Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0571204	03/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	13112 Evening Creek Drive, South Ste 300, San Diego, 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 policies and procedures, record review, observations and interviews it was determined that the laboratory failed to establish policies and procedures for five test processes (refer to D5403); failed to perform gynecologic specimen testing according to the manufacturer's instructions (refer to D5411); failed to test "Diff-Quik"staining materials for intended reactivity and staining characteristics (refer to D5473); failed to follow policies and procedures for the review of prior negative gynecologic specimens from patients with a current high grade lesion (refer to D5625); failed to establish policies and procedures for the evaluation and comparison of six annual statistics and failed to document six required annual statistics (refer to D5629); failed to establish policies and procedures to include the Technical Supervisor's feedback on Cytotechnologists' interpretations when assessing the individual workload limit (refer to D5635); failed to follow policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to maintain the identity of the personnel performing comparative reviews of discrepant cytology and histopathology specimens (refer to D5787); and failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of cytology testing (refer to D5791). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to assess the competency of five of five Technical Supervisors that performed microscopic evaluations of cytology specimens in 2018 and to the date of the survey. Findings include: 1. The laboratory failed to follow the policy titled PROFESSIONAL COMPETENCY ASSESSMENT. a. Laboratory records titled PROFESSIONAL COMPETENCY ASSESSMENT did not include assessments or documentation of the items stated in the policy for five of five Technical Supervisors. -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for five of five Technical Supervisors to reflect microscopic evaluation responsibilities in the analytic phase of testing. 3. During interviews on January 9, 2019 at 2:15 PM and March 5, 2019 at 3:40 PM, the Anatomic Pathology Manager confirmed these findings.
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, laboratory records and interview it was determined that the laboratory failed to establish written polices and procedures for nongynecologic specimen processing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to process all types of nongynecologic cytology specimens. a. There were no written policies or procedures for the following types of nongynecologic specimens, which were listed on the laboratory document titled NONGYN/FNA REPORT 01/01/2018 THROUGH 12/21/2018: -Fine Needle Aspiration (FNA); -Bronchial Washing; -Pleural Fluid; -Abdominal Fluid; -Urine; -Sputum; -Miscellaneous Smear; -Breast Discharge; -Anal Rectal; -Bronchial Brushing; -Pneumocystis Carinii Pneumonia Special; -Cell Block; -Nongynecologic (NONGYN) Problem Specimen. 2. During an interview on March 7, 2019 at 3:40 PM, the Anatomic Pathology Manager confimed these findings.
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 114 laboratory policies and procedures, interviews and review of laboratory documents it was determined that the laboratory failed to establish written policies and procedures for five laboratory processes. Cross refer to D5473 Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedure to detail how the testing for intended reactivity of the "Diff-Quik" stains would be performed and documented. 2. The Survey Team requested and the laboratory failed to provide a written procedure to detail how the stain maintenance tasks for "Diff-Quik" stains and solutions would be performed and documented. a. During an interview on March 7, 2019 at 2:00 PM, the Anatomic Pathology Manager confirmed this finding. 3. The Survey Team requested and the laboratory failed to provide a written procedure for the laboratory's microscopic examination and reporting system for thyroid specimens. a. During an interview on March 7, 2019 at 9: 45 AM, the Anatomic Pathology Manager searched in the CYTOLOGY MANUAL and the CYTOPREPARATION LABORATORY MANUALS VOLUME V and VOLUME VI and stated "there isn't a procedure in there." b. The Anatomic Pathology Manager stated "the Cytotechnologists are using thyroid codes from a document." The Anatomic Pathology Manager provided a document titled THYROID FINE NEEDLE ASPIRATE DIAGNOSIS CODES and stated that it was "not part of a written policy or procedure." 4. The Survey Team requested and the laboratory failed to provide a written procedure for sending slides to other facilities. a. During an interview on February 8, 2019 at 3:50 PM, the Anatomic Pathology Manager stated "we don't have a policy" for sending slides to other facilities. 5. The Survey Team requested and the laboratory failed to provide a written procedure for receiving slides from other facilities. a. During an interview on February 8, 2019 at 3:50 PM, the Anatomic Pathology Manager stated "we don't have a policy" for receiving slides from other facilities.
