Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0664386	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Carolina Baptist Hospital Pathology Lab	Medical Center Boulevard, Winston-Salem, NC	

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 the review of written procedures, record review, surveyor interviews, and observation the laboratory failed to follow written procedures to ensure positive identification of patient specimens (refer to D5203); failed to establish written procedures for stain maintenance (refer to D5403); failed to perform and document equipment maintenance defined by the manufacturer (refer to D5429); failed to test Diff Quik staining materials each day of use (refer to D5473); failed to establish written procedures to prevent cross-contamination between gynecologic and non-gynecologic specimens (refer to D5617); failed to establish written procedures to prevent cross contamination between non-gynecologic specimens with a high potential for cross-contamination (refer to D5619); failed to establish written procedures for a review program to include high risk patients (refer to D5621); failed to follow written procedures to document and evaluate one annual statistic (refer to D5629); and failed to follow written procedures to establish and prorate workload limits (refer to D5633 and D5637). 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 the review of written laboratory procedures, observation of glass slides, and interview it was determined that the laboratory failed to follow the written procedure to ensure the positive identification of eighty-five of eighty-five gynecologic glass slides and twenty-five of twenty-five non-gynecologic glass slides sampled from January 2018. Findings include: 1. The laboratory failed to follow the written procedure titled CYT-C-1 CYTOLOGY SLIDE LABELING. The procedure stated that "two patient identifiers are placed on cytology specimen slides. The two identifiers include the patient name and unique case number assigned by the CoPath system. The number consists of the letter "P" the last two digits of the current year and the number." a. The Survey Team observed the slide labeling on eighty-five randomly selected gynecologic cases (eighty-five slides) and ten randomly selected non-gynecologic cases (twenty-five slides) from January 2018. The slides were not labeled with the complete accession number prior to attaching a permanent patient identification slide label. Gynecologic Cases include: Specimen Specimen Slide Accession #: Labeled as: -P18-44 44 -P18-45 45 -P18-46 46 -P18-47 47 -P18-48 48 -P18-49 49 -P18-50 50 -P18-51 51 -P18-52 52 -P18-53 53 -P18-54 54 -P18-55 55 -P18-56 56 -P18-57 57 -P18-65 65 -P18-66 66 -P18-67 67 -P18-68 68 -P18-69 69 -P18-70 70 -P18-71 71 -P18-72 72 -P18-73 73 -P18-74 74 -P18-75 75 -P18-76 76 -P18-77 77 -P18-78 78 -P18-79 79 -P18-80 80 -P18-81 81 -P18-82 82 -P18-83 83 -P18-84 84 -P18-162 162 -P18-163 163 -P18-164 164 -P18-165 165 -P18-166 166 -P18-167 167 -P18-168 168 -P18-169 169 -P18-170 170 -P18-171 171 -P18-172 172 -P18-219 219 -P18-220 220 -P18-221 221 -P18-222 222 -P18-223 223 -P18-225 225 -P18-226 226 -P18-227 227 -P18-228 228 -P18-229 229 -P18-230 230 -P18-231 231 -P18-279 279 -P18-280 280 -P18-281 281 -P18-282 282 -P18-283 283 -P18-284 284 -P18-285 285 -P18-286 286 -P18-295 295 -P18-296 296 -P18-297 297 -P18-298 298 -P18-299 299 -P18-300 300 -P18-301 301 -P18-302 302 -P18-303 303 -P18-304 304 -P18-305 305 -P18-306 306 -P18-307 307 -P18-308 308 -P18-309 309 -P18-310 310 -P18-311 311 -P18-312 312 -P18-313 313 -P18-314 314 Non-Gynecologic Cases include: Specimen Specimen Slide Accession #: Labeled as: -P18-7 7 1 slide -P18-8 8 3 slides -P18-38 38 2 slides -P18-41 41 7 slides -P18-95 95 4 slides -P18-99 99 1 slide -P18-103 103 2 slides -P18-173 173 1 slide -P18-175 175 2 slides -P18-267 267 2 slides 3. The Laboratory Manager/Cytotechnologist #1 and Laboratory Director confirmed during a survey overview on 6/19/18 at 4:30 PM that the laboratory practice for labeling slides prior to and during processing did not include the prefix and year.
