Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0252092	02/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Grand Strand Regional Medical Center Laboratory	809 82nd Pkwy, Myrtle Beach, SC	

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 interviews and observation the laboratory failed to follow written policies and procedures to ensure optimum integrity of a patient's specimen from the time of slide labeling through completion of testing (refer to D5203); failed to follow written procedures (refer to D5401); failed to establish written procedures for cytology test processes (refer to D5403); failed to perform required instrument maintenance, as specified by the manufacturer (refer to D5429); failed to test staining materials for intended reactivity (refer to D5473); failed to follow written procedures to prevent cross-contamination by staining nongynecologic specimens that have a high potential for cross-contamination separately from other nongynecologic specimens (refer to D5619); failed to establish written procedures to document and evaluate annual statistics (refer to D5629); failed to establish written procedures for the evaluation of individual case reviews against the laboratory's overall statistical values (refer to D5631); failed to establish written procedures for establishing workload limits, reassessing workload limits, prorating workload limits and maintaining workload slides and hours (refer to D5633, D5635, D5637, D5641, D5645); failed to maintain the identity of the personnel who performed comparative reviews of cytology and histopathology specimens, and failed to maintain the date the comparative reviews were performed (refer to D5787). 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, review of specimen slides and interviews 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 twenty-nine of thirty patient specimens from January 2018 had specimen slides labeled with accurate patient specimen information. Findings include: 1. The laboratory failed to follow the procedure CY.201 titled NONGENITAL PROCESSING/STAINING SOLUTIONS (signed and dated by the Laboratory Director on 8/14/17) which stated: "Label a thinprep slide for each vial/specimen withCR, the accession number, patient last name, first initial and specimen type." "Non-gyn specimens to include brushings and FNA's must be submitted with patient last name and first initial. A CR plus unique accession number for that specimen will be written in pencil on the slide." 2. The Survey Team reviewed thirty consecutive specimens for accurate specimen labeling. Twenty-nine of thirty cases were not labeled with the full accession accession number. Specimens include: CR18:QV:1 CR18:QV:2 CR18:QV:3 CR18:QV:4 CR18:QV:5 CR18:QV:6 CR18:QV:7 CR18:QV:8 CR18:QV:9 CR18:QV:11 CR18:QV:12 CR18:QV:13 CR18:QV:14 CR18:QV:15 CR18:QV:16 CR18:QV:17 CR18:QV:18 CR18:QV:19 CR18:QV:20 CR18:QV:21 CR18:QV:22 CR18:QV:23 CR18:QV:24 CR18:QV:25 CR18:QV:26 CR18:QV:27 CR18:QV:28 CR18:QV:29 CR18:QV:30 3. During an interview on 2/27/18 at 8:30 AM, Staff C stated that the full accession number was to be written on specimen slides. Staff C further stated that sometimes fine needle aspiration (FNA) slides were processed without the full accession number being written on the slides and a paper label was placed on the slides after staining. 4. During an interview on 2/27/18 at 3:05 PM, Staff A and Staff B confirmed that specimen slides were not labeled with the full accession number. 5. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A 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, lack of laboratory records, and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of 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 assessing the competency of two of two Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for two of two Technical Supervisors who

	performed microscopic evaluations during 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: Technical Supervisor A Technical Supervisor B 3. During an interview on 2/26/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A 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 and interview 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 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor and assess the quality of the general laboratory system. 2. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A 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: Based on review of laboratory policies and procedures and interview 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. 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. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of fifty-seven laboratory policies and procedures, observation and interviews it was determined that the laboratory failed to follow three written policies

	and procedures. Findings include: 1. The laboratory failed to follow the written procedure CY.00.01 titled REVIEW OF CYTOLOGY PROCEDURE MANUAL (signed and dated by the Laboratory Director on 9/5/13) which stated: "All procedures are reviewed annually by the laboratory director and/ or designee." a. During an interview on 2/27/18 at 3:05 PM, Staff A stated that procedures were reviewed biennially by Staff A and the Laboratory Director/Technical Supervisor A. 2. The laboratory failed to follow the written procedure CY.203.01 titled RICHARD ALLAN CYTOLOGY STAINING (signed and dated by the Laboratory Director on 9/5/13) which stated: "A daily QC check is made on the non-gynecological stain quality and the quality of preparation by the cytotechnologist and pathologist. This is documented in the staining QC book." "Richard Allan Hematoxylin and Richard Allan cytology stain are replaced once a week, usually Friday's and filtered daily." "At the beginning of each day, all solutions must be replaced in this setup." a. The Survey Team reviewed laboratory records titled "NON-GYN CYTOLOGY SETUP & MAINTENANCE" from January 2017 through the date of the survey in 2018. The records did not document when the stains were changed. b. During an interview on 2 /27/18 at 3:05 PM, Staff B stated that the laboratory did not check the staining characteristics of the nongynecologic stains. 3. The laboratory failed to follow the written procedure CY.601.01 titled INSTRUMENT MAINTENANCE, FUNCTION /EVALUATION NIKON ECLIPSE, THINPREP 2000, LABOFUGE 400 (signed and dated by the Laboratory Director on 9/5/13) which described the weekly maintenance to be performed on the centrifuge and the Hologic ThinPrep 2000 Processor. a. During an interview on 2/27/18 at 8:30 AM, Staff C stated that the laboratory did not perform weekly maintenance on the centrifuge or the Hologic ThinPrep 2000 Processor. b. During an interview on 2/27/18 at 3:05 PM, Staff A and Staff B confirmed that the laboratory did not perform weekly maintenance on the centrifuge or the Hologic ThinPrep 2000 Processor. 4. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of fifty-seven written laboratory procedures and interview it was

