Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080242	07/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Associates Resolute	555 Creekside Crossing, New Braunfels, TX	

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 and surveyor interviews the laboratory failed to follow policies and procedures to determine the cause of discrepancies between the cytology diagnosis and the histopathology (refer to D5623); failed to follow policies and procedures to document the search for prior negative gynecologic specimens for patients with a current HSIL, adenocarcinoma, or other malignant neoplasm (refer to D5625); failed to follow policies and procedures for the evaluation and comparison of two of six laboratory statistics (refer to D5629) and failed to document procedures performed (refer to D5667). 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.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on lack of records and interview it was determined that Facility A laboratory (CLIA 45D2080242) failed to ensure that records were available to show that

	complaints were documented and investigated. Findings include: 1. The Survey Team requested, and Facility A laboratory failed to provide, records of complaints received from 2016 and 2017. 2. The Clinical Pathology Support Manager confirmed during an interview on 7/18/18 at 2:00 PM that these records were kept at the executive office and not at Facility A laboratory.
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 records, and interview it was determined that Facility A laboratory failed to assess the competency of three of three Technical Supervisors who performed the microscopic evaluation of cytology specimens in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The policy titled "PATHOLOGISTS' COMPETENCY ASSESSMENTS" did not reference or describe the newly created form ("PATHOLOGIST COMPETENCY QA CHECKLIST") to document the competency for three of three Technical Supervisors. 2. The Survey Team requested, and the Facility A laboratory failed to provide, completed competency assessment records for three of three Technical Supervisors that performed the microscopic examination and reporting of cytology test results in 2016, 2017 and to the date of the survey in 2018. Laboratory Director/Technical Supervisor #1 Technical Supervisor #2 Technical Supervisor #3 3. The Clinical Pathology Support Manager confirmed these findings during an interview on 7/17/18 at 2:03 PM.
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, lack of laboratory records, and interviews it was determined that the Facility A laboratory failed to follow policies or procedures to document the transportation of cytology slides from Facility A to Facility B (CLIA 45D0505003) for the years 2016, 2017 and to the date of the survey in July 2018. Findings include: 1. The policy "CYTOLOGICAL EXAMINATIONS" stated "5. Slides are tracked by (Facility B) at their main location. All slides sent to this laboratory (Facility A) for pathology review via (Facility B) courier." The policy referenced two Facility B procedures ("AUS250646SOP NON-GYN CASE ALLOCATION/DISTRIBUTION" and "AUS251461SOP GYN SLIDE TRACKING AND DISTRIBUTION") which were not followed. 2. The Survey Team requested, and Facility A laboratory failed to provide, transport records for slides received at

	Facility A from Facility B for 2016, 2017 and to the date of the survey in July 2018. 3. During interviews with the Facility B Cytology Manager on 7/17/18 at 3:17 PM and again on 7/18/18 at 8:50 AM, the Survey Team requested slide transport records. a. During the interview on 7/18/18 at 8:50 AM, the Facility B Cytology Manager stated that the process of keeping slide transport records began in May and that Facility B stopped sending cytology slides to Facility A in May. Facility B Cytology Manager further stated that there were no slide transport records for May 2018 or for the previous months because Facility B was not keeping these records. 4. These findings were confirmed during an interview on 7/19/18 at 11:27 AM with the Facility A Laboratory Director/Technical Supervisor #1, the Clinical Pathology Support Manager and the Facility B Cytology Manager.