Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0925263	04/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	605 E Huntington Dr Ste 209, Monrovia, 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, record review, observation and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure accurate specimen slide labeling (refer to D5203); failed to establish written policies and procedures to describe processing cytology specimens (refer to D5311); failed to perform testing according to manufacturer's instructions (refer to D5411); failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions (refer to D5423); failed to ensure that the required maintenance for two of two Hologic ThinPrep 2000 Processors was performed, as specified by the manufacturer (refer to D5429); failed to ensure that at least 10 percent of the cases interpreted as negative for epithelial cell abnormalities and other malignant neoplasms were reviewed (refer to D5621); failed to establish written policies and procedures to determine the cause of discrepancies between the cytology diagnosis and the histopathology diagnosis, and failed to identify and document the reason for the discrepancy on ten of 57 cases (refer to D5623); failed to follow written policies and procedures for the review of prior negative gynecologic specimens from current HSIL cases, failed to identify three of 34 prior negative specimens as having a more significant lesion, and failed to identify one of 34 prior negative specimens as being "Unsatisfactory for Evaluation" (refer to D5625); failed to establish written policies and procedures for the annual evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics (refer to D5629); failed to follow written policies and procedures for establishing workload limits, reassessing workload limits,

	prorating workload limits and maintaining workload slides and hours (refer to D5633, D5635, D5637, D5641, D5645); and failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory, and failed to identify and report 33 gynecologic cytology cases as being "Unsatisfactory for Evaluation" (refer to D5655). 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.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, glass slide preparations and interview it was determined that the laboratory failed to follow written policies and procedures to ensure accurate specimen slide labeling. The laboratory failed to ensure that 40 of 40 patient specimens from January 2019 had specimen slides labeled with accurate patient specimen information. Findings include: 1. The laboratory failed to follow the procedure ACCESSIONING GUIDELINES FOR IMAGED GUIDED GYN SPECIMENS which stated: "Write in pencil the corresponding accession number on the frosted end of the slide(s) along with the patients first initial of the first name and the full last name as it appears on the vial." 2. The Survey Team reviewed 40 random slides from January 2019 for specimen labeling. a. Forty of 40 slides failed to have the accession number written on the frosted end of the slide. Slides include: 002-C45-0021-0 002-C45-0024-0 002-C45-0033-0 002-C45-0035-0 002-C45-0037-0 002-C45-0045-0 002-C45-0055-0 002-C45-0133-0 002-C45-0177-0 002-C45-0178-0 002-C45-0182-0 002-C45-6045-0 002-C45-6199-0 002-C45-6212-0 002-C45-6220-0 002-C45-6222-0 002-C58-5021-0 002-C58-5033-0 002-C58-5044-0 002-C58-5092-0 003-C45-0213-0 003-C45-6023-0 003-C45-6031-0 003-C45-6152-0 003-C58-5001-0 003-C58-5002-0 003-C58-5004-0 003-C58-5005-0 003-C58-5007-0 003-C58-5008-0 003-C58-5010-0 003-C58-5012-0 003-C58-5013-0 003-C58-5014-0 003-C58-5015-0 003-C58-5020-0 003-C58-5035-0 003-C58-5036-0 003-C58-5038-0 003-C58-5039-0 b. Twenty-nine of 40 slides slides failed to have the patient's first initial of the first name and the full last name written on the frosted end of the slide. Slides include: 002-C45-0021-0 002-C45-0024-0 002-C45-0033-0 002-C45-0035-0 002-C45-0037-0 002-C45-0045-0 002-C45-0055-0 002-C58-5021-0 002-C58-5033-0 002-C58-5044-0 003-C45-6023-0 003-C45-6031-0 003-C45-6152-0 003-C58-5001-0 003-C58-5002-0 003-C58-5004-0 003-C58-5005-0 003-C58-5007-0 003-C58-5008-0 003-C58-5010-0 003-C58-5012-0 003-C58-5013-0 003-C58-5014-0 003-C58-5015-0 003-C58-5020-0 003-C58-5035-0 003-C58-5036-0 003-C58-5038-0 003-C58-5039-0 3. During an interview on April 9, 2019 at 3:35 PM, the Anatomic Pathology Manager confirmed these findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of seven of seven Technical Supervisors in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the diagnostic competency of seven of seven Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for seven of seven Technical Supervisors who performed microscopic evaluations during 2017, 2018 and to the date of the survey in 2019. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E - Technical Supervisor F - Technical Supervisor G 3. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, glass slide preparations and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Cross refer to D5203, D5209
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 interviews it was determined that the laboratory failed to establish written policies and procedures to describe the step-by-step process for processing cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written