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 the review of eighty-two written laboratory procedures and interview it was determined that the laboratory failed to have a written procedure to designate how the stain maintenance tasks for the Papanicolaou stain in the automatic stainer and the manual stain process would be documented. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedure to designate how the daily and weekly stain maintenance tasks (rotating, filtering, and replacing stains and solutions) would be documented. a. The Survey Team requested and the laboratory failed to provide records to document the daily and weekly stain maintenance tasks for the stains and solutions in the automatic stainer and the manual stain process for any date in 2017 and to the date of the survey in 2018. 2. The Cytopreparatory Technician #2 stated during an interview on 6/19/18 at 12:00 PM that the daily and weekly stain maintenance tasks were not documented on any laboratory records. 3. These findings were reviewed with and confirmed by the Laboratory Manager/Cytotechnologist #1 and Laboratory Director during a survey overview on 6 /19/18 at 4:30 PM.
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 the review of the Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records for the Hologic ThinPrep Pap Test, and interviews it was determined that the laboratory failed to ensure that two of four 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, CYTYC Part Number 70354-001, 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 morphology training records for two of four Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. There were no training records for: - Technical Supervisor #1 - Technical Supervisor #2 2. These findings were confirmed by the Laboratory Manager/Cytotechnologist #1 during an interview on 6/20/18 at 10:30 AM and by the Laboratory Director during a

	survey overview on 6/20/18 at 1:30 PM. B. Based on the review of the Becton Dickinson (BD) SUREPATH IMPLEMENTATION GUIDE, review of certification records for the BD SurePath Pap Test, and interviews it was determined that the laboratory failed to ensure that four of four 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 that the "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 four of four Technical Supervisors who performed diagnostic interpretations on BD SurePath Pap Tests. There were no training records for: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4. 2. These findings were confirmed by the Laboratory Manager/Cytotechnologist #1 during an interview on 6/20/18 at 10:30 AM and by the Laboratory Director during a survey overview on 6/20/18 at 1:30 PM.
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: A. Based on the review of laboratory records, observation, and interviews it was determined that the laboratory failed to ensure that the required maintenance of the Hologic 2000 ThinPrep processor was performed, as specified by the manufacturer, in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team reviewed the Hologic 2000 ThinPrep maintenance forms provided by the laboratory for January 2018 through May 2018. a. The laboratory failed to document the identity of the employee who performed the maintenance tasks for any date in 2018. 2. On 6/20 /18 at 8:30 AM the Survey Team asked the Cytopreparatory Technician #1 to demonstrate the routine cleaning and maintenance tasks performed on the equipment. a. The Survey Team observed that the maintenance performed did not include the CAP SEAL CLEANING which is a required daily task as specified by the manufacturer (ThinPrep T2000 Maintenance: Chapter 7; Section G; CAP SEAL CLEANING). b. The Survey Team asked the Cytopreparatory Technician #1 to specifically demonstrate how the CAP SEAL was cleaned. The Survey Team observed that the Cytopreparatory Technician #1 cleaned the FILTER CAP but not the CAP SEAL which is a stainless steel part inside the processor that covers the top of the filter cap during sample processing. c. The Cytopreparatory Technician #1 stated during an interview on 6/20/18 at 8:30 AM that "I don't really touch anything on the inside." d. The CAP SEAL cleaning was not performed as documented on the laboratory maintenance records on 19 of 19 days in January, 19 of 19 days in February, 22 of 22 days in March, 20 of 20 days in April, and 22 of 22 days in May. 3. These findings were reviewed with and confirmed by the Laboratory Manager /Cytotechnologist #1 during an interview on 6/20/18 at 9:30 AM. B. Based on observation, the review of laboratory records, and interviews it was determined that the laboratory failed to ensure that the required maintenance on the Shandon Cytospin 4 was performed, as specified by the manufacturer, for any date in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team observed one Shandon Cytospin 4 in the laboratory. 2. The Survey Team requested and the