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: A. Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, observation and interview it was determined that the laboratory failed to follow the manufacturer's instructions when processing Hologic ThinPrep Pap Test specimens on three of five Hologic T2000 Processors. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL 5A-SECTION 1 states: "Fill a fixative vial with standard laboratory fixative alcohol until the fluid level is between the 'MIN' and 'MAX' marks on the vial." 2. During an observation of Hologic ThinPrep Pap Test processing on January 9, 2019 at 11:35 AM, Cytopreparatory Staff B was observed ejecting ThinPrep Pap Test slides into the fixative vial with fixative alcohol below the minimum level required, on three of five Hologic T2000 Processors. Hologic T2000 Processors include: -R1 Serial #07218 -R2 Serial #04287007C0 -R3 Serial #04176A07C0 3. During an interview with the Anatomic Pathology Manager on January 9, 2018 at 11:50 AM, the observation findings were discussed and confirmed. B. Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records for the Hologic ThinPrep Pap Test and interview it was determined that the laboratory failed to ensure that one of five Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test, according to the manufacturer's instructions. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states "the evaluation of microscopic slides produced with the THINPREP 2000 System should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by CYTYC Corporation or by organizations or individuals designated by CYTYC Corporation." a. The Survey Team requested and the laboratory failed to provide training records for one of five Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests during 2018 and to the date of the survey. Technical Supervisor includes: - Technical Supervisor B 2. During an interview on January 8, 2019 at 9:00 AM, the Anatomic Pathology Manager stated that the laboratory "did not have any training records" for Technical Supervisor B. C. Based on the review of the Becton Dickinson (BD) SUREPATH IMPLEMENTATION GUIDE, certification records for BD SurePath and interview it was determined that the laboratory failed to ensure that one of five Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the BD SurePath, according to the manufacturer's instructions. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states "BD SurePath Morphology Training must be completed for cytotechnologists and pathologists who evaluate BD SurePath prepared slides." a. The Survey Team requested and the laboratory failed to provide morphology training records for one of five Technical Supervisors who performed diagnostic interpretations on BD SurePath prepared slides during 2018 and to the date of the survey. Technical Supervisor includes: - Technical Supervisor B 2. During an interview on January 8, 2019 at 9:00 AM, the Anatomic Pathology Manager stated that the laboratory "did not have any training records" for Technical Supervisor B.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials

	for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, observation and interview it was determined that the laboratory failed to test "Diff-Quik"staining materials for intended reactivity and specimen staining characteristics, for each day of use in 2018 and to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide stain assessment records for the "Diff-Quik" staining solutions, for each day of use in 2018 and to the date of the survey. 2. During an observation of the "Diff-Quik" nongynecologic staining processes on January 10, 2019 at 11:50 AM, the Anatomic Pathology Manager confirmed that there were no laboratory records to document the staining characteristics of the "Diff-Quik" staining. 3. During an interview with the Anatomic Pathology Manager on March 7, 2019 at 2:00 PM, these findings were reviewed and confirmed.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (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)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of gynecologic specimen slides and laboratory records it was determined that the laboratory failed to identify two of 54 prior negative gynecologic cases as having a more significant lesion than initially reported. The laboratory failed to identify one of 54 prior negative gynecologic cases as being "Unsatisfactory for Evaluation." Findings include: 1. The laboratory failed to follow the procedure titled PREVIOUS FIVE YEAR REVIEW. The procedure stated: "All previous negative cases are first reviewed by a cytotechnologist authorized to perform Quality Control Review. If a discrepancy is found, the slides and reports are returned to a Pathologist for review." 2. The Survey Team reviewed 54 prior negative gynecologic cases and corresponding laboratory records from 45 patients with a current HSIL in January through March 2018. a. The Survey Team Pathologist confirmed that the laboratory failed to identify two of 54 prior negative cases as having a more significant lesion than was originally reported. Prior Negative Cases Include: -2017-031-G44-0479-0 -2017-114-G44-0606-0 b. The Survey Team Pathologist confirmed that the laboratory failed to identify one of 54 prior negative cases as being "Unsatisfactory for Evaluation." Prior Negative Case Includes: -2017-040-G44-0894-0
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, interviews and review of laboratory records it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics for 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six required statistics for the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide six of six required annual statistics for the laboratory being surveyed. 3. During an interview on March 6, 2019 at 3:15 PM, the Anatomic Pathology Manager confirmed that documents included statistics from cases that were not evaluated and reported at the laboratory.