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of records, review of specimen slides and their corresponding reports, and interview it was determined that the laboratory failed to maintain documentation of all cytology slide and preparation issues for 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The policy "CYTOLOGICAL EXAMINATIONS" stated "9. Any quality issues will be documented in the laboratory information system QA module (see (Facility B) SOP AUS260812SOP LabIS QA Flags Procedure) to be transcribed onto QC Forms maintained by (Facility B). The corrective action required will be noted on the form." a. The Survey Team requested, and Facility A failed to provide, documentation of slide and preparation quality issues reported by Facility A for 2016, 2017 and to the date of the survey in 2018. 2. The policy "MICROSCOPIC EXAMINATION OF ANATOMIC PATHOLOGY SPECIMENS" stated "The pathologist reviews each case prior to testing to ensure the accession numbers and patient name on the slides match the corresponding requisition. The pathologist follows all policies set forth by (Facility B) regarding specimen identity and bar code scanning of the case." a. The Survey Team identified one of 469 slides (ZK970640) where the last name on the slide did not match the last name on the final report. This was reviewed with the Facility B Cytology Manager during an interview on 7/17/18 at 8:50 AM. 3. During an interview on 7/18/18 at 2:00 PM, the Clinical Pathology Support Manager and the Facility A Laboratory Director/Technical Supervisor #1, confirmed that the quality assessment records were not kept at Facility A.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on review of the laboratory policies and procedure manual and interview it was determined that the laboratory failed to ensure that fifteen of fifteen policies were signed and dated by the Laboratory Director prior to implementation. Findings include: 1. The policy "PROCEDURE MANUAL" stated "Each policy and procedure will be reviewed by the Laboratory Director before being put into place. Once the Laboratory Director reviews the policy, the policy may be enacted. The date the policy becomes active will be documented in the header of the policy under "Policy Date". The Laboratory Director will sign and date the bottom of the procedure once it has been approved." 2. The following fifteen procedures were not signed and dated by Facility A Laboratory Director/Technical Supervisor #1 prior to the policy date: -RES-1 PROCEDURE MANUAL Policy Date: 4/2/18, Signed Date: 4/20/18 -RES-2 LABORATORY DIRECTOR RESPONSIBILITIES Policy Date: 4/2/18, Signed Date: 4/20/18 -RES-3 MICROSCOPIC EXAMINATION OF ANATOMIC PATHOLOGY SPECIMENS Policy Date: 5/29/18, Signed Date: 6/25/18 -RES-4 QUALITY PROGRAM Policy Date: 5/29/18, Signed Date: 6/25/18 -RES-5 SPECIMEN ACCEPTABILITY Policy Date: 4/2/18, Signed Date: 4/20/18 -RES-6 RANDOM CASE REVIEW Policy Date: 5/29/18, Signed Date: 6/25/18 -RES-7 PATHOLOGISTS' COMPETENCY ASSESSMENTS Policy Date: 5/29/18, Signed Date: 6/23/18 -RES-8 TECHNICAL SUPERVISOR/GENERAL SUPERVISOR Policy Date: 5/29/18, Signed Date: 6/28/18 -RES-9 PROFICIENCY TESTING AND TRAINING RECORDS Policy Date: 4/2/18, Signed Date: 6/3/18 -RES-10 CYTOLOGICAL EXAMINATIONS Policy Date: 5/29/18, Signed Date: 6/23/18 -RES-11 RETROSPECTIVE RESCREEN PROCESS Policy Date: 4/2/18, Signed Date: 6/3/18 -RES-12 CASE CORRELATIONS Policy Date: 3/22/18, Signed Date: 4/20/18 -RES-13 GYNECOLOGIC CASE STATISTICAL DATA Policy Date: 5/29/18, Signed Date: 6/28/18 -RES-14 AMENDING REPORTS FOR (FACILITY B) CASES Policy Date: 5/26/18, Signed Date: 6/3/18 -RES-15 LABORATORY SAFETY Policy Date: 5/26/18, Signed Date 6/3/18 3. These findings were confirmed by Facility A Laboratory Director/Technical Supervisor #1 and the Clinical Pathology Support Manager during an interview on 7/18/18 at 2:00 PM.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). 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 identify and document the date of discontinuance on seven of fifteen procedures. Findings include: 1. The Survey Team identified seven policies in the Facility A procedure manual that had copies with the same title but different policy dates. -RES-3 MICROSCOPIC EXAMINATION OF ANATOMIC PATHOLOGY SPECIMENS (Policy Dates: 5/25/18 and 5/29/18) -RES-4 QUALITY PROGRAM (Policy Dates: 3/2/18 and 5/29/18) -RES-6 RANDOM CASE REVIEW (Policy Dates: 4/2/18 and 5/29/18) -RES-7 PATHOLOGISTS' COMPETENCY ASSESSMENTS (Policy Dates: 2/1/18 and 5/29/18) -RES-8 TECHNICAL SUPERVISOR/GENERAL SUPERVISOR (Policy Dates: 4/2/18 and 5/29/18) -RES-10 CYTOLOGICAL EXAMINATIONS (Policy Dates: 2/26/18 and 5/29/18) -RES-13 GYNECOLOGIC CASE STATISTICAL DATA (Policy Dates: 4/2/18 and 5/29/18) 2. During an interview on 7/18/18 at 2:00 PM, the Facility A Laboratory Director/Technical Supervisor #1 and the Clinical Pathology Support Manager

	confirmed that the policies with the earlier dates were outdated and should have been discontinued.
