Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316753	02/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Delta Health System - The Medical Center	1400 East Union St - Laboratory, Greenville, MS	

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 record review, surveyor interview and observation, the laboratory failed to establish written policies and procedures to assess the competency of the cytology staff (refer to D5209); failed to establish written policies and procedures for cytology specimen submission and handling (refer to D5311); failed to establish four written policies and procedures (refer to D5403); failed to perform testing according to the manufacturer's instructions (refer to D5411); failed to ensure all solutions were labeled to identify content (refer to D5415); failed to establish written policies and procedures to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis (refer to D5623); failed to establish written policies and procedures to ensure the search and review of all prior negative gynecologic specimens received within the previous five years was performed (refer to D5625); failed to establish written policies and procedures for the evaluation and comparison of six laboratory statistics (refer to D5629); failed to establish policies and procedures for the evaluation of case reviews of each individual examining slides against the laboratory's overall statistics (refer to D5631); failed to establish written policies and procedures for establishing workload limits, reassessing workload limits, not exceeding workload limits, prorating workload, and documenting workload (refer to D5633, D5637, D5639, D5641, and D5645); failed to establish written policies and procedures to identify and report unsatisfactory specimens or slide preparations (refer to D5655); failed to establish written policies and procedures to ensure nongynecologic test reports contained narrative descriptive nomenclature (refer to D5657); failed to establish written policies and procedures to ensure that corrected

	reports indicated the basis for correction (refer to D5659); and failed to include the name and address of the laboratory location where the cytology test was performed (refer to D5805). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview, it was determined that the laboratory failed to establish written policies and procedures to assess Technical Supervisor competency and failed to assess the competency of two of two Technical Supervisors. 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 Technical Supervisor competency. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for two of two Technical Supervisors who performed cytology microscopic evaluations during 2016, 2017 and to the date of the survey in 2018. 3. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director /Technical Supervisor A and Laboratory Manager confirmed these findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures for the collection and submission of gynecologic and nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the following specimen processing requirements for cytology specimens: a. Patient preparation b. Specimen collection c. Specimen storage and preservation d. Conditions for transportation to the laboratory e. Specimen acceptability and rejection 2. During an interview on 2/13/18 at 8:30 AM, the Laboratory Manager stated there were no written procedures for the collection and submission of gynecologic and nongynecologic cytology specimens. 3. During an interview on 2/14/18 at 12:00 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings.
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: Cross Refer to D5311 Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to monitor and assess the preanalytic systems. There were no programs to ensure cytology requirements for specimen submission and handling. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the cytology preanalytic laboratory system. 2. The Survey Team requested and the laboratory failed to provide documentation of any cytology preanalytic quality assessment activities or problems.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of twenty-eight written laboratory policies and procedures, laboratory records and interview, it was determined that the laboratory failed to have four written policies and procedures. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy or procedure to detail the process for microscopic review of gynecologic and nongynecologic slides by Technical Supervisors performing primary screening. a. During an interview on 2/13/18 at 9:30 AM, the Laboratory Director/Technical Supervisor A described the process for Technical Supervisors performing microscopic evaluation of gynecologic and nongynecologic slides at Facility A and Facility B. The Laboratory Director/Technical Supervisor A confirmed that there was no procedure for these processes. 2. The Survey Team requested and the laboratory failed to provide a written policy or procedure to detail the process for the electronic entry and reporting of final cytology test results. a. During an interview on 2/13/18 at 9:30 AM, the Laboratory Director