	policies and procedures describing how nongynecologic specimens were to be processed. a. During an interview on February 28, 2019 at 10:50 AM, the Anatomic Pathology Manager confirmed there were no written policies and procedures to describe nongynecologic processing. b. During an interview on February 28, 2019 at 3: 50 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures describing how gynecologic specimens were to be processed. a. During an interview on April 9, 2019 at 3:35 PM, the Anatomic Pathology Manager confirmed there were no written policies and procedures to describe gynecologic processing.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, glass slide preparations and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems. Cross refer to D5311
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, review of training records for the Hologic ThinPrep Pap Test and interview it was determined that the laboratory failed to ensure that four of seven 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 the training records for four Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor D - Technical Supervisor F - Technical Supervisor G 2. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings. B. Based on review of the BECTON DICKINSON (BD) SUREPATH IMPLEMENTATION GUIDE, review of training

	records for the BD SurePath Pap Test and interview it was determined that the laboratory failed to ensure that four of seven Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the BD SurePath Pap Test, according to the manufacturer's instructions. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states: "Training on the preparation and evaluation of BD SurePath test slides is a product labeling requirement." a. The Survey Team requested and the laboratory failed to provide the training records for four Technical Supervisors who performed diagnostic interpretations on BD SurePath Pap Tests. Technical Supervisors include: - Technical Supervisor B - Technical Supervisor D - Technical Supervisor F - Technical Supervisor G 2. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings. C. Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL and interviews it was determined that the laboratory failed to follow the manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 2000 Processor. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL (Part Number 70354-001) states: "Specimens must be centrifuged and washed in CytoLyt Solution and transferred to PreservCyt Solution prior to being processed on the ThinPrep 2000 Processor." "The purpose of this procedure is to concentrate the cellular material in order to separate the cellular component(s) from the supernatant. This step is performed with fresh samples and after the addition of CytoLyt Solution. When specified in the protocol, centrifuge the sample at 600 times normal gravity (600g) for 10 minutes to force the cells in solution into a pellet at the bottom of the centrifuge tube." "After pouring off the supernatant, place the centrifuge tube onto a vortexor and agitate the cell pellet for 3 seconds. Manual vortexing may be achieved by syringing the pellet back and forth with a plastic pipette. The intention of this vortexing step is to randomize the cell pellet before transferring to the PreservCyt Solution vial and to improve the results of the CytoLyt Solution washing step." "Evaluate Cell Pellet Appearance" "Addition of CytoLyt Solution to cell pellets is required to wash the sample." 2. During an interview on February 28, 2019 at 9:15 AM, Staff A stated that nongynecologic specimens were not washed with CytoLyt Solution. Staff A further stated that the specimen supernatant was transferred to the PreservCyt Vial and not the cell pellet. 3. During an interview on February 28, 2019 at 9:40 AM, the Anatomic Pathology Manager confirmed these findings. 4. During an interview on February 28, 2019 at 3:50 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings.
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: Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL and interviews it was determined that the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of processing nongynecologic cytology specimens. Cross refer to D5411 Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified procedure, reportable range of test results or any other performance characteristic was adequate to provide accurate diagnostic interpretations.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that the laboratory failed to ensure that the required maintenance for two of two Hologic ThinPrep 2000 Processors used for nongynecologic processing was performed, as specified by the manufacturer, for 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide maintenance records for the two Hologic ThinPrep 2000 Processors used for nongynecologic processing. Hologic ThinPrep 2000 Processors include: - Serial #03321J04A0 - Serial #02918A04A0 2. During an interview on February 28, 2019 at 3:50 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings.