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 Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records for the Hologic ThinPrep Pap Test and interview it was determined that the Facility A laboratory failed to ensure that one of three 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 Facility A failed to provide morphology training records for one of three Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. There were no training records for Technical Supervisor #3. 2. These findings were confirmed by the Facility B Cytology Manager during an interview on 7/19/18 at 8:27 AM.
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, lack of laboratory records, and interviews it was determined that the Facility A laboratory failed to follow a policy for a program to compare the cytology diagnosis and the histopathology diagnosis to determine the causes of any discrepancies. Findings include: 1. The policy "CASE CORRELATIONS" stated "The results of the abnormal GYN case will be correlated with results obtained by biopsy in the histopathology report. A monthly report is produced that includes the number of cases evaluated and the percent of the cases that correlate with the Cytology diagnosis. (Facility A) follows the policies set forth by (Facility B). AUS250690SOP is the reference for this policy." The policy further

	stated "1. (Facility B) cytology staff generate a monthly correlation cytology report that identifies all in-house biopsy and previous abnormal cytology cases report by (Facility A). 2. (Facility B) Technical Supervisor reviews the data from the Cyto/Histo correlation log and orders the cytology and biopsy cases that require further review. Although there may be exceptions, the general guidelines for assigning a discrepancy classification (Code) are: Slides are reviewed from cases with codes A + C or A + D or any QA code. 3. (Facility B) Technical Supervisor will review the cases that were designated for further review and document the type of discrepancy on the log. 4. (Facility B) Technical Supervisor will generate the correlation report. 5. Cases with major discrepancies are returned to the original Cytotechnologist/Pathologist for review. 6. Amended reports and/or calls to the physician are only done when patient care would be affected and at the request of the Technical Supervisor. 7. All necessary information is recorded on the correlation report. The report and slides will be sent to the original pathologist. The reports and forms are maintained at (Facility B)." 2. The Survey Team requested, and Facility A laboratory failed to provide, cytology and histology correlation reports for the cases examined at Facility A for 2016, 2017 and to the date of the survey in 2018. 3. During an interview with the Clinical Pathology Support Manager on 7/16/18 at 11:47 AM and 7/18/18 at 2:00 PM, the Survey Team requested the cytology and histology correlation records for 2016, 2017 and to the date of the survey in 2018. These records were also requested during an interview with the Facility B Cytology Manager on 7/18/18 at 8:50 AM. a. On 7/17/18 at 2:17 PM, Facility A Laboratory Director/Technical Supervisor #1 stated that correlation information was received from Facility B for review but correlation records were not kept at Facility A. 4. These findings were confirmed by Facility A Laboratory Director /Technical Supervisor #1, Facility B Cytology Manager and the Clinical Pathology Support Manager during an interview on 7/19/18 at 11:27 AM.