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 interviews it was determined that the laboratory failed to follow written policies and procedures to compare the Cytotechnologists' interpretations with Technical Supervisors' confirmations. The laboratory failed to establish workload limits to include comparative reviews for 27 of 27 Cytotechnologists in 2018 and to the date of the survey. Findings include: 1. The laboratory failed to follow three written policies and procedures to compare the individual Cytotechnologists' interpretations with the Technical Supervisors' confirmations of patient specimens, when assessing individual workload limits. a. The procedure titled TECHNICAL SUPERVISOR CYTOLOGY QUALIFICATIONS AND RESPONSIBILITIES stated: -"3. Ensure that the slide performance of each cytotechnologist is evaluated and documented, including performance evaluation through the reexamination of normal and negative cases and feedback on the abnormal cases. -4. In accordance with the cytotechnologist's

	capability based on the performance evaluation described in (3) above, -a) Establishes the workload limit for each new cytotechnologist. -b) Reassesses and documents on a monthly basis the workload limit and percent QC review for each cytotechnologist and adjusts the workload limit and/or percent QC review as necessary." b. The procedure titled DIAGNOSTIC FEEDBACK FOR CYTOTECHNOLOGISTS stated: -"The feedback is documented on the CYTOTECHNOLOGIST'S DAILY GYN QUALITY CONTROL RESCREEN RECORD." c. The procedure titled QUALITY PERFORMANCE WORKLOAD REASSESSMENT REVIEW stated: -"Other information attached to the (CYTOTECHNOLOGIST MONTHLY QUALITY CONTROL) report may include: Cytotechnologists/Pathologists discrepancies report." 2. The Survey Team requested and the laboratory failed to provide documentation of the results of comparative reviews of the Cytotechnologists' interpretations with the Technical Supervisors' interpretations, when assessing individual workload limits. a. The Survey Team reviewed records titled CYTOTECHNOLOGIST MONTHLY QUALITY CONTROL for January through December of 2018. The records failed to include comparative reviews when assessing the workload limits for 27 of 27 Cytotchnologists. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C -Cytotechnologist D -Cytotechnologist E -Cytotechnologist F -Cytotechnologist G -Cytotechnologist H -Cytotechnologist I -Cytotechnologist J -Cytotechnologist K -Cytotechnologist L -Cytotechnologist M -Cytotechnologist N -Cytotechnologist O -Cytotechnologist P -Cytotechnologist Q -Cytotechnologist R -Cytotechnologist S -Cytotechnologist T -Cytotechnologist U -Cytotechnologist V -Cytotechnologist W -Cytotechnologist X -Cytotechnologist Y -Cytotechnologist Z -Cytotechnologist AA 3. During interviews on January 8, 2019 at 1:40 PM and January 9, 2019 at 8:20 AM, the Anatomic Pathology Manager confirmed that the laboratory did not include the comparison of interpretations as part of a workload limit assessment for the 27 Cytotechnologists. 4. During an interview on March 4, 2019 at 3:45 PM, the Anatomic Pathology Manager stated "We are starting to include the Cytotechnologist and Pathologist discordances in the Cytotechnologists' binders, since you were here in January."
