICAL CLEARPREP slides." c. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A. 2. The RESOLUTION BIOMEDICAL CLEARPREP PRODUCT INSERT states: -"The cells are examined under a microscope by trained cytotechnologists and pathologists." -"LIMITATIONS -Training by persons authorized by Resolution Biomedical, Inc. is required to ensure optimal results." a. The Survey Team requested and the laboratory failed to provide documentation of training to evaluate RESOLUTION BIOMEDICAL CLEARPREP Pap Tests. Training documents were not provided for: -Cytotechnologist -Laboratory Director/Technical Supervisor A b. During an interview on December 6, 2022 at 10:35 AM when asked if the Cytotechnologist and Laboratory Director/Technical Supervisor A had documentation of the required training to evaluate RESOLUTION BIOMEDICAL CLEARPREP Pap Tests, the Cytotechnologist replied "no." c. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director /Technical Supervisor A. 3. The RESOLUTION BIOMEDICAL CLEARPREP PRODUCT INSERT states: "STORAGE -The storage limit for ClearPrep Collection Vials with cellular samples is 6 months at refrigerated temperature (2-10 degrees Celsius) or 4 weeks at room temperature." a. The Survey Team observed on December 6, 2022 at 10:00 AM RESOLUTION BIOMEDICAL CLEARPREP Collection Vials with cellular samples dating from February 2022 to the date of the survey stored at room temperature in a cabinet. The samples from February though

	October 2022 exceeded the storage limit of four weeks at room temperature. (Refer to D5413) b. The Survey Team randomly identified one RESOLUTION BIOMEDICAL CLEARPREP Pap Test that was stored at room temperature, processed, evaluated and reported 5 1/2 months after the collection date. Specimen case includes: -Case #682398 Collection date: 01/17/2022 Received date: 01/17/2022 Request to process ClearPrep Pap Test: 06/27/2022 Date reported: 07/06/2022 c. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, observation, review of laboratory policies and procedures and interviews the laboratory failed to define criteria for proper storage of RESOLUTION BIOMEDICAL CLEARPREP Collection Vials with cellular samples. Findings include: 1. The laboratory failed to follow the RESOLUTION BIOMEDICAL CLEARPREP PRODUCT INSERT which states: "STORAGE -The storage limit for ClearPrep Collection Vials with cellular samples is 6 months at refrigerated temperature (2-10 degrees Celsius) or 4 weeks at room temperature." a. The Survey Team observed on December 6, 2022 at 10:00 AM RESOLUTION BIOMEDICAL CLEARPREP Collection Vials with cellular samples from February 2022 to the date of the survey stored at room temperature in boxes in a cabinet. b. During an interview on December 6, 2022 at 10:00 AM, when asked how long the RESOLUTION BIOMEDICAL CLEARPREP Collection Vials with cellular samples were stored at room temperature, Staff C replied "three months or so." 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the laboratory's criteria for proper storage of RESOLUTION BIOMEDICAL CLEARPREP Collection Vials with cellular samples. 3. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any

	other performance characteristic required for test performance. This STANDARD is not met as evidenced by: A. Based on review of manufacturer's instructions and interviews the laboratory failed to establish performance specifications when the laboratory modified the manufacturer's instructions with an alternate method of processing gynecologic cytology specimens with RESOLUTION BIOMEDICAL CLEARPREP Pap Tests. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy and precision, analytical sensitivity, reportable range of test results or any other performance characteristic of the modified RESOLUTION BIOMEDICAL CLEARPREP Pap Test was adequate to provide accurate diagnostic interpretations. a. The laboratory failed to establish performance specifications when preparing RESOLUTION BIOMEDICAL CLEARPREP Pap Tests onto Hologic ThinPrep glass slides, which was modified from the manufacturer's instructions to use RESOLUTION BIOMEDICAL CLEARPREP glass slides. b. The RESOLUTION BIOMEDICAL CLEARPREP PRODUCT INSERT states: -"8. Using a disposable pipette, transfer sufficient volume of the mixed cell suspension onto a ClearPrep