	laboratory failed to provide any maintenance logs or records of daily, weekly, and monthly equipment maintenance required by the manufacturer for the Shandon Cytospin 4 for any date in 2017 and to the date of the survey in 2018. 3. The Cytopreparatory Technician #1 confirmed during an interview on 6/19/18 at 12:00 PM that there were no daily, weekly, or monthly maintenance tasks performed on the equipment and that the only maintenance performed was an annual maintenance check completed by the facility and an outside vendor. 4. These findings were reviewed with and confirmed by the Laboratory Manager/Cytotechnologist #1 during an interview on 6/19/18 at 4:30 PM. C. Based on observation, the review of laboratory records, and interview it was determined that the laboratory failed to ensure that the required maintenance on the Hettich Centrifuge was performed, as specified by the manufacturer, for any date in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team observed one Hettich Centrifuge in the laboratory. 2. The Survey Team requested and the laboratory failed to provide any maintenance logs or records of the daily, weekly, and monthly equipment maintenance required by the manufacture for the Hettich Centrifuge for any date in 2017 and to the date of the survey in 2018. 3. The Cytopreparatory Technician #1 confirmed during an interview on 6/19/18 at 12:00 PM that there were no daily, weekly, or monthly maintenance tasks performed on the equipment and that the only maintenance performed was an annual maintenance check completed by the facility and an outside vendor. 4. These findings were reviewed with and confirmed by the Laboratory Manager /Cytotechnologist #1 during an interview on 6/19/18 at 4:30 PM.
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 the review of laboratory records and interview it was determined that the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics for the Diff Quik stain each day of use in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide Diff-Quik stain assessment records. The laboratory failed to document the staining characteristics of three of three Diff-Quik stain processes. 2. The Laboratory Manager/Cytotechnologist #1 confirmed during an interview on 6/19 /18 at 3:45 PM that there were no laboratory records to document the staining characteristics of the Diff Quik staining performed for each day of use in 2017 and to the date of the survey in 2018. 3. These findings were reviewed with and confirmed by the Laboratory Director during a survey overview on 6/19/18 at 4:30 PM.
D5617	CYTOLOGY CFR(s): 493.1274(b)(2) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

	This STANDARD is not met as evidenced by: Based on review of written laboratory procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to define effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written procedures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process. a. The laboratory procedure entitled CYT-D-1 PAPANICOLAOU STAINING AND DESTAINING PROCEDURE stated that both gynecologic and non-gynecologic specimens were stained on the automatic stainer. There was no requirement to filter or replace solutions and stains between staining gynecologic and non-gynecologic specimens. 2. The Cytopreparatory Technician #1 and Cytopreparatory Technician #2 confirmed during an interview on 6/20/18 at 8:45 AM that both gynecologic and non-gynecologic specimens were stained on the automatic stainer. Both used the same solutions and stains and none of the solutions or stains were filtered or replaced between gynecologic and non-gynecologic specimen staining. 3. These findings were confirmed during an interview with the Cytology Manager/Cytotechnologist #1 on 6/20/18 at 9:30 AM and by the Laboratory Director during a survey overview on 6/20/18 at 1:30 PM.