D5621	CYTOLOGY CFR(s): 493.1274(c)(1) (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)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section). (c)(1)(i) The review must be performed by an individual who meets one of the following qualifications: (c)(1)(i)(A) A technical supervisor qualified under 493.1449(b) or (k). (c)(1)(i)(B) A cytology general supervisor qualified under 493.1469. (c)(1)(i)(C) A cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). (c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information. (c)(1)(iii) The review of those cases selected must be completed before reporting patient results. 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 ensure that at least 10 percent of the cases interpreted by two of 14 Cytotechnologists as negative for epithelial cell abnormalities and other malignant neoplasms were reviewed from January through December 2018. Findings include: 1. The laboratory failed to follow the procedure QC RESCREEN REQUIREMENTS which stated: "At least 10% of gyn cases interpreted to be Negative (NIL) or as Negative with Benign Cellular Changes (excluding Reactive/Reparative Diagnosis) from each cytotechnologist must be selected for rescreening daily." 2. The Survey Team reviewed laboratory records titled CYTOLOGY QUALITY ASSURANCE CYTOTECHNOLOGIST MONTHLY PERFORMANCE REPORT FOR IMAGE GUIDED/NON IMAGE GUIDED CASES from January through December 2018. a. Cytotechnologist G failed to have at least 10 percent of the negative cases reviewed for one of 12 months. Month includes: - October 2018 (9.7%) b. Cytotechnologist L failed to have at least 10 percent of the negative cases reviewed for ten of 12 months. Months include: - January 2018 (9.9%) - March 2018 (9.1%) - April 2018 (9.8%) - May 2018 (9.9%) - June 2018 (9.7%) - July 2018 (9.1%) - August 2018 (8.9%) - September 2018 (7.7%) - November 2018 (8.9%) - December 2018 (9.6%) 3. During an interview on February 26, 2019 at 3:30 PM, the Cytology Supervisor stated "we think its definitely a Copath issue and we need to talk with them about it." 4. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings.
D5623	CYTOLOGY CFR(s): 493.1274(c)(2) (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)(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, interview, review of laboratory records and review of gynecologic specimen slides it was determined that the laboratory failed to establish written policies and procedures to determine the cause of discrepancies between the cytology diagnosis and the histopathology diagnosis. The laboratory failed to identify and document the reason for the discrepancy on ten of 58 cases from July through December 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. 2. During an interview on February 26, 2019 at 8:20 AM, the Anatomic Pathology Manager stated the laboratory correlated all cytology specimens received within one year of the histopathology specimen. The Anatomic Pathology Manager further stated that the Technical Supervisors completed a laboratory record titled HISTOLOGY-CYTOLOGY CORRELATION FORM for all cases that were correlated. 3. During an interview on February 28, 2019 at 3:50 PM, the Laboratory Director/Technical

	Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed there were no written policies and procedures to describe the laboratory's current process. 4. The Survey Team reviewed gynecologic specimen slides and corresponding laboratory records for 58 cases with discrepant cytology and histopathology. The laboratory failed to correctly document the reason for ten of 58 discrepancies. Cases include: - 089-C58-5213-0 - 117-C58-5015-0 - 149-C58-5015-0 - 173-Y05-4673-0 - 183-C58-5030-0 - 212-G44-0193-0 - 236-C58-5164-0 - 243-C45-0008-0 - 250-C45-6194-0 - 257-C58-5129-0