microscope slide to cover the 18 x 22 mm oval." -"ClearPrep Slide. The microscope slide is also an innovative product that is integral to the ClearPrep process." -"LIMITATIONS. -Proper performance requires use of supplies provided or recommended by Resolution Biomedical, Inc. for use with ClearPrep. Product performance may be compromised if other supplies are used." c. During an interview on December 7, 2022 via telephone at 10:15 AM Laboratory Director/Technical Supervisor A confirmed the laboratory had modified the manufacturer's instructions and was not using the required RESOLUTION BIOMEDICAL CLEARPREP microscope slides for gynecologic cytology specimen preparations. B. Based on review of manufacturer's instructions, laboratory documents and interviews the laboratory failed to establish performance specifications when the laboratory modified the manufacturer's instructions with an alternate method of processing gynecologic cytology specimens with RESOLUTION BIOMEDICAL CLEARPREP Pap Tests. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy and precision, analytical sensitivity, reportable range of test results or any other performance characteristic of the modified RESOLUTION BIOMEDICAL CLEARPREP Pap Test was adequate to provide accurate diagnostic interpretations. a. The laboratory failed to establish performance specifications for the following diagnoses when comparing a SurePath Pap Test slide preparation with a RESOLUTION BIOMEDICAL CLEARPREP Pap Test slide preparation from a SurePath specimen vial: -ASC-H -AGUS -LSIL -HSIL -Malignancy b. During an interview on December 6, 2022 at 10:40 AM Cytotechnologist provided a document (without a date or signature) titled VALIDATION STUDY SUREPATH VS CLEARPREP. The document stated: "The post analytical portion consists of an evaluation of the statistical clinical data using the following diagnosis: 1. Unsatisfactory 2. Satisfactory 3. NILM 4. ASCUS 5. ASC-H 6. LSIL 7. AGUS 8. HSIL 9. Malignancy Outcome=out of the 40 slides prepared and screened by the pathologist were as follows: 1. ASCUS=1 case 2. NILM=34 cases 3. Reactive =4 cases 4. LSIL=0 cases 5. Unsatisfactory=1 cases" c. During an interview on December 6, 2022 at 10:40 AM the Cytotechnologist 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, statistical records and interviews the laboratory failed to establish 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. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. 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 2. The Survey Team requested and the laboratory failed to provide records of the three required annual statistics for 2021. 3. During interviews on December 5, 2022 at 9:00 AM and 4:30 PM Cytotechnologist stated that nongynecologic statistics were not maintained because nongynecologic specimens were not evaluated and reported at this facility. 4. During an interview on December 6 , 2022 7 at 11:00 AM Staff B stated "the nongynecologic slides are filed here because they are ours." When asked if nongynecologic cases are evaluated and reported by pathologists at this facility Staff B replied "of course...they are our specimens." 5. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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, laboratory records and interviews the laboratory failed to establish written policies and procedures to ensure the Technical Supervisor established maximum workload limits for Technical Supervisors who performed primary screening of nongynecologic cytology specimens. Cross refer to D6130 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established maximum workload limits for Technical Supervisors who performed primary screening of nongynecologic cytology specimens. 2. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5635	CYTOLOGY CFR(s): 493.1274(d)(1)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to follow written policies and procedures to use evaluations of the individual Cytotechnologist's performance when assessing the workload limits for the Cytotechnologist. The laboratory failed to establish workload limits for one of one Cytotechnologists in 2021 and 2022 using the results of the 10 percent review of negative cases. Cross refer to D6167 Findings include: 1. The laboratory failed to follow the written procedure INDIVIDUAL CYTOTECHNOLOGIST WORKLOAD LIMIT which stated: "CRITERIA FOR EVALUATING WORKLOAD LIMIT: The Cytology Laboratory Director will determine the individual workload limits by evaluating the following information: -Hours required to complete daily workload -Errors detected by Q.C. 10% Normal reviews -Evaluation of cases submitted for: -Pathologist review -10% Normal Q.C. review." a. The "hours required to complete the daily workload" was not evaluated to determine the workload limit. (Refer to D6167) b. The "10% Normal Q.C. review" was not evaluated to determine the workload limit. 2. The Survey Team requested and the laboratory failed to provide documentation that the workload limit for one of one Cytotechnologists was established in 2021 and 2022 using the results of the 10 percent review of negative cases. a. The Cytotechnologist provided documents titled CYTOTECHNOLOGIST PERFORMANCE EVALUATION which were used by the laboratory to establish a workload limit. The documents failed to include the data from an evaluation of the 10 percent review of negative cases for December 2021, June 2022 and December 2022. Cytotechnologists include: -Cytotechnologist b. During an interview on December 5, 2022 at 10:00 AM these findings were confirmed with Cytotechnologist. 3. During an interview on December 5, 2022 via telephone at 4: 00 PM these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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: A. Based on review of laboratory policies and procedures, lack of workload limit records and interview 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 specimens. Cross refer to D6130 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor's workload limits would be reassessed at least every six months and adjusted when necessary. 2. The Survey Team requested and the laboratory failed to provide reassessed workload limits for Technical Supervisors who performed primary screening of nongynecologic specimens in 2022. (Refer to D6130) 3. During an interview on December 7 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow written policies and procedures to ensure maximum workload limits were reassessed at least every six months, for one of one Cytotechnologists in 2022. Cross refer to D6130 Findings include: 1. The laboratory failed to follow the written procedure INDIVIDUAL CYTOTECHNOLOGIST WORKLOAD LIMIT which stated: "The Cytology Laboratory Director will determine individual workload limits. This limit is evaluated at least every six months , concurrent with the Cytotechnologist interim and annual performance evaluations. Evaluation by the Medical Director will be performed on every six months and documented using, Cytotechnologist Performance Evaluation Form." 2. The Survey Team requested and the laboratory failed to provide reassessed workload limits for one of one Cytotechnologist in 2022. (Refer to D6130) 3. During an interview on December 5 via telephone at 4:00 PM these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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: A. Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to establish written policies and procedures to ensure 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. Cross refer to D6133 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 an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director /Technical Supervisor A. B. Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to follow written policies and procedures to ensure records were maintained of the total number of hours the Cytotechnologist spent examining slides during each 24-hour period from January to the date of the survey in 2022. Cross refer to D6167 Findings include: 1. The laboratory failed to follow the written policy and procedure QUALITY ASSURANCE MANUAL which stated: "Cytotechnologists are responsible for the daily case workload sheet and must enter your name, date, starting time, ending time, number of slides and first and last slide number of each tray." 2. During an interview on December 5, 2022 at 4:30 PM these findings were confirmed with the

	Cytotechnologist who stated "I do not put down when I start or stop screening and the real screening time is not kept."