D5619	CYTOLOGY CFR(s): 493.1274(b)(3) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining. This STANDARD is not met as evidenced by: Based on the review of written laboratory procedures, lack of laboratory records, and interviews it was determined that the laboratory failed to establish written policies and procedures to filter or change stains following the staining of non-gynecologic specimens that have a high potential for cross-contamination. Findings include: 1. The Survey Team requested and the laboratory failed to provide written procedures to prevent cross-contamination between non-gynecologic specimens with a high potential for cross-contamination which included filtering or replacing all stains following staining. a. The Cytopreparatory Technician #2 stated during an interview on 6/19/18 at 12:00 PM that there was no process for determining which specimens had a high potential for cross contamination prior to staining so all effusions were stained separately using the manual stain process. b. The Cytopreparatory Technician #2 confirmed in an interview on 6/19/18 at 12:00 PM that the OG and Eosin counterstains were not filtered or replaced after each effusion was stained. 2. The Survey Team requested and the laboratory failed to provide records to document when the stains and solutions in the manual stain process had been filtered or replaced after an effusion was stained. a. The Cytopreparatory Technician #2 confirmed in an interview on 6/19/18 at 12:00 PM that there were no laboratory records to document when any of the stains or solutions were filtered or replaced after an effusion was stained for any date in 2017 or to the date of the survey in 2018. 3. The Laboratory Manager/Cytotechnologist #1 confirmed these findings during an interview on 6/20

	/18 at 9:30 AM. 4. These findings were reviewed with and confirmed by the Laboratory Director during a survey overview on 6/20/18 at 1:30 PM
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 the review of written laboratory procedures and interview it was determined that the laboratory failed to establish policies and procedures to ensure that the program to select negative gynecologic cases for review included cases from patients that have a higher than average probability of developing cervical cancer. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedure to define the criteria used to identify a patient as having a higher than average probability of developing cervical cancer. 2. The Laboratory Manager /Cytotechnologist #1 confirmed during an interview on 6/19/18 at 10:30 AM that there were no written procedures that defined the laboratory's criteria used to identify patients with a higher risk of developing cervical cancer to ensure that a portion of these negative cases were included in the review. 3. These findings were reviewed with and confirmed by the Laboratory Director during a survey overview on 6/19/18 at 4:30 PM
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 the review of written laboratory procedures, review of laboratory records, and interview it was determined that the laboratory failed to follow written policies and procedures to maintain statistics for a program to include an annual evaluation of one required statistic for gynecologic specimens in 2016 and 2017. Findings include: 1. The laboratory failed to follow the written procedure titled CYT-G-8 STATISTICAL REPORTS POLICY which stated that statistical data was analyzed for the "Number of gynecologic cases for which a review of a negative specimen results in reclassification as pre-malignant or malignant." 2. The Survey Team requested and the laboratory failed to provide an annual statistic evaluation of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms. 3. The Laboratory Manager/Cytotechnologist #1 confirmed during an interview on 6/20/18 at 1:15 PM that the laboratory had not compiled and evaluated this statistic for 2016 or 2017.
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 the review of written laboratory procedures, review of 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 #1 for five of five Cytotechnologists in 2017 and to the date of the survey in 2018 and one of one Cytotechnologist from February to the date of the survey in 2018. Findings include: 1. The laboratory failed to follow the written procedure titled CYT-F-8 WORKLOAD SURVEILLANCE CYTOTECHNOLOGIST which stated the following: "individual workload limits for each Cytotechnologist will be set by the technical supervisor according to individual performance capabilities." 2. The Survey Team requested and the laboratory failed to provide documentation that a maximum workload limit was established by the Technical Supervisor #1 for five of five Cytotechnologists (Cytotechnologists #1 through #5) in 2017 and to the date of the survey in 2018 and one of one Cytotechnologist (Cytotechnologist #6) from February to the date of the survey in 2018. Cytotechnologists include: Cytotechnologist #1 (Laboratory Manager) Cytotechnologist #2 Cytotechnologist #3 Cytotechnologist #4 Cytotechnologist #5 Cytotechnologist #6. 3. The Laboratory Manager/Cytotechnologist #1 confirmed during an interview on 6/18/18 at 4:15 PM that there were no laboratory records to document that an individual workload limit had been established for the six Cytotechnologists in 2017 or 2018 to the date of the survey. 4. These findings were confirmed by the Laboratory Director during a survey overview on 6/19/18 at 4:30 PM.
