

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D2082399	<b>(X3) Date Survey Completed</b>  04/11/2019
<b>Name of Provider or Supplier</b>  Colorado Springs Pathology Associates, Pc	<b>Street Address, City, State</b>  2838 Janitell Road, Colorado Springs, CO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5032</b>	<p>CYTOLOGY CFR(s): 493.1221</p> <p>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.</p> <p>This CONDITION 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 failed to follow the manufacturer's instructions for evaluating Hologic ThinPrep Pap Test specimens (refer to D5411); failed to test staining materials for intended reactivity to ensure predictable staining characteristics (refer to D5473); failed to establish policies and procedures to prevent cross-contamination during staining of nongynecologic specimens that have a high potential for cross-contamination (refer to D5619); failed to establish policies and procedures for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis (refer to D5623); failed to establish policies and procedures for the review of negative gynecologic specimens for each patient with a current high-grade squamous intraepithelial lesion (HSIL) or malignancy (refer to D5625); failed to establish policies and procedures for the annual evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics (refer to D5629); failed to establish policies and procedures to assess and reassess workload limits (refer to D5633 and D5637); failed to establish policies and procedures to ensure workload limits for two of two Technical Supervisors, when examining slides in less than an 8-hour workday, would be prorated (refer to D5641); failed to establish policies and procedures to ensure the laboratory maintained records of the number of slides examined and the number of hours spent examining slides in each 24-hour period (refer to D5645); failed to establish policies and procedures to ensure that unsatisfactory gynecologic and nongynecologic slide preparations were identified and</p>

reported as unsatisfactory (refer to D5655); failed to establish policies and procedures to ensure gynecologic and nongynecologic cytology test reports contained narrative descriptive nomenclature (refer to D5657); and failed to maintain the identity of the personnel who performed the required daily maintenance (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.

**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 thirty laboratory policies and procedures, interviews and review of laboratory documents it was determined that the laboratory failed to establish written policies and procedures for two laboratory processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedure to detail how the testing for intended reactivity of the Papanicolaou stains would be performed and documented. 2. The Survey Team requested and the laboratory failed to provide a written procedure to detail how the testing for intended reactivity of the Diff-Quick stains would be performed and documented. 3. During an interview on April 10, 2019 at 1:10 PM, Technical Supervisor B 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 HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, lack of laboratory records and interview it was determined that the

laboratory failed to ensure two 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 HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states "the evaluation of microscopic slides produced with the THINPREP 2000 System should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by CYTYC Corporation or by organizations or individuals designated by CYTYC Corporation." 2. The Survey Team requested and the laboratory failed to provide training records for two of two Technical Supervisors that performed diagnostic interpretations on Hologic ThinPrep Pap Tests from January 2016 to the date of the survey. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B 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 interviews it was determined that the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics for two of two stain processes, each day of use in 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide Diff-Quick stain assessment records. a. The laboratory failed to document the staining characteristics of one of one Diff-Quick stain process from January 2018 to the date of the survey on the "Daily Staining Quality Log." 2. The Survey Team requested and the laboratory failed to provide Papanicolaou stain assessment records. a. The laboratory failed to document the staining characteristics of one of one Papanicolaou stain process from January 2018 to the date of the survey on the "Daily Staining Quality Log." 3. During an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B confirmed these findings. 4. During an interview on April 10, 2019 at 12:30 PM, the Histotechnologist 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, observation and interview it was determined that the laboratory failed to establish 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 Survey Team requested and the laboratory failed to provide written policies and procedures to prevent cross-contamination of nongynecologic specimens that have a high potential for cross-contamination with other nongynecologic specimens during the Papanicolaou staining process. 2. The Survey Team observed the Histotechnologist perform nongynecologic specimen staining on April 10, 2019 at 12:15 PM. a. The Survey Team interviewed the Histotechnologist and asked if the stains were filtered or changed following staining of nongynecologic specimen slides. The Histotechnologist replied, "no." b. The Histotechnologist confirmed there was no process to identify nongynecologic specimens with a high potential for cross-contamination, and stain them separately from other nongynecologic specimens.

**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, final test reports and interviews it was determined that the laboratory failed to establish written policies and procedures to compare clinical information with the cytology reports and to compare gynecologic cytology with a diagnosis of HSIL or malignancy, with available histopathology reports. The laboratory failed to compare eight of eight gynecologic cytology reports from January 2017 to the date of the survey with clinical information and histopathology reports, to determine the causes of any discrepancies. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to compare clinical information with cytology reports and to compare HSIL or malignant gynecologic cytology cases with available histopathology reports. a. The laboratory failed to establish written procedures to describe what constituted a discrepancy between a cytology diagnosis and the correlating histology report and how the causes of discrepancies would be determined and documented. 2. The Survey Team requested and the laboratory failed to provide documentation of comparative reviews between clinical information and the cytology report and documentation of comparative reviews between HSIL and malignant gynecologic cytology cases with available histopathology reports to determine the causes of any discrepancies. 3. The Survey Team reviewed laboratory records titled HIGH GRADE SQUAMOUS LESION QUERY RESULTS and HSIL QUERY RESULTS, which were printed by Technical Supervisor B during the course of the survey. Eight of eight cytology cases with available histopathology or clinical information were not documented as being reviewed as part of a comparative review program. Cases include: -S17-119 -S17-1528 -S17-3033 -S17-3210 -S17-3964 -S18-1218 -S18-2412 -S18-2683 a. One of eight cases was not documented as being discrepant and a reason was not provided for the discrepancy. Case includes: -S17-1528 4. During interviews on April 9, 2019 at 1:40 PM and April 10, 2019 at 8:40 AM, Technical Supervisor B 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 and interviews it was determined that the laboratory failed to establish written policies and procedures for the search and review of negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy. The laboratory additionally failed to document the search for prior negatives on 14 of 14 current HSIL cases. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the search and review of all negative gynecologic specimens received within the previous 5 years, for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm reported by the laboratory. 2. The Survey Team requested and the laboratory failed to provide documentation of the search for prior negatives on 14 of 14 current HSIL cases from January 2017 to the date of the survey. HSIL cases include: -S17-169 -S17-347 -S17-557 -S17-1427 -S17-1528 -S17-1737 -S17-1867 -S17-2278 -S17-2650 -S17-2785 -S17-2907 -S17-3125 -S17-3210 -S18-2412 3. During interviews on April 9, 2019 at 1:40 PM and April 10, 2019 at 1:10 PM, Technical Supervisor B 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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics for 2017 and 2018. Findings