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, manufacturer's instructions, laboratory records, 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); failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094); and failed to ensure that one of one Technical Supervisors and one of one Cytotechnologists had received the appropriate training prior to reporting RESOLUTION BIOMEDICAL CLEARPREP Pap Tests (refer to D6102); failed to specify in writing the responsibilities and duties of each Technical Supervisor engaged in the performance of analytic cytology testing (refer to D6107).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Cross refer to D5305, D5309, D5411, D5413, D5623, D5629, D5633, D5637, D6130, D6133, D6167 Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure the laboratory's electronic test requisitions solicited required patient information. (Refer to D5305) 2. The Laboratory Director failed to provide direction and oversight to ensure that cytology specimen information was transcribed accurately into the LIS. (Refer to D5309) 3. The Laboratory Director failed to provide direction and oversight to ensure RESOLUTION BIOMEDICAL CLEARPREP testing was performed following the manufacturer's instructions and

	failed to establish performance specifications when modifying the manufacturer's instructions. (Refer to D5411, D5413 and D5423) 4. The Laboratory Director failed to provide direction and oversight to ensure the accurate compilation and documentation of annual statistics. (Refer to D5629). 5. The Laboratory Director failed to provide direction and oversight to ensure technical supervisors performing evaluation and reporting of nongynecologic cytology specimens had an established workload limit assessed and failed to ensure criteria were established to reassess workload limits every 6 months. (Refer to D5633, D5637 and D6130) 6. The Laboratory Director failed to provide direction and oversight to ensure technical supervisors performing evaluation and reporting of nongynecologic cytology specimens maintained records of the number of slides evaluated and the time spent evaluating the slides. (Refer to D6133) 7. The Laboratory Director failed to provide direction and oversight to the Cytotechnologist to ensure the accurate documentation of the number of hours spent examining slides in each 24-hour period. (Refer to D6167)
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, laboratory records and interview the Laboratory Director 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. Cross refer to D5305, D5309, D6167 Findings include: 1. The Laboratory Director failed to establish a program to monitor electronic test requisitions to ensure the test requisition provided to physicians solicited the required patient information for cytology Pap Tests. (Refer to D5305) 2. The Laboratory Director failed to establish a program to monitor the accuracy of cytology specimen information transcribed into the laboratory information system (LIS) for cytology specimens. (Refer to D5309) 3. The Laboratory Director failed to establish a program to monitor the accuracy of the Cytotechnologists documentation of the time spent evaluating cytology specimen slides. (Refer to D6167) 4. The Laboratory Director failed to establish a program to monitor the accuracy and completeness of the laboratory's program for review of monthly and annual statistical data. a. The 2022 monthly and annual statistical report 2022 CYTOLOGY STATISTICS SUMMARY failed to document the number of RESOLUTION BIOMEDICAL CLEARPREP Pap Tests, which was the only method of Pap Tests reported by the laboratory. The form documented HOLOGIC THINPREP and BD SUREPATH Pap Tests but neither of those two tests were being reported by the laboratory. b. The 2022 monthly and annual statistical report 2022 CYTOLOGY STATISTICS SUMMARY failed to document one of one LSIL reported in 2022. Case includes: -#70353 Report Date: 09 /13/2022 c. The 2022 monthly and annual statistical report 2022 CYTOLOGY REPREP CASES failed to document one of one reprep case in 2022. Case includes: -#707171 Report Date: 09/26/22 d. During an interview on December 6, 2022 at 11:20 AM these findings were confirmed with the Cytotechnologist. 5. The Laboratory Director failed to establish a program to monitor the accuracy and completeness of the laboratory's program for a monthly quality assessment document. a. The document MONTHLY QUALITY ASSESSMENT CHECK marked the following as "completed" daily and monthly for the months of January through November 2022.