	/Technical Supervisor A described the process for the electronic entry and reporting of final cytology test results. The Laboratory Director/Technical Supervisor A confirmed that there was no procedure for these processes. 3. The Survey Team requested and the laboratory failed to provide a written policy or procedure to detail the process for testing the Papanicolaou (Pap) staining materials to ensure predictable staining characteristics for each day of use. (Refer to D5473) 4. The Survey Team requested and the laboratory failed to provide a written policy or procedure to detail the laboratory's process for internal and external consultations on cytology cases. a. During an interview on 2/13/18 at 9:30 AM, the Laboratory Director/Technical Supervisor A described the process for requesting internal and external consultations on cytology cases using the form titled "ANATOMIC PATHOLOGY CONSULTATION FORM." The Laboratory Director/Technical Supervisor A confirmed that there was no procedure for these processes. 5. During an interview on 2 /13/18 at 4:30 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the THINPREP 2000 SYSTEM OPERATOR'S MANUAL, laboratory policies and procedures, laboratory records and interview, it was determined that the laboratory failed to ensure that one of two 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 THINPREP 2000 SYSTEM OPERATOR'S MANUAL, CYTYC Part Number 70354-001, states "the evaluation of microscopic slides produced with the HOLOGIC 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." 2. The Survey Team requested and the laboratory failed to provide the training records for one of two Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. There were no training records for Technical Supervisor B. 3. The Survey Team reviewed laboratory records titled "ABNORMAL GYN PAP/NONGYN LOG" from September 2017 through December 2017. Twelve days were identified in the log when Technical Supervisor B performed diagnostic interpretations on Hologic ThinPrep Pap Tests. Technical Supervisor B had evaluated 255 ThinPrep specimens without being certified to evaluate ThinPrep prepared slides. Dates include: 9/12/17 10/3/17 10/11/17 10/16/17 10/17/17 10/18/17 10/23/17 10/31/17 11/14/17 11/21/17 11/27/17 11/28/17 4. During an interview on 2 /14/18 at 12:00 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview, it was determined that the laboratory failed to ensure that 24 of 24 solutions and reagents were labeled to indicate content. Findings include: 1. The Survey Team observed the laboratory processing area on 2/12/18 at 2: 05 PM and observed that the laboratory failed to label 24 of 24 staining buckets in the Papanicolaou stain line to indicate content. 2. During an interview on 2/12/18 at 2:30 PM, Preparatory Staff A confirmed that the staining buckets were not labeled to indicate content. 3. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview, it was determined that the laboratory failed to record the testing of Pap staining materials on each day of use for nongynecologic cytology specimens. Findings include: 1. The Survey Team reviewed laboratory records titled "ABNORMAL GYN PAP/NONGYN LOG" from September 2017 through December 2017. Seventeen days were identified in the log when nongynecologic cytology cases were processed and evaluated. The lab failed to document the testing of the Pap stain materials on the section labeled "Stain Quality" for seventeen of seventeen days. Dates include: 9/18/17 9/19/17 9/25/17 10/5/17 10/9 /17 10/25/17 10/26/17 10/28/17 11/14/17 11/16/17 11/18/17 12/6/17 12/7/17 12/13/17 12/18/17 12/20/17 12/27/17 2. During an interview on 2/14/18 at 12:00 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager 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, laboratory records and interview, it was determined that the laboratory's written policies and procedures failed to include how the cause of discrepancies would be determined between the cytology diagnosis and the histopathology diagnosis. The laboratory additionally failed to identify the cause of 2 of 3 discrepant cases in 2016 and 2017. Findings include: 1. The Survey Team reviewed the written laboratory procedure titled "QA CYTO GYN." a. The procedure did not determine how all gynecologic cytology reports with a diagnosis of HSIL or malignancy were identified or compared with available histopathology reports. b. The procedure did not define criteria to determine a discrepancy between a cytological diagnosis of HSIL or malignancy and the correlating histology report. 2. The Survey Team reviewed laboratory records titled "HIGH GRADE CYTOLOGY QA/LOOKBACK" from 2016 through 2017. a. The records did not identify or indicate the cause of discrepancies between the cytology diagnosis and the histopathology diagnosis for 2 of 3 discrepant cases. Cases include: GY-16-2852 GY-16-3188 b. The records did not indicate the date when the review was performed for 11 of 11 reviewed cases. Cases include: GY-16-2536 GY-16-2811 GY-16-2852 GY-16-2984 GY-16-3188 GY-16-3235 GY-16-3293 GY-16-3842 GY-16-3893 GY-17-387 GY-17-2652 3. During an interview on 2/13/18 at 9:30 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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, review of glass slides and interview, it was determined that the laboratory failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years for each patient with a current high-grade squamous intraepithelial lesion (HSIL) or malignancy. The laboratory additionally failed to identify one of seven prior negative specimens as having a more significant lesion than initially reported. Findings include: 1. The Survey Team reviewed the written laboratory procedure titled "QA CYTO GYN." a. The procedure did not detail how all previous negative gynecologic Cytology specimens from current HSIL were identified for review. b. The procedure did not define criteria to determine discrepancies when reviewing prior negative specimens. 2. The Survey Team reviewed laboratory records titled "HIGH GRADE CYTOLOGY QA/LOOKBACK" from 2016 through 2017. a. The records included six HSIL cases with a total of seven previous negative cytology slides. The records did not indicate the date when the reviews were performed for seven of seven previous negative slides. Cases include: GY-13-2348 GY-14-770 GY-14-3678 GY-15-1460 GY-15-1915 GY-16-1492 GY-16-3674 b. The Survey Team reviewed glass slides for the six HSIL cases and seven corresponding previous negative cytology slides. The Survey Team identified and the