	determined that the laboratory failed to have one laboratory procedure. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for performing comparative reviews of discrepant cytology and histopathology specimens. a. During an interview on 2/26/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A stated that when there was a discrepancy between cytology and histopathology specimens the slides were reviewed and documented on the laboratory record titled "QA CYTOLOGY/HISTOLOGY DIAGNOSIS CORRELATION DISCREPANCIES". b. The Laboratory Director/Technical Supervisor A confirmed there were no written policies and procedures to describe this process.
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 the lack of laboratory records and interviews it was determined that the laboratory failed to ensure that the required maintenance for one Hologic ThinPrep 2000 Processor was performed, as specified by the manufacturer, for 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide maintenance records for the Hologic ThinPrep 2000 Processor. 2. During an interview on 2/27/18 at 8:30 AM, Staff C stated the the laboratory did not perform any of the required maintenance on the Hologic ThinPrep 2000 Processor except for preventative maintenance performed by Hologic. 3. During an interview on 2/27/18 at 3:05 PM, Staff A and Staff B confirmed that the laboratory did not perform the required maintenance on the Hologic ThinPrep 2000 Processor. 4. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A 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 the lack of laboratory records and interviews it was determined that the laboratory failed to test staining materials for intended reactivity of the nongynecologic Papanicolaou stain and Diff Quick stain for 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the nongynecologic Papanicolaou stain and Diff Quick stain were assessed each day of use. 2. During an interview on 2/27/18 at 3:05 PM, Staff B stated that the laboratory

	did not check the staining characteristics of the nongynecologic stains. 3. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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 review of laboratory policies and procedures and interviews it was determined that the laboratory failed to follow written policies and procedures to prevent cross-contamination during Papanicolaou staining of nongynecologic specimens that have a high potential for cross-contamination. Findings include: 1. The laboratory failed to follow the procedure CY.202.01 titled DETERMINATION OF SPECIMEN POTENTIAL FOR CROSS CONTAMINATION (signed and dated by the Laboratory Director on 9/5/13) which stated: "Non-gynecologic specimens with a high potential for cross-contamination are stained separately from other non-gynecologic specimens. These are highly cellular body fluid samples. Stains and solutions are replaced after staining each such sample." "Spin down the cytology specimen to concentrate. Place a small drop of concentrated specimen on a slide and mix with a drop of Toluidine blue stain. Apply a cover slip and assess the cellularity microscopically." 2. During an interview on 2/27/18 at 8:30 AM, the Survey Team asked Staff C how specimens with a high potential for cross-contamination were identified. Staff C stated that some direct smears and bloody specimens were stained separately and the stains and solutions were changed. a. The Survey Team asked Staff C if a slide was prepared from body fluids and stained with Toluidine blue. Staff C said "no" and did not know what Toluidine blue was. 3. During an interview on 2/27 /18 at 3:05 PM, Staff B stated that the laboratory did not use Toluidine blue to assess the cellularity of specimens. 4. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A 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 interviews it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required statistics for nongynecologic cytology specimens in 2016 and 2017. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical laboratory evaluation of three required statistics for the nongynecologic specimens: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis, to include unsatisfactory. 2. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A confirmed these findings and stated that the laboratory did not have a documented evaluation of the statistics prior to the survey.
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, lack of 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 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 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 documenting the evaluation of the case reviews of two of two Technical Supervisors against the laboratory's overall statistical values. Technical Supervisors include: Technical Supervisor A Technical Supervisor B 3. During an interview on 2/26/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A 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, lack of 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