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, laboratory records and review of gynecologic specimen slides it was determined that the laboratory failed to follow written policies and procedures for the review of prior negative gynecologic specimens from current HSIL cases. The laboratory failed to identify three of 34 prior negative specimens as having a more significant lesion than initially reported, and failed to identify one of 34 prior negative specimens as being "Unsatisfactory for Evaluation." Findings include: 1. The laboratory failed to follow the procedure PREVIOUS FIVE YEAR REVIEW which stated: "If a discrepancy is found, the slides and reports are referred to a pathologist for review." 2. The Survey Team reviewed 34 prior negative cases from 30 current HSIL's from July through December 2018. a. The Survey Team Pathologist confirmed on March 1, 2019 and April 12, 2019 that the laboratory did not identify three of 34 prior negative specimens as having a more significant lesion than was originally reported. Cases include: - 151-C58-5063-0 - 184-C45-0067-0 - 266-G44-0309-0 b. The Survey Team Pathologist confirmed on March 1, 2019 that the laboratory failed to identify one of 34 prior negative specimens as being "Unsatisfactory for Evaluation." Case includes: - 186-C45-0320-0
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, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for the annual evaluation and comparison of six of six laboratory statistics. The laboratory failed to document six of six required annual statistics for 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for an annual statistical evaluation of six of six required annual statistics. 2. The Survey Team requested and the laboratory failed to provide records of the six of six required annual statistics for 2017 and 2018 for this facility. 3. During an interview on February 25, 2019 at 10:45 AM, the Anatomic Pathology Manager stated that the laboratory statistics did not include cases reported by Technical Supervisor G. 4. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director /Technical Supervisor A, Anatomic Pathology Manager and Cytology Supervisor confirmed these findings.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for the Cytology Supervisor in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The laboratory failed to follow the procedure CYTOPATHOLOGY MISSION STATEMENT AND QUALITY IMPROVEMENT PLAN which stated: "The technical supervisor each month reviews QI/QA data regarding cytotechnologist's screening performance from the previous month. This data includes screening volumes, individual's diagnostic submission rates compared against the laboratory's overall statistical values, random/high risk QC discrepancies, KDQC performance data, and proficiency testing scores/results. This review allows the technical supervisor to establish slide workload limits and/or remedial training if needed." 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor established a maximum workload limit for the Cytology Supervisor in 2017, 2018 and to the date of the survey in 2019. 3. During an interview on February 26, 2019 at 12:10 PM, the Anatomic Pathology Manager stated that workload limits for the Cytology Supervisor had not been established. 4. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager and Cytology Supervisor confirmed these findings.
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 it was determined that the laboratory failed to establish written policies and procedures to use evaluations of the individual Cytotechnologist's performance when assessing the workload limit for 14 of 14 Cytotechnologists for 2018 through the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the workload limit for Cytotechnologists was based on individual capabilities to include evaluations of the following: a. A comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides. 2. The Survey Team requested and the laboratory failed to provide records to reflect that a comparison of the individual Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient specimens was included to assess the workload limit. Cytotechnologists include: - Cytology Supervisor - 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 3. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director /Technical Supervisor A, Anatomic Pathology Manager and Cytology Supervisor confirmed these findings.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that the workload limit for the Cytology Supervisor was reassessed at least every six months and adjusted when necessary in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The laboratory failed to follow the procedure CYTOPATHOLOGY MISSION STATEMENT AND QUALITY IMPROVEMENT PLAN which stated: "The technical supervisor each month reviews QI/QA data regarding cytotechnologist's screening performance from the previous month. This data includes screening volumes, individual's diagnostic submission rates compared against the laboratory's overall statistical values, random/high risk QC discrepancies, KDQC performance data, and proficiency testing scores/results. This review allows the technical supervisor to establish slide workload limits and/or remedial training if needed." 2. The Survey Team requested and the laboratory failed