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 written policies and procedures, gynecologic cytology slides and corresponding laboratory records it was determined that the laboratory failed to follow policies and procedures to ensure unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report 20 gynecologic cytology cases sampled from January 2018 through February 2019, as being "Unsatisfactory for Evaluation." Findings include: 1. The laboratory failed to follow the procedure titled SPECIMEN ADEQUACY CRITERIA. 2. The laboratory failed to identify and report 20 gynecologic cytology cases from January 2018 through February 2019 as being "Unsatisfactory for Evaluation." 2019 Cases include: -003-G44-0704-0 -028-G44-9010-0 -032-G44-0893-0 -035-G44-0662-0 -035-G44-0988-0 -037-G44-0142-0 -037-G44-1210-0 -039-G44-0632-0 -039-G44-0373-0 -043-G44-0373-0 2018 Cases include: -018-G44-1999-0 -057-C45-0463-0 -297-Y05-4696-0 -306-G44-0156-0 -325-G44-0808-0 -327-G44-

	0004-0 -330-G44-0454-0 -332-G44-0522-0 -332-G44-1162-0 -354-G44-1219-0 3. These findings were reviewed and confirmed by the Survey Team Pathologist on March 8, 2019.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that the laboratory failed to maintain the identity of the personnel who performed the review and the date of the review for 23 of 188 discrepant cytology and histopathology specimens. Findings include: 1. The Survey Team reviewed 188 laboratory records titled HISTOLOGY-CYTOLOGY CORRELATION REVIEW from April 2018, which documented the comparative reviews for discrepant cytology and histopathology specimens. a. The laboratory failed to document the identity of the personnel who performed the review and the date the review was performed for 23 cases. Cases include: -037-G01-3060-0 -040-G44-0881-0 -045-G44-0089-0 -053-G44-0020-0 -057-C45-0463-0 -059-C45-0313-0 -071-C45-0457-0 -072-G01-3942-0 -072-G44-0637-0 -078-C45-0425-0 -079-G44-0636-0 -079-G44-0540-0 -080-C45-0328-0 -085-G44-0038-0 -085-Y05-4543-0 -101-G44-0646-0 -103-G01-3030-0 -106-G01-3043-0 -146-G44-0434-0 -215-G44-0604-0 -224-G44-0019-0 -271-G44-0862-0 -284-C45-0322-0 2. During an interview on March 4, 2019 at 3:10 PM, the Anatomic Pathology Manager stated "They are not signed because the pathologists are suppose to do that. After you came we realized some things were not being done the way we thought. We are going through it now and doing it different in 2019."
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of cytology testing in 2018 and to the date of the survey in 2019. Cross refer to D5635 Findings include: 1. The laboratory failed to follow the procedure titled DIAGNOSTIC FEEDBACK FOR CYTOTECHNOLOGISTS. a. The laboratory failed to document feedback on the CYTOTECHNOLOGIST DAILY GYN QUALITY CONTROL RESCREEN RECORD. b. The laboratory failed to attach feedback from the COPATH VARIANCE REPORT to the individual

	CYTOTECH MONTHLY PERFORMANCE SUMMARY. 2. The laboratory failed to follow the procedure titled CYTOLOGIC DISCREPANCIES AND CORRECTIVE ACTION-Section THRESHOLD FOR EVALUATION. a. The laboratory failed to include assessments of discordances between the Cytotechnologists' interpretations and the final Technical Supervisors' reporting of test results. 3. The Survey Team requested and the laboratory failed to provide documentation to monitor and assess the number and type of discordances between the Cytotechnologists' interpretations and the final Technical Supervisors' reporting of test results. a. During an interview on January 9, 2019 at 8:10 AM, the Anatomic Pathology Manager stated, "if the doctor says 'discrepancy' in the computer, a form (CYTO/PATH DISAGREE) prints for me. But they don't always click on the button so then a report doesn't print out for me." b. During an interview January 9, 2019 at 9:40 AM, the Anatomic Pathology Manager provided an untitled spreadsheet that listed the number of discordances identified for each Cytotechnologist. When asked if this spreadsheet had been completed during the course of the survey, the Anatomic Pathology Manager replied "yes." When asked if the discordances had been monitored and evaluated prior to the start of the survey the Anatomic Pathology Manager replied "no." 4. During staff interviews, Cytotechnologists were asked how they receive feedback on the results of microscopic evaluations of cases that are sent to the pathologists: a. Cytotechnologist B stated during an interview on February 8, 2019 at 12:15 PM "I don't think there is any feedback in the binder, we kind of keep track on our own." b. Cytotechnologist C stated during an interview on February 8, 2019 at 12:45 PM "we don't always get feedback on the cases we send to the pathologists." c. Cytotechnologist D stated during an interview on February 8, 2019 at 1:40 PM "we don't get feedback." d. Cytotechnologist E stated during an interview on February 9, 2019 at 8:40 AM "we must ask for feedback and do not receive feedback on the cytology and histology correlations. We just have to look up anything interesting." e. Cytotechnologist F stated during an interview on February 9, 2019 at 9:40 AM "we don't get timely feedback from the pathologists. When a Cytotechnologist disagrees with a Pathologist we don't know what happens after that."