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, lack of retrospective review records, and interviews it was determined that Facility A failed to follow a policy for a program to search for prior negative gynecologic cytology slides received within the past five years for all high grade intraepithelial lesion (HSIL) and malignant cases reported by Facility A and to review the prior negative slides. Findings include: 1. The policy "RETROSPECTIVE RESCREEN PROCESS" stated "(Facility A) follows the policies set forth by (Facility B). All gynecologic smears interpreted as High Grade Intraepithelial Lesion (HGSIL), Adenocarcinoma in Situ (AIS), Squamous Carcinoma or Adenocarcinoma will have all prior negative cases within the past five years reviewed." 2. The Survey Team requested, and Facility A laboratory failed to provide, all the 5-year retrospective review records for cases reported at Facility A for 2016, 2017 and to the date of the

survey in 2018. a. On 7/17/18 at 8:30 AM, Facility B Cytology Manager provided the Survey Team a computer-generated "Cyto5YearRetroRescreen Log" for October 2017. When asked if this document was specific to the cases reported at Facility A, Facility B Cytology Manager stated it was not specific to Facility A and that the log included only one High Grade Squamous Intraepithelial Lesion (HSIL) case reported at Facility A. 3. On 7/18/18 at 8:50 AM, Facility B Cytology Manager provided the Survey Team three computer-generated lists titled "CytoPathologistCases" that contained the accession numbers of all the HSIL and malignant cases reported by Facility A for 2016, 2017 and 2018. a. There was no documentation of the search for prior negative cases for 26 of 26 HSIL and malignant cases reported by Facility A from 1/1/18 to 6/30/18. 2018 Cases Include: - ZJ374299 - ZJ471265 - ZJ476501 - ZJ661994 - ZJ857849 - ZJ953381 - ZK009552 - ZK014033 - ZK326489 - ZK580171 - ZK687598 - ZK688227 - ZK656377 - ZK809841 - ZK920236 - ZK964455 - ZK981705 - ZL002300 - ZJ256240 - ZJ561095 - ZJ677564 - ZJ643047 - ZJ723228 - ZK104382 - ZJ871347 - ZK298938 b. There was no documentation of the search for prior negative cases for 81 of of 89 HSIL and malignant cases in 2017. 2017 Cases Include: - YY343603 - YY402320 - YY611974 - YY641150 - YY747112 - YY796458 - YY960788 - YY971601 - YZ029644 - YZ047132 - YZ207942 - YZ236819 - YZ476815 - YZ573185 - YZ573981 - YZ664600 - YZ666435 - YZ749073 - YZ951690 - ZF452608 - ZF755212 - ZG046046 - ZG304614 - ZG800873 - ZG857437 - ZG983432 - ZH188963 - ZH267163 - ZH735891 - ZH789669 - ZJ002195 - ZJ003577 - ZJ005141 - YY513721 - YY513703 - YY683347 - YY891054 - YZ139861 - YZ216674 - YZ427786 - Y2034241 - Y2080987 - ZF360284 - ZF486553 - ZF528706 - ZF536511 - ZF572428 - ZF626494 - ZF726220 - ZF729642 - ZF906228 - ZF917099 - ZG196615 - ZG415551 - ZG444811 - ZG436005 - ZG525339 - ZG774085 - ZG771323 - ZG815179 - ZG825139 - ZG832803 - ZG708858 - ZH073160 - ZH078068 - ZH082801 - ZH295408 - ZH386324 - ZH575205 - ZH577676 - ZH577792 - ZH583207 - ZH668251 - ZH727488 - ZH753737 - ZH733387 - ZH877242 - ZH899992 - ZH908581 - ZH976410 - YZ237173 c. There was no documentation of the search for prior negative cases for 114 of 114 HSIL and malignant cases in 2016. 