	The equipment was not in use and had been stored and labeled as "Do Not Use." -SurePath Instruments and Equipment -ThinPrep Instruments and Equipment b. The document MONTHLY QUALITY ASSESSMENT CHECK marked the following statistical record as completed for the months of January through November 2022. The record failed to identify and include the following: -the omission of Nongynecologic data -the omission of a LSIL from September 2022 -the omission of slide reprocessing from September 2022 c. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director /Technical Supervisor A.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of training records, review of manufacturer's instructions and interviews the Laboratory Director failed to ensure that one of one Technical Supervisors and one of one Cytotechnologists who performed RESOLUTION BIOMEDICAL CLEARPREP Pap Test evaluations had received the appropriate RESOLUTION BIOMEDICAL CLEARPREP Pap Test training prior to reporting patient specimens in 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation of training to evaluate RESOLUTION BIOMEDICAL CLEARPREP Pap Tests. Training documents were not provided for: -Cytotechnologist -Laboratory Director /Technical Supervisor A 2. The RESOLUTION BIOMEDICAL CLEARPREP PRODUCT INSERT states: -"The cells are examined under a microscope by trained cytotechnologists and pathologists." -"LIMITATIONS -Training by persons authorized by Resolution Biomedical, Inc. is required to ensure optimal results." 3. During an interview on December 6, 2022 at 10:35 AM when asked if the Cytotechnologist and Laboratory Director/Technical Supervisor A had documentation of the required training to evaluate RESOLUTION BIOMEDICAL CLEARPREP Pap Tests, the Cytotechnologist replied "no." 4. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were confirmed with the Laboratory Director /Technical Supervisor A.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review of policies and procedures, lack of laboratory records and interviews the Laboratory Director failed to specify in writing the responsibilities and duties of each technical supervisor engaged in the performance of analytic cytology testing. The Laboratory Director failed to provide written record to detail responsibilities, duties and which examinations and procedures each technical supervisor is authorized to perform and whether director review is required prior to reporting patient cytology test results. Cross refer to D5403, D6133 and D5209 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the Laboratory Directors assigned duties and responsibilities for each technical supervisor engaged in analytic cytology testing. a. The Laboratory Director failed to specify responsibility requirements for microscopic examination of nongynecologic specimens and the requirements for entering cytology results in the patient record and reporting cytology results. (Refer to D5403) b. The Laboratory Director failed to specify responsibility requirements for the documentation of the number of slides screened and the number of hours devoted to screening slides. (Refer to D6133) c. The Survey Team requested and the laboratory failed to provide a list of all technical supervisors engaged in cytology testing. The CMS form 209 provided by the laboratory and signed by the Laboratory Director on 11/29/2022 and again on 12 /21/2022 failed to include all technical supervisors engaged in cytology testing. 2. The Survey Team requested and the laboratory failed to provide a written record authorized by the Laboratory Director, to detail the responsibilities, duties and which examinations and procedures each technical supervisor is authorized to perform. 3. During an interview on December 5, 2022 via telephone at 4:00 PM the Laboratory Director/Technical Supervisor A confirmed these findings and stated that the laboratory "does not do pathologist evaluations." (Refer to D5209)
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: A. Based on review of lack of laboratory records and interviews the Technical Supervisor failed to establish and failed to reassess maximum workload limits for Technical Supervisors who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The Technical Supervisor failed to provide an established maximum workload limit for Technical Supervisors who performed primary slide screening in 2021 and to the date of the survey in 2022. a. The number of Technical Supervisors who performed primary slide screening in 2021 and to the date of the survey in 2022 was not provided by the laboratory at the time of the survey. b. During an interview on December 6, 2022 at 2:30 PM Staff A stated that Technical Supervisor B performed primary slide screening of nongynecologic cases /slides at this facility in 2022. c. During an interview on December 6, 2022 at 11:30 AM Cytotechnologist provided documents titled CYTOLOGY DATA COLLECTION FORM TOTAL VOLUMES 2022-PATHOLOGIST PRIMARY SCREENING WORKLOAD VOLUME that documented primary screening of cases /slides by Laboratory Director/Technical Supervisor A at this facility in 2022. 2. During an interview on December 7, 2022 via telephone at 10:15 AM these findings