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, record review and interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that quality assessment programs were established (refer to D6094); and failed to ensure the competency of five of five Technical Supervisors and identify needs for remedial training (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
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, review of laboratory records and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5311, D5403, D5411, D5473, D5625, D5629, D5635, D5655, D5787
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, review of laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5791
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: A. Based on review of laboratory polices and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to monitor, assess and maintain competency of five of five Technical Supervisors who performed cytology test procedures. Cross refer to D5209 B. Based on review of laboratory polices and procedures, laboratory

	records and interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to identify needs for remedial training or continuing education to improve upon diagnostic skills of the Cytotechnologists and Technical Supervisors, when evaluating nongynecologic specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to identify needs for remedial training or continuing education to improve upon diagnostic skills of the Cytotechnologists and Technical Supervisors, when evaluating nongynecologic specimens. 2. The Survey Team requested and the laboratory failed to provide documentation to identify needs for remedial training or continuing education to improve upon diagnostic skills of the Cytotechnologists and Technical Supervisors, when evaluating nongynecologic specimens. 3. The Survey Team randomly identified 74 thyroid cases in the CYTO /PATH DISAGREE binder, from January through December 2018. The cases were identified by the laboratory as having a discordant interpretation between a Cytotechnologist and a Technical Supervisor. Thyroid Cases include: -004-G44-5203 -005-G44-5212 -008-G44-5217 -009-G44-5245 -012-G44-5205 -015-G44-5209 -015-G44-5216 -016-G44-5222 -016-G44-5904 -017-G44-5203 -023-G44-5206 -023-G44-5230 -023-G44-5240 -025-G44-5209 -026-G44-5201 -026-G44-5222 -026-G44-5226 -026-G44-5233 -033-G44-5201 -036-G44-5206 -037-G44-5214 -054-G44-5107 -058-G44-5225 -058-G44-5227 -067-G44-5213 -068-G44-5205 -071-G44-5204 -071-G44-5213 -072-G44-5208 -089-G44-5201 -094-G44-5210 -096-G44-5209 -096-G44-5213 -096-G44-5217 -096-G44-5221 -096-G44-5224 -100-G44-5205 -100-G44-5214 -101-G44-5206 -115-G44-5210 -117-G44-5212 -121-G44-5210 -128-G44-5206 -136-G44-5210 -138-G44-5214 -141-G44-5201 -145-G44-5212 -149-G44-5211 -170-G44-5209 -176-G44-5204 -191-G44-5201 -193-G44-5233 -198-G44-5211 -200-G44-5222 -221-G44-5218 -226-G44-5217 -232-G44-5208 -242-G44-5222 -255-G44-5905 -256-G44-5206 -256-G44-5208 -268-G44-5902 -278-G44-5212 -278-G44-5221 -282-G44-5214 -283-G44-5211 -284-G44-5208 -292-G44-5206 -295-G44-5212 -304-G44-5216 -306-G44-5218 -324-G44-5208 -331-G44-5202 -339-G44-5222 4. During an interview on January 10, 2019 at 10:55 AM, Technical Supervisor B stated "the Cytotechnologists are not good at evaluating thyroids. They need additional training. And they are not good at evaluating nongynecologic specimens." 5. During an interview on March 5, 2019 at 3:45 PM, the Anatomic Pathology Manager stated "we are aware and plan to have some thyroid training."