	to provide documentation that the workload limit for the Cytology Supervisor had been reassessed every month for 2017, 2018 and to the date of the survey in 2019. 3. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director /Technical Supervisor A, Anatomic Pathology Manager and Cytology Supervisor confirmed that the Cytology Supervisor's workload limit had not been reassessed.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure that the workload limit for one of 14 Cytotechnologists, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated using a period of eight hours to determine the number of slides that may be examined. Cytotechnologist D exceeded the prorated workload limit on 38 of 38 days slides were examined in January through February 2019. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY PROCESS MANAGEMENT - CYTOTECHNOLOGIST'S GUIDE which stated: "For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined." 2. The Survey Team reviewed laboratory records titled CYTOLOGY QUALITY ASSURANCE CYTOTECHNOLOGIST MONTHLY PERFORMANCE REPORT FOR IMAGE GUIDED/NON IMAGE GUIDED CASES. The record stated that Cytotechnologist D's current maximum workload limit was 70 slides. 3. The Survey Team reviewed laboratory records titled CYTOTECH DATA COLLECTION FORM for Cytotechnologist D from January through February 2019. Cytotechnologist D exceeded the prorated workload limit of 8.75 slides per hour on 38 of 38 days slides were examined. Dates include: DATE: 01 /02/19 HOURS SCREENING: 3:42 SLIDES EVALUATED: 37 PRORATED SLIDES ALLOWED: 32 DATE: 01/03/19 HOURS SCREENING: 5:57 SLIDES EVALUATED: 59.5 PRORATED SLIDES ALLOWED: 52 DATE: 01/04/19 HOURS SCREENING: 5:00 SLIDES EVALUATED: 50 PRORATED SLIDES ALLOWED: 53 DATE: 01/07/19 HOURS SCREENING: 6:03 SLIDES EVALUATED: 60.5 PRORATED SLIDES ALLOWED: 52 DATE: 01/08/19 HOURS SCREENING: 5:24 SLIDES EVALUATED: 54 PRORATED SLIDES ALLOWED: 47 DATE: 01/09/19 HOURS SCREENING: 6:00 SLIDES EVALUATED: 60 PRORATED SLIDES ALLOWED: 52 DATE: 01/10/19 HOURS SCREENING: 6:18 SLIDES EVALUATED: 63 PRORATED SLIDES ALLOWED: 55 DATE: 01/11/19 HOURS SCREENING: 5:57 SLIDES EVALUATED: 59.5 PRORATED SLIDES ALLOWED: 52 DATE: 01/14/19 HOURS SCREENING: 5:45 SLIDES EVALUATED: 57.5 PRORATED SLIDES ALLOWED: 50 DATE: 01/15 /19 HOURS SCREENING: 6:00 SLIDES EVALUATED: 60 PRORATED SLIDES

	ALLOWED: 52 DATE: 01/16/19 HOURS SCREENING: 5:45 SLIDES EVALUATED: 57.5 PRORATED SLIDES ALLOWED: 50 DATE: 01/17/19 HOURS SCREENING: 6:15 SLIDES EVALUATED: 62.5 PRORATED SLIDES ALLOWED: 54 DATE: 01/18/19 HOURS SCREENING: 6:03 SLIDES EVALUATED: 60.5 PRORATED SLIDES ALLOWED: 52 DATE: 01/21/19 HOURS SCREENING: 5:27 SLIDES EVALUATED: 54.5 PRORATED SLIDES ALLOWED: 47 DATE: 01/22/19 HOURS SCREENING: 6:06 SLIDES EVALUATED: 61 PRORATED SLIDES ALLOWED: 53 DATE: 01/23/19 HOURS SCREENING: 5:48 SLIDES EVALUATED: 58 PRORATED SLIDES ALLOWED: 50 DATE: 01/24/19 HOURS SCREENING: 5:42 SLIDES EVALUATED: 57 PRORATED SLIDES ALLOWED: 49 DATE: 01/25/19 HOURS SCREENING: 5:00 SLIDES EVALUATED: 50 PRORATED SLIDES ALLOWED: 43 DATE: 01/28/19 HOURS SCREENING: 6:03 SLIDES EVALUATED: 60.5 PRORATED SLIDES ALLOWED: 52 DATE: 01/29/19 HOURS SCREENING: 6:15 SLIDES EVALUATED: 61.5 PRORATED SLIDES ALLOWED: 54 DATE: 01/30/19 HOURS SCREENING: 5:27 SLIDES EVALUATED: 54.5 PRORATED SLIDES ALLOWED: 47 DATE: 01/31/19 HOURS SCREENING: 5:15 SLIDES EVALUATED: 52.5 PRORATED SLIDES ALLOWED: 45 DATE: 02/01/19 HOURS SCREENING: 6:30 SLIDES EVALUATED: 65 PRORATED SLIDES ALLOWED: 57 DATE: 02/04/19 HOURS SCREENING: 6:24 SLIDES EVALUATED: 64 PRORATED SLIDES ALLOWED: 56 DATE: 02/05/19 HOURS SCREENING: 7:12 SLIDES EVALUATED: 72 PRORATED SLIDES