	Laboratory Director/Technical Supervisor A confirmed on 2/14/18 one of seven prior negative specimens (GY-16-01492) had a more severe lesion than was initially reported or identified by the laboratory, as part of a quality control review program. 3. During an interview on 2/14/18 at 12:00 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview, it was determined that the laboratory failed to establish written policies or procedures and failed to maintain statistics for a program to evaluate six of six required annual laboratory statistics for 2016 and 2017. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy or procedure to include an annual statistical evaluation for six of six required statistics. 2. The Survey Team requested and the laboratory failed to provide records of six of six required annual statistics for 2016 and 2017. 3. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings.
D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (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)(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. 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 for a program to evaluate the case reviews of two of two Technical Supervisors against the laboratory's overall statistical values in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures for a program to evaluate

	the case reviews of two of two Technical Supervisors against the laboratory's overall statistical values. 2. The Survey Team requested and the laboratory failed to provide records for comparative reviews to evaluate the case reviews of two of two Technical Supervisors against the laboratory's overall statistical values. 3. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager 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 interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for two of two Technical Supervisors when performing primary screening of gynecologic and non-gynecologic specimen slide preparations in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide laboratory policies and procedures to ensure that a maximum workload limit was established for two of two Technical Supervisors by the Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide laboratory records for established maximum workload limits for two of two Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. 3. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager 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 written laboratory policies and procedures, laboratory records and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that a workload limit was reassessed at least every six months and adjusted when necessary for the two of two Technical Supervisors in 2016, 2017 and to the date of the survey in 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 reassessing individual workload limits at least every 6 months for two of two Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide written documentation of the reassessment of workload limits for two of two Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. 3. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director /Technical Supervisor A and Laboratory Manager confirmed these findings.
D5639	CYTOLOGY

	CFR(s): 493.1274(d)(2)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure the maximum number of slides examined would not exceed 100 slides in each 24-hour period for two of two Technical Supervisors in 2016, 2017 and to the date of the survey in 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 ensuring that the maximum number of slides to be examined by the two of two Technical Supervisors would not exceed 100 slides in each 24-hour period. 2. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director /Technical Supervisor A and Laboratory Manager confirmed these findings.
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 and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure the number of slides that could be examined by two of two Technical Supervisors were prorated. The laboratory failed to establish a prorated slide limit for two of two Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to ensure that the established workload limits were prorated for two Technical Supervisors who examined slides in less than an 8 hour workday and with duties other than slide examination. 2. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director /Technical Supervisor A and Laboratory Manager 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 and interview, it was determined that the laboratory failed to establish written policies and procedures to maintain records of the total number of slides examined by two of two Technical Supervisors and the number of hours devoted to examining slides during each 24 hour period in 2016, 2017 and to the date of the survey in 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 maintaining records of the total number of slides examined and the number of hours devoted to examining slides during each 24-hour period for two of two Technical Supervisors. 2. The Survey Team reviewed laboratory records titled "ABNORMAL GYN PAP/NONGYN LOG" from September 2017 through December 2017. Forty-nine days were identified in the log when the two Technical Supervisors performed primary evaluations on cytology specimens. a. Laboratory Director/Technical Supervisor A failed to document the number of hours devoted to screening and evaluating cytology slides on twenty-one of twenty-one days. Dates include: 9/13/17 9/18/17 9/19/17 9/25/17 9/27/17 10/5/17 10/9 /17 10/20/17 10/24/17 10/25/17 10/26/17 10/28/17 11/14/17 11/16/17 11/18/17 12/6 /17 12/7/17 12/13/17 12/18/17 12/20/17 12/27/17 b. Technical Supervisor B failed to document the number of hours devoted to screening and evaluating the slides on one day (11/28/17). c. During an interview on 2/14/18 at 12:00 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings. 2. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager 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, review of glass slides and interview, it was determined that the laboratory failed to establish written policies and procedures to identify and report unsatisfactory specimens or slide preparations as unsatisfactory. The laboratory failed to identify and report three of three gynecologic cytology specimens sampled from January 1, 2017 through February 7, 2017 as being unsatisfactory for diagnostic evaluation. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for identifying and reporting unsatisfactory specimens. 2. The Survey Team identified three of three unsatisfactory gynecologic cytology cases/slides that were initially evaluated and reported as being Negative for Intraepithelial Lesion by the laboratory. Cases include: GY-17-00113 GY-17-00120 GY-17-00283 3. During an interview on 2 /14/18 at 9:20 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5657	CYTOLOGY

	CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure nongynecologic test reports contained narrative descriptive nomenclature. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy or procedure to describe the laboratory's nomenclature system for reporting nongynecologic test results. 2. During an interview 2/13/18 at 9:30 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. 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 ensure that corrected reports indicated the basis for the correction on the report. Three of three corrected test reports in 2017 failed to indicate the basis for correction. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to ensure that corrected reports indicated the basis for the correction. 2. The Survey Team reviewed three corrected test reports in 2017. Three of three corrected test reports failed to indicate the basis for correction. Reports include: GY-17-2745 GY-17-2757 GY-17-3746 3. During an interview on 7/19/17 at 12:00 PM, the Laboratory Director/Technical Supervisor A and Laboratory Manager confirmed these findings.
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 interview, it was determined the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of testing. Cross Refer to D5411, D5473, D5623, D5625, D5629, D5631, D5633, D5637, D5641, D5645, D5655 and D5659 Findings include: 1. The Survey Team requested and the laboratory failed to provide laboratory policies and

	procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on interview and the review of cytology test reports, it was determined that the laboratory failed to ensure that the cytology test reports indicated the name and address of the location where the test was performed when the cytology tests were sent to Facility B (CLIA #25D1066924) for final interpretation and evaluation. Ten of ten cytology reports sampled from September 2017 through October 2017 failed to include the name and address of Facility B. Findings include: 1. During an interview on 2/12/18 at 4:30 PM, the Laboratory Director/Technical Supervisor A stated that the slides for all cytology cases evaluated by Technical Supervisor B are examined at Facility B. a. During an interview on 2/13/18 at 11:15 AM, Technical Supervisor B confirmed this process. 2. The Survey Team reviewed ten cytology test reports for cases evaluated by Technical Supervisor B from September 2017 through October 2017. a. Ten of ten reports failed to indicate the name and address of Facility B, where the test was performed. Reports include: GY-17-2714 GY-17-3186 GY-17-3188 GY-17-3189 GY-17-3190 GY-17-3191 GY-17-3192 GY-17-3193 GY-17-3194 GY-17-3195 3. During an interview on 2/14/18 at 12:00 PM, the Laboratory Director /Technical Supervisor A and Laboratory Manager confirmed these findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, interview and review of glass slides, 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 and oversight with applicable regulations (refer to D6079); failed to ensure that quality control programs were established to assure the quality of cytology testing (refer to D6093); failed to ensure that quality assessment programs were established to assure the quality of laboratory services (refer to D6094); failed to ensure that one of two Technical Supervisors had received the training required to

	evaluate Hologic Thin Prep Pap test specimens (refer to D6102); and failed to ensure the competency of two of two Technical Supervisors (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, glass slides and interview, it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations by having cytology procedures and programs established and followed. Cross Refer to D5311, D5403, D5655, D5657, D5659, and D5805
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 laboratory policies and procedures, laboratory records, glass slides 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 D5623, D5625, D5629 and D5631
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, glass slides and interview, it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of cytology testing and identify failures in quality as they occur. Cross refer to D5391 and 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 review of the THINPREP 2000 SYSTEM OPERATOR'S MANUAL, certification records for the Hologic ThinPrep Pap Test and interview, it was determined that the Laboratory Director failed to ensure that one of two Technical Supervisors that performed Hologic ThinPrep Pap Test evaluations in 2016, 2017 and to the date of the survey in 2018 had received the appropriate morphology training and certification according to the manufacturer's instructions. 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 policies and procedures, laboratory records and interview, it was determined that the Laboratory Director failed to ensure the competency of two of two Technical Supervisors for 2016, 2017 and to the date of the survey in 2018. Cross Refer to D5209
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview, it was determined that the Technical Supervisor failed to establish individual workloads limits for two of two Technical Supervisors. The Technical

	Supervisor also failed to reassess the workload limits at least every six months and make adjustments when necessary in 2016, 2017 and to the date of the survey in 2018. Cross Refer to D5633 and D5637
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview, it was determined that two of two Technical Supervisors failed to document the number of hours spent examining slides during each 24-hour period in 2016, 2017 and to the date of the survey in 2018. 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.