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of gynecologic specimen slides and corresponding final test reports it was determined that the Technical Supervisor failed to verify the accuracy of 34 gynecologic test reports (refer to D6115). The cumulative effect of these practices resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
A. Based on review of 3780 negative and unsatisfactory gynecologic cases/3790 slides sampled from January 2018 through February 2019 and confirmation by the Survey Team Pathologist on March 8, 2019 it was determined that the Technical Supervisor failed to verify the accuracy of 31 gynecologic tests. Cases include: 1. 064-G44-0787-0 03/12/2018 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Unsatisfactory for Evaluation SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 2. 035-G44-0568-0 02/07/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 3. 042-G44-0289-0 02/13 /2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 4. 035-G08-4003-0 02/06/2019 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells; cannot exclude High Grade Intraepithelial Lesion 5. 042-G44-1139-0 02/13/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells; cannot exclude High Grade Intraepithelial Lesion 6. 053-G44-0145-0 03/02/2018 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells; cannot exclude High Grade Intraepithelial Lesion 7. 042-G44-0524-0 02/14/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 8. 044-G44-0579-0 02/16 /2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 9. 365-Y05-4504-0 01/01/2019 FocalPoint SurePath Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 10. 185-Y05-4620 07/18/2018 FocalPoint SurePath Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 11. 263-Y05-4575-0 09/25/2018 FocalPoint SurePath Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 12. 018-G44-1999-0 03/01 /2018 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 13. 057-C45-0463-0 03/02/2018 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 14. 297-Y05-4696-0 11/07/2018 FocalPoint SurePath Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 15. 306-G44-0156-0 11 /12/2018 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 16. 325-G44-0808-0 11/26/2018 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation;

scant cellularity 17. 327-G44-0004-0 11/26/2018 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 18. 330-G44-0454-0 11/27/2018 SurePath Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 19. 332-G44-0522-0 12/01/2018 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 20. 332-G44-1162-0 11/30/2018 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 21. 354-G44-1219-0 12/26/2018 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 22. 003-G44-0704-0 01/05/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 23. 028-G44-9010-0 02/05/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 24. 032-G44-0893-0 02/04/2019 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 25. 035-G44-0662-0 02/06/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 26. 035-G44-0988-0 02/07/2019 Conventional Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 27. 037-G44-0142-0 02/08/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 28. 037-G44-1210-0 02/11/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 29. 039-G44-0632-0 02/11/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 30. 039-G44-0373-0 02/12/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity 31. 043-G44-0373-0 02/15/2019 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Evaluation; scant cellularity B. Based on review of 187 non-negative gynecologic cases/193 slides sampled from January 2018 through February 2019 and confirmation by the Survey Team Pathologist on March 8, 2019 it was determined that the Technical Supervisor failed to verify the accuracy of three (3) gynecologic tests. Cases include: 1. 108-Y05-4623-0 04/21/2018 FocalPoint SurePath Pap Test LABORATORY DIAGNOSIS: Atypical Glandular Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for Intraepithelial Lesion 2. 124-Y05-4611-0 05/09/2018 FocalPoint Sure Path Pap Test LABORATORY DIAGNOSIS: Atypical Glandular Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for Intraepithelial Lesion 3. 362-G44-0117-0 01/01/2019 ThinPrep Pap Test

	LABORATORY DIAGNOSIS: Atypical Squamous Cells; cannot exclude High Grade Squamous Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for Intraepithelial Lesion
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.