	Laboratory Director/Technical Supervisor A for two of two Technical Supervisors when performing primary evaluation of cytology specimen slide preparations 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 and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor A for two of two Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide an established workload limit for two of two Technical Supervisors for 2017 and to the date of the survey in 2018. Technical Supervisors include: Technical Supervisor A Technical Supervisor B 3. During an interview on 2/26/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A 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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that two of two Technical Supervisor's workload limits were 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 Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that a workload limit for the two of two Technical Supervisors would be reassessed at least every 6 months and adjusted when necessary. 2. The Survey Team requested and the laboratory failed to provide reassessed workload limits for two of two Technical Supervisors for 2017 and to the date of the survey in 2018. Technical Supervisors include: Technical Supervisor A Technical Supervisor B 3. During an interview on 2 /26/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A 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 that the workload limit for two of two Technical Supervisors, when examining slides in less than an 8-hour workday, would be prorated using a period of eight hours to determine the number of slides that may be examined 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 and procedures to determine how to prorate the workload limit for two of two Technical Supervisors, when examining slides in less than an 8-hour workday or on activities other than primary examinations of cytology slides. 2. During an interview on 2/26/18 at 3:00 PM, the Laboratory Director /Technical Supervisor A 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 establish written policies and procedures to ensure that the laboratory would maintain records for two of two Technical Supervisors of the total number of slides examined and the number of hours devoted to examining slides. The laboratory failed to maintain records of the number of hours devoted to examining slides 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 and procedures to ensure that the laboratory would maintain records of the total number of slides examined during each 24-hour period 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 "CYTOLOGY DAILY WORKLOAD" for two of two Technical Supervisors from 2017 to the date of the survey in 2018. The records failed to document the number of hours devoted to examining slides during each 24-hour period. Technical Supervisors include: Technical Supervisor A Technical Supervisor B 3. During an interview on 2 /26/18 at 11:00 AM, Staff B stated that the records were generated by Facility B (CLIA #10D0964885) and confirmed the records did not document the number of hours devoted to examining slides. 4. During an interview on 2/27/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that the laboratory failed to maintain the identity of the personnel who performed twenty-five of twenty-five comparative reviews of discrepant cytology and histopathology

	specimens, and failed to maintain the date the comparative reviews were performed. Findings include: 1. The Survey Team reviewed laboratory records titled "QA CYTOLOGY/HISTOLOGY DIAGNOSIS CORRELATION DISCREPANCIES" which described the comparative reviews for discrepant cytology and histopathology specimens. a. Twenty-five of twenty-five comparative reviews did not document the identity of the personnel performing the review or the date the review was performed. Cases include: CR17-486 CR17-517 CR17-531 CR17-545 CR17-550 CR17-554 CR17-555 CR17-567 CR17-569 CR17-573 CR17-574 CR17-583 CR17-586 CR17-587 CR17-598 CR17-603 CR17-618 CR17-641 CR17-644 CR17-673 CR17-728 CR17-731 CR17-795 CR17-816 CR17-818 2. During an interview on 2/26/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A 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 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 cytology testing. Cross refer to D5401, D5403, D5429, D5473, D5619, D5629, D5631, D5633, D5637, D5641, D5645, D5787 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. 2. During an interview on 2/28/18 at 8:45 AM, Staff A stated that Facility B was responsible for all of the quality assurance activities for Facility A (CLIA #42D0252092). 3. During an interview on 2/28/28 at 9:10 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. 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 an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic systems. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor and assess the quality of the postanalytic system. 2. During an interview on 2/28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A 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 written laboratory policies and procedures, laboratory records, observation 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 and oversight with applicable regulations (refer to D6079); failed to ensure that quality assessment programs were established (refer to D6094); and failed to ensure the competency of six of six personnel 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, observation and interviews 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 D5203, D5209, D5401, D5403, D5429, D5473, D5619, D5629, D5631, D5633, D5637, D5641, D5645, D5787
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, 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, D5891.
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 interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain competency of four of four Staff and two of two Technical Supervisors performing cytology test procedures. Cross refer to D5209 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 competency of four of four staff performing cytology processing. 2. The Survey Team reviewed competency assessment records from for four of four Staff performing cytology processing. The records failed to document that a competency assessment was performed for cytology processing from 2017 and to the date of the survey in 2018. Staff include: Staff B Staff C Staff D Staff E 3. During an interview on 2/27/18 at 3:05 PM, Staff B stated that the laboratory "needs to add a cytology component to the competencies." 4. During an interview on 2 /28/18 at 9:10 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.
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, lack of laboratory records and interview it was determined that the Technical Supervisor failed to establish an individual workload limit and failed to reassess the workload limit at least every six months and make adjustments when necessary in 2017 and to the date of the survey in 2018 for two of two Technical Supervisors. 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 the lack of laboratory records and interview it was determined that two of two Technical Supervisors failed to document the number of hours devoted to examining slides in each 24-hour period for 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.