ALLOWED: 63 DATE: 02/06/19 HOURS SCREENING: 6:27 SLIDES EVALUATED: 64.5 PRORATED SLIDES ALLOWED: 56 DATE: 02/07/19 HOURS SCREENING: 6:21 SLIDES EVALUATED: 63.5 PRORATED SLIDES ALLOWED: 55 DATE: 02/08 /19 HOURS SCREENING: 6:12 SLIDES EVALUATED: 62 PRORATED SLIDES ALLOWED: 54 DATE: 02/11/19 HOURS SCREENING: 6:03 SLIDES EVALUATED: 60.5 PRORATED SLIDES ALLOWED: 52 DATE: 02/12/19 HOURS SCREENING: 6:57 SLIDES EVALUATED: 69.5 PRORATED SLIDES ALLOWED: 60 DATE: 02/13/19 HOURS SCREENING: 6:39 SLIDES EVALUATED: 66.5 PRORATED SLIDES ALLOWED: 58 DATE: 02/14/19 HOURS SCREENING: 6:39 SLIDES EVALUATED: 66.5 PRORATED SLIDES ALLOWED: 58 DATE: 02/15/19 HOURS SCREENING: 6:57 SLIDES EVALUATED: 69.5 PRORATED SLIDES ALLOWED: 60 DATE: 02/18/19 HOURS SCREENING: 6:18 SLIDES EVALUATED: 63 PRORATED SLIDES ALLOWED: 55 DATE: 02/19/19 HOURS SCREENING: 7:03 SLIDES EVALUATED: 70.5 PRORATED SLIDES ALLOWED: 61 DATE: 02/20/19 HOURS SCREENING: 6:18 SLIDES EVALUATED: 63 PRORATED SLIDES ALLOWED: 55 DATE: 02/21/19 HOURS SCREENING: 6:18 SLIDES EVALUATED: 63 PRORATED SLIDES ALLOWED: 55 DATE: 02/22/19 HOURS SCREENING: 6:09 SLIDES EVALUATED: 61.5 PRORATED SLIDES ALLOWED: 53 4. During an interview on February 26, 2019 at 11:30 AM, the Cytology Supervisor stated that Cytotechnologist D "was entering it at 10 slides per hour." 5. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager, and Cytology Supervisor confirmed these findings.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period

	and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure that the laboratory would maintain records for the Cytology Supervisor of the total number of slides examined and the number of hours devoted to examining slides in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The laboratory failed to follow the procedure CYTOTECHNOLOGIST QUALIFICATIONS/JOB DESCRIPTION which stated: "The cytotechnologist is responsible for maintaining his/her own records and/or documentation of slides/hours screened for each 24 hour period." 2. The Survey Team requested and the laboratory failed to provide workload records to document the number of slides examined and time spent examining slides for the Cytology Supervisor in 2017, 2018 and to the date of the survey in 2019. 3. During an interview on February 26, 2019 at 11:43 AM, the Anatomic Pathology Manager stated "We don't have the workload records." 4. During an interview on February 27, 2019 at 3:15 PM, the Laboratory Director/Technical Supervisor A, Anatomic Pathology Manager and Cytology Supervisor confirmed these findings.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, gynecologic cytology slides and the corresponding final test reports it was determined that the laboratory failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report 33 gynecologic cytology cases from October 2018 through February 2019 as being "Unsatisfactory for Evaluation." Findings include: 1. The laboratory failed to follow the procedure titled SPECIMEN ADEQUACY CRITERIA which stated: "There should be a minimum 5,000 well-preserved and well-visualized squamous cells (estimated) for liquid based slides." 2. The laboratory failed to identify and report 33 gynecologic cytology cases as being "Unsatisfactory for Evaluation." Cases include: - 002-C45-0132-0 - 002-C45-6090-0 - 003-C45-0262-0 - 003-C58-5072-0 - 003-C45-0168-0 - 003-C45-6095-0 - 003-C58-5037-0 - 003-C58-5040-0 - 003-C58-5009-0 - 003-C58-5029-0 - 003-C58-5102-0 - 003-C58-5105-0 - 004-C45-0058-0 - 004-C45-0138-0 - 004-C45-0166-0 - 004-C58-5108-0 - 004-C58-5147-0 - 008-C45-0063-0 - 008-C45-0279-0 - 008-C45-0354-0 - 008-C45-0366-0 - 008-C45-6067-0 - 008-C45-0086-0 - 059-C58-5076-0 - 063-C58-5096-0 - 066-C45-6122-0 - 063-C58-5097-0 - 016-C45-0168-0 - 022-C45-6148-0 - 029-C58-5011-0 - 030-C45-0341-0 - 031-C45-6172-0 - 035-C58-5097-0 3. These findings were confirmed by the Survey Team Pathologist on March 1, 2019 and on April 12, 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 that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of cytology testing. Cross refer to D5411, D5423, D5429, D5621, D5623, D5625, D5629, D5633, D5635, D5637, D5641, D5645, D5655