	were discussed with the Laboratory Director/Technical Supervisor A. The Laboratory Director/Technical Supervisor A stated during the interview "I do not screen urine cases at the lab. I will have to see the form that has the case numbers on it." B. Based on review of laboratory records and interviews the Technical Supervisor failed to reassess maximum workload limits at least every six months for one of one Cytotechnologists in 2022. Findings include: 1. The Technical Supervisor failed to reassess a maximum workload limit at least every six months for one of one Cytotechnologists in 2022. Cytotechnologist includes: - Cytotechnologist 2. The Cytotechnologist provided documents titled CYTOTECHNOLOGIST PERFORMANCE EVALUATION which were used by the laboratory to establish a workload limit, but failed to include an assigned reassessed workload limit for the Cytotechnologist on the following evaluation dates: -June 2022 -November 28, 2022. 3. During an interview on December 5, 2022 via telephone at 4:00 PM these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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, laboratory records and interviews Technical Supervisors 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 2021 and to the date of the survey in 2022. The number of Technical Supervisors who performed primary screening of nongynecologic specimens could not be ascertained at the time of the survey, based on information provided by the laboratory. 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 Technical Supervisors devoted to screening nongynecologic cytology specimen slides during each 24-hour period in 2021 and to the date of the survey in 2022. The number of Technical Supervisors performing primary evaluations of nongynecologic cytology tests was not provided during the course of the survey. 2. During an interview on December 6, 2022 at 11:30 AM Cytotechnologist provided documents titled CYTOLOGY DATA COLLECTION FORM TOTAL VOLUMES 2022-PATHOLOGIST PRIMARY SCREENING WORKLOAD VOLUME for January through August 2022. a. The Cytotechnologist stated that the forms included the numbers of cases (not slides) that were evaluated by the Laboratory Director /Technical Supervisor A at this facility and at other facilities. The laboratory did not provide the number of slides per cases during the survey. Cases that were documented as being evaluated at this facility January through August 2022 include: -Urine Cytology: January 6-1 case January 22-1 case February-0 cases March 10-1 case April 11-1 case April 13-1 case April 18-1 case May 4-1 case May 7-1 case May 17-1 case June 2-1 case June 8-1 case July-0 cases August-0 cases b. The CYTOLOGY DATA COLLECTION FORM TOTAL VOLUMES 2022-PATHOLOGIST PRIMARY SCREENING WORKLOAD VOLUME form failed to include the time Laboratory Director/Technical Supervisor A spent evaluating the cases and slides. 3. During an interview on December 6, 2022 at 2:30 PM Staff A confirmed that the following ten

	randomly identified nongynecologic cases were evaluated and reported by Technical Supervisor B at this facility. The laboratory did not provide documentation of the number of slides per case during the survey. Cases include: -691332 -691487 -693615 -693617 -693643 -694027 -694032 -695042 -701193 -701877 a. Draft reports printed by Staff A for the ten cases failed to include the name of the Technical Supervisor who evaluated the cases and Staff A stated that laboratory staff were not located to assist with the printing of a final test report to reflect the name of the Technical Supervisor/Technical Supervisors. 4. During an interview on December 7, 2022 via telephone at 10:15 AM these findings were discussed with the Laboratory Director /Technical Supervisor A.
D6167	CYTOTECHNOLOGIST RESPONSIBILITIES CFR(s): 493.1485(c) The cytotechnologist is responsible for documenting the number of hours spent examining slides in each 24-hour period. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview one of one Cytotechnologists failed to document the number of hours spent examining slides in each 24-hour period, in 2022 from January to the date of the survey. Findings include: 1. Cytotechnologist provided laboratory records CYTOLOGY DATA COLLECTION FORM-TOTAL VOLUMES 2022 from January through October 2022 for Cytotechnologist. The records failed to include the actual time spent evaluating slides during each 24-hour period spent examining slides. 2. During an interview on December 5, 2022 at 4:30 PM Cytotechnologist stated: -"I use an excel sheet and a formula to figure out the TOTAL SCREENING TIME/24 HOURS on the form." -"Others do it wrong when they hand-write in the time but I use the excel form so the time matches the slide numbers." a. When asked if the time documented was the actual time spent evaluating the slides Cytotechnologist replied "no." b. When asked if the start time and stop time was recorded per the laboratory policy QUALITY ASSURANCE MANUAL Cytotechnologist replied "no." c. Cytotechnologist confirmed that the number of hours spent examining slides in each 24-hour period in 2022 was not documented.
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.