2016 Cases Include: - YT312044 - YT381981 - YT803525 - YT804649 - YT891519 - YU093467 - YU586808 - YU835556 - YU969040 - YV022170 - YV054478 - YV134793 - YV203433 - YV196910 - YV261633 - YV664056 - YV574736 - YV572052 - YV579133 - YV817146 - YV835378 - YV935874 - YV933600 - YV972582 - YW177137 - YW206963 - YW352676 - YW519082 - YW550233 - YW656715 - YW879775 - YW934812 - YX009801 - YX046387 - YX152218 - YX177244 - YX193749 - YX221871 - YX235526 - YX389971 - YX412219 - YX412282 - YX551769 - YX585598 - YX656967 - YX853797 - YX955465 - YY123065 - YT803712 - YS789248 - YS789945 - YS923229 - YS838173 - YS949771 - YS979289 - YS984064 - YT177610 - YR420883 - YT217761 - YT341028 - YT386128 - YT562001 - YT599083 - YT685950 - YT940838 - YT950128 - YU073876 - YU081626 - YU101424 - YU103840 - YU197078 - YU309094 - YU409563 - YU424560 - YU466229 - YU608871 - YU622403 - YU862910 - YV082356 - YU019989 - YV152746 - YV149482 - YV200469 - YV254129 - YV285251 - YV410297 - YV433513 - YV477204 - YV477222 - YV614958 - YV820615 - YV845258 - YV923926 - YV974578 - YW284960 - YW274195 - YW546830 - YW543847 - YW906569 - YW916707 - YX521840 - YX523639 - YX614251 - YX664118 - YX669366 - YX703726 - YX818528 - YX883384 - YY161502 - YY156235 - YY156315 - YW009982 - YX202973 - YX346599 4. On 7/18/18 at 12:15 PM, the Survey Team received a computer-generated "Cyto5YearRetroRescreenLogTest" for "Reporting Period: 01/01/2017 - 08/31/2017" that included the 5-year retrospective review documentation for seven cases reported

	as HSIL at Facility A. a. During an interview with Facility B Cytology Manager on 7 /19/18 at 8:27 AM, the Survey Team asked why there were only seven HSIL cases on the 5-year Retrospective Log, as the computer-generated 2017 "CytoPathologistCases" report showed that there were a total of 89 HSIL and malignant cases reported by Facility A. b. The Facility B Cytology Manager stated that the seven HSIL cases were the only ones that had prior negative gynecologic slides for review and confirmed that there was no documentation of the search for prior negatives slides if there were none.
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 and interview it was determined that the Facility A laboratory failed to to provide documentation for two of six statistics in 2016 and 2017. Findings include: 1. The policy "GYNECOLOGIC CASE STATISTICAL DATA" was not being followed. The policy stated "(Facility B) retains all statistical data for each testing location. Reference (Facility B SOP AUS250575SOP. #1. (Facility B) Cytology pulls statistical information by location on an annual basis. 2. The data sets include the following information: d. Number of HSIL, adenocarcinoma, or other malignancy cases for which histology results were available for comparison, e. Number of cases where cytology and histology were discrepant." 2. The Survey Team requested, and Facility A failed to provide, documentation that the required annual statistics had been compiled and evaluated in 2016 and 2017 for two of six required statistics: - Gynecologic cases where cytology and histology are discrepant; - Gynecologic cases with a diagnosis of High Grade Squamous Intraepithelial Lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison. 3. These findings were confirmed by Facility A Laboratory Director/Technical Supervisor #1, Facility B Cytology Manager, and Clinical Pathology Support Manager during an interview on 7 /19/18 at 11:27 AM.