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 the review of written laboratory procedures, review of laboratory records, and interview it was determined that the laboratory failed to follow the written procedure to ensure that the workload limit for five of five Cytotechnologists was reassessed at least every six months and adjusted when necessary in 2017 and to the date of the survey in 2018. Findings include: 1. The laboratory failed to follow the written procedure titled CYT-F-8 WORKLOAD SURVEILLANCE CYTOTECHNOLOGIST which stated the following: -"individual workload limits for each Cytotechnologist will be set by the technical supervisor according to individual performance capabilities. These limits must be reviewed every six months and reassessed using laboratory defined performance standards." a. The Survey Team requested and the laboratory failed to provide documentation that the workload limits for five of five Cytotechnologists had been reassessed every six months in 2017 and to the date of the survey in 2018. Cytotechnologists include: Cytotechnologist #1 (Laboratory Manager) Cytotechnologist #2 Cytotechnologist #3 Cytotechnologist #4 Cytotechnologist #5. 2. These findings were reviewed with and confirmed by the Laboratory Manager/Cytotechnologist #1 during an interview on 6/18/18 at 4:15 PM.
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 the review of written procedures, record review, surveyor interviews and observation 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 (refer to D6093); and failed to ensure that two of four Technical Supervisors had received the training required to evaluate Hologic ThinPrep specimens and four of four Technical Supervisors had received the training required to evaluate BD SurePath Specimens (refer to D6102). 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 written laboratory procedures, review of laboratory records, observation, 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 D5203, D5403, D5429, D5617, D5619, D5633, and D5637.
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, review of laboratory records, and interview it was determined that the Laboratory Director failed to ensure that quality control programs were established to assure the quality of cytology testing and identify failures in quality as they occur. Cross Refer to D5473, D5621, and D5629.
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 interviews it was determined that the Laboratory Director failed to ensure appropriate training according to the manufacturer's instructions. Two of four Technical Supervisors had not received the appropriate training to evaluate the ThinPrep Pap Test. Four of four Technical Supervisors had not received the appropriate training to evaluate the BD SurePath Pap Test. Cross Refer to D5411
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 the review of written procedures, record review, glass slides and corresponding test reports, and surveyor interviews it was determined that the Technical Supervisor failed to verify the accuracy of four gynecologic test reports and one non-gynecologic test report (refer to D6115) and failed to ensure that workload limits were established and reassessed (refer to D6130). 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 the review of 264 routine negative gynecologic cases (266 slides) from January 2018 and confirmation by the Technical Supervisor #1 on June 20, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of four gynecologic tests. 1. P18-323 1/12/18 SurePath Pap Test (SPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. P18-50 1/8/18 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity 3. P18-373 1/11/18 SPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity 4. P18-420 1/16/18 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity B. Based on the review of 61 negative non-gynecologic cases (163 slides) from January 2018 and confirmation by the Technical Supervisor #1 on June 20, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of one non-gynecologic test. 1. P18-94 1/4/18 Pelvic Wash LABORATORY DIAGNOSIS: No Malignancy Identified SURVEY TEAM DIAGNOSIS: Suspicious for Adenocarcinoma TECHNICAL SUPERVISOR DIAGNOSIS: Rare Atypical Cluster (1) Suspicious for Adenocarcinoma
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least

	every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the review of laboratory records and interviews it was determined that the Technical Supervisor #1 failed to establish individual workload limits and failed to reassess the workload limits at least every six months for five of five Cytotechnologists in 2017 and to the date of the survey in 2018 and for one Cytotechnologist from February to the date of the survey in 2018. Cross Refer to D5633 and D5637
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.