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 control programs were established and maintained (refer to D6093); failed to ensure appropriate training according to the manufacturer's instructions (refer to D6102); and failed to ensure the competency of seven of seven Technical Supervisors performing cytology test procedures (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, 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 D5209, D5311, D5411, D5423, D5429, D5633, D5635, D5637, D5641, D5645, D5655
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of written laboratory procedures, laboratory records and interview it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross Refer to D5621, D5623, D5625, D5629.
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 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 D5291, D5391, D5791
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 the review of the Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, the BD SUREPATH IMPLEMENTATION GUIDE, review of certification records and interview it was determined that the Laboratory Director failed to ensure appropriate training according to the manufacturer's instructions. Four

	of seven Technical Supervisors had not received the appropriate training to evaluate the Hologic ThinPrep Pap Test. Four of seven Technical Supervisors had not received the appropriate training to evaluate the BD SurePath Pap Test. Cross Refer to D5411
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of seven of seven Technical Supervisors performing cytology test procedures. Cross refer to D5209
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 slides and corresponding final test reports, it was determined that the Technical Supervisor failed to verify the accuracy of 50 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: Based on review of 1567 random negative gynecologic cases/1612 slides and the corresponding final test reports from October 2018 through March 2019 and confirmation by the Survey Team Pathologist on March 1, 2019 and April 12, 2019 it was determined that the Technical Supervisor failed to verify the accuracy of 48 gynecologic tests. 1. 340-G44-0955-0 12/08/18 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High-

Grade Squamous Intraepithelial Lesion 2. 008-C45-0280-0 01/11/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High-Grade Squamous Intraepithelial Lesion 3. 008-C45-0163-0 01/15/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High-Grade Squamous Intraepithelial Lesion 4. 028-C58-5168-0 01/30/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Rare Atypical Squamous Cells, cannot exclude High-Grade Squamous Intraepithelial Lesion Low Grade Squamous Intraepithelial Lesion 5. 031-C45-6184-0 02/05/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High-Grade Squamous Intraepithelial Lesion 6. 003-C45-6083-0 01/08/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 7. 007-C58-5124-0 01/19/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells Abundant Mucinous Cells, Gastric Type with Atypia 8. 046-G44-0630-0 02/20/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 9. 003-C58-5018-0 01/04/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 10. 007-C58-5123-0 01/09/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 11. 004-C45-0168-0 01/10/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 12. 008-C45-0282-0 01/10/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 13. 008-C45-0285-0 01/10/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 14. 031-C45-6122-0 02/02/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 15. 064-C58-5171-0 03/09/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 16. 002-C45-0132-0 01/04/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity, Obscuring Blood 17. 002-C45-6090-0 01/04/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 18. 003-C45-0262-0 01/04/19 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity due to Lubricant 19. 003-C58-5077-0 01/04/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity Probably due to Use of Lubricant 20. 003-C45-0168-0 01/05/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 21. 003-C45-6095-0 01 /05/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion

SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 22. 003-C58-5037-0 01/05/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Abundant Blood 23. 003-C58-5040-0 01/05/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity due to Lubricant 24. 003-C58-5102-0 01/05/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Obscuring Inflammation 25. 003-C58-5105-0 01/05/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 26. 003-C58-5009-0 01/07/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Abundant Blood 27. 003-C58-5029-0 01/07/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 28. 004-C45-0058-0 01/07/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 29. 004-C45-0138-0 01/07/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Obscuring Inflammation 30. 004-C45-0166-0 01/09/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity with Obscuring Lubricant 31. 004-C58-5108-0 01/09/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 32. 004-C58-5147-0 01/09/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Obscuring Inflammation 33. 008-C45-6067-0 01/09/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 34. 008-C45-0063-0 01/10/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 35. 008-C45-0086-0 01/10/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Abundant Blood 36. 008-C45-0279-0 01/10/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 37. 008-C45-0354-0 01/11/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 38. 008-C45-0366-0 01/11/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Obscuring Inflammation 39. 022-C45-6148-0 01/24/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Insufficient Cellularity 40. 016-C45-0168-0 01/26/19 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM

	PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Insufficient Cellularity 41. 029-C58-5011-0 01/31/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Insufficient Cellularity 42. 030-C45-0341-0 02/01/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Insufficient Cellularity 43. 031-C45-6172-0 02/02/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Insufficient Cellularity 44. 035-C58-5097-0 02/06/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Insufficient Cellularity 45. 059-C58-5076-0 03/07/19 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity 46. 063-C58-5096-0 03 /08/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Obscuring Inflammation 47. 063-C58-5097-0 03/08 /19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity and Abundant Blood 48. 066-C45-6122-0 03/09/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Squamous Cellularity B. Based on review of 250 random non-negative gynecologic cases/255 slides and the corresponding final test reports from December 2018 through February 2019 and confirmation by the Survey Team Pathologist on April 12, 2019 it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic test. 1. 003-C45-0065-0 01/05/19 I-TPPT LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion C. Based on review of 27 random negative nongynecologic cases/85 slides and the corresponding final test reports from December 2018 through February 2019 and confirmation by the Survey Team Pathologist on April 12, 2019 it was determined that the Technical Supervisor failed to verify the accuracy of one nongynecologic test. 1. 032-C45-4015-0 2/04/19 Anal Pap LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion and Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Nucleated Squamous Cellularity
D6160	CYTOLOGY SUPERVISOR RESPONSIBILITIES CFR(s): 493.1471(b)(3) The cytology general supervisor must for each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews it was determined that the Cytology Supervisor failed to document the number of slides examined for each 24-hour period in 2017, 2018 and to the date of the survey in 2019. Cross refer to D5645
D6161	CYTOLOGY SUPERVISOR RESPONSIBILITIES CFR(s): 493.1471(b)(4)

	The cytology general supervisor must document 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 interviews it was determined that the Cytology Supervisor failed to document the number of hours spent examining slides in each 24-hour period in 2017, 2018 and to the date of the survey in 2019. Cross refer to D5645
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.