D5667	CYTOLOGY CFR(s): 493.1274(h) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and interviews it was determined that the Facility A laboratory failed to maintain records to compare the cytology diagnosis and the histopathology diagnosis to determine the causes of any discrepancies and to search for prior negative gynecologic cytology slides for all high grade intraepithelial lesion (HSIL) and malignant cases reported by Facility A. Cross refer to D5623 and D5625
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, lack of quality assessment records, review of laboratory records, and interview it was determined that the laboratory failed to ensure that documentation was maintained for all analytic systems assessment activities performed in 2016, 2017 and to the date of the survey in 2018. Cross Refer to D5625 and D5667 Findings include: 1. The policy "QUALITY PROGRAM" (under "Quality Assessment of Microscopic Examination") stated "In addition, random retrospective case reviews in gynecologic cytopathology are performed (Pap smear RR; See (Facility B) SOP AUS251475SOP Gynecologic Cytology Competency Assessment for Pathologists)." 2. The policy "PATHOLOGISTS' COMPETENCY ASSESSMENTS" stated "On a quarterly basis (Facility B) will provide a report to the (Executive Office) Scheduling and Credentialing detailing results of (Facility B)-based quality metrics: 2. Random retrospective case review in gynecologic cytopathology (Pap smear RR; See (Facility B) SOP AUS251475SOP Gynecologic Cytology Competency Assessment for Pathologists)." 3. The Survey Team requested, and Facility A laboratory failed to provide, records to monitor the performance of three of three Technical Supervisor's for 2016, 2017 and to the date of the survey in 2018. a. On 7/17/18 at 2:03 PM, the Clinical Pathology Support Manager confirmed that there were no records available for 2016 and 2017 to monitor the Technical Supervisors' performance. b. On 7/17/18 at 2:03 PM, the Clinical Pathology Support Manager provided the "Path Cumulative Summary" and monthly "Pathologist Summary Report" for the three Technical Supervisors examining slides at Facility A for January through April 2018. The Clinical Pathology Support Manager stated that these records were "new", having been created since May, and this was the first time they were being used to assess the Technical Supervisors' performance and competency. i. The records did not provide any comparative data between the initial diagnoses provided by Facility B and the final diagnoses reported by Facility A. ii. The records were not signed by Facility A Laboratory Director/Technical Supervisor #1. iii. The records were reviewed with Facility A Laboratory Director/Technical Supervisor #1 during an interview on 7/19 /18 at 11:27 AM. The Facility A Laboratory Director/Technical Supervisor #1 had not seen these records prior to the interview.
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, review of laboratory records, lack of laboratory records, and interviews it was determined that the Facility A laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Facility A 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); failed to ensure that one of three Technical Supervisors had received appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test (refer to D6102); and failed to ensure the competency of three of three Technical Supervisors who reported cytology test results (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, lack of laboratory records, and interviews it was determined that the Facility A Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5311, D5407, and D5409.
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 Facility A 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 D5393 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 Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records, and interview it was determined that the Facility A Laboratory Director failed to ensure appropriate training according to the manufacturer's instructions. One of three Technical Supervisors had not received the appropriate training to evaluate the ThinPrep Pap Test. Cross Refer to D5411
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records, and interview it was determined that the Facility A Laboratory Director failed to ensure the competency of three of three Technical Supervisors for 2016, 2017 and to the date of the survey in 2018. Cross Refer to D5209
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the review of specimen slides and their corresponding test reports it was determined that the Technical Supervisor failed to verify the accuracy of five

	gynecologic test reports (refer to D6115). The cumulative effect of this practice resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of 424 gynecologic cytology cases (428 slides) from January 2018 to March 2018 and May 2018 and confirmation by the Survey Team Pathologist on 7/19 /18 it was determined that the Technical Supervisor failed to verify the accuracy of five (5) gynecologic cytology tests. Findings include: 1. ZJ342670 1/9/18 SurePath Pap Test (SPPT) FACILITY A LABORATORY DIAGNOSIS: Atypical Squamous Cell of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 2. ZJ705364 2/7/18 Imaged ThinPrep Pap Test (I-TPPT) FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or malignancy. Reactive cellular changes present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 3. ZJ730993 2/9/18 ThinPrep Pap Test (TPPT) FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. Reactive cellular changes present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 4. ZK911077 5/3/18 SPPT FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy. Reactive cellular changes present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells of Undetermined Significance 5. ZL021145 5/8/18 TPPT FACILITY A LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance. Herpes present.
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.