include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of six of six laboratory statistics. 2. The Survey Team requested and the laboratory failed to provide documentation of the laboratory's evaluation of six of six required annual statistics. 3. During an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B stated that "a query could be run for some statistics" and confirmed there were no annual statistics compiled for the laboratory.

**D5633**

**CYTOLOGY**  
CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:  
Based on the review of 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 Technical Supervisor A for two of two Technical Supervisors in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that maximum workload limits were established by Technical Supervisor A for two of two Technical Supervisors that performed the primary evaluation of nongynecologic cytology specimens. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B 2. The Survey Team requested and the laboratory failed to provide documentation of an established maximum workload limit for the two Technical Supervisors in 2017, 2018 and to the date of the survey in 2019. 3. During an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B confirmed that there were no procedures or records for assigned workload limits.

**D5637**

**CYTOLOGY**  
CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:  
Based on the review of 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 the workload limit for two of two Technical Supervisors was reassessed at least every six months and adjusted when necessary in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that maximum workload limits for two of two Technical Supervisors were reassessed at least every six months and adjusted when necessary in 2017, 2018 and to the date of the survey in 2019. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B 2. The Survey Team requested and the laboratory failed to provide documentation of workload limit reassessments every six months for the two Technical Supervisors for 2017, 2018 and to the date of the survey in 2019. 3. During

an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B confirmed that there were no procedures or records to reassess workload limits.

**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, lack of laboratory records 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 and with duties other than slide examination, would be prorated using a period of eight hours to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to determine how to prorate the workload limit for the two Technical Supervisors when time was spent on activities other than performing primary examinations of cytology slides. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for the two of two Technical Supervisors in 2017, 2018 and to the date of the survey in 2019. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B 3. During an interview on April 10, 2019 at 1: 10 PM, Technical Supervisor B 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, lack of laboratory records and interview it was determined that the laboratory failed to establish policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and the number of hours spent examining slides in each 24-hour period for two of two Technical Supervisors in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained workload records to document the number of slides examined and the time spent examining slides for two of two Technical Supervisors. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B 2. The Survey Team requested and the laboratory failed to provide workload records to document the

	<p>number of slides examined and the time spent examining slides for the two Technical Supervisors who performed the primary examination of nongynecologic slides in 2017, 2018 and to the date of the survey in 2019. 3. During an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B confirmed that there were no workload records for the two Technical Supervisors.</p>
<p><b>D5655</b></p>	<p><b>CYTOLOGY</b> CFR(s): 493.1274(e)(4)</p> <p>(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.</p> <p>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 unsatisfactory gynecologic and nongynecologic slide preparations were identified and reported as unsatisfactory. Findings include: 1. The laboratory failed to establish written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The laboratory failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 3. During an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B confirmed these findings.</p>
<p><b>D5657</b></p>	<p><b>CYTOLOGY</b> CFR(s): 493.1274(e)(5)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, final test reports and interview it was determined that the laboratory failed to establish written policies and procedures to ensure gynecologic and nongynecologic cytology test reports contained narrative descriptive nomenclature. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's nomenclature system for reporting gynecologic cytology test results. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's nomenclature system for reporting nongynecologic cytology test results. 3. During an interview on April 9, 2019 at 1:40 PM, Technical Supervisor B confirmed these findings.</p>
<p><b>D5787</b></p>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(a)</p> <p>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)</p>

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 the Papanicolaou stain maintenance on 16 of 16 days from January 2019 to the date of the survey. The laboratory failed to maintain the identity of the personnel who performed the "Diff-Quick" stain maintenance on 69 of 69 days from January 2019 to the date of the survey. Findings include: 1. The Survey Team reviewed records titled PAP STAIN ROTATION LOG from January 2019 to the date of the survey. There was no documentation to indicate the identity of the personnel performing the stain maintenance on 16 of 16 days. 2019 Dates include: -January 4, 14, 15, 22 -February 5, 6, 8, 12 -March 6, 9, 14, 20, 29 -April 1, 3, 5 2. The Survey Team reviewed records titled DIFF QUICK/MODIFIED GIEMSA ROTATION LOG from January 2019 to the date of the survey. There was no documentation to indicate the identity of the personnel performing the stain maintenance on 69 of 69 days. 2019 Dates include: - January 2, 3, 4, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28, 29, 30, 31 - February 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 22, 25, 26, 27, 28 -March 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 22, 25, 26, 27, 28 -April 1, 2, 3, 4, 5, 8, 9 3. During an interview on April 10, 2019 at 12:30 PM, the Histotechnologist 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, review of laboratory records, observation and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of cytology testing. Cross refer to D5403, D5411, D5473, D5619, D5623, D5625, D5629, D5633, D5637, D5641, D5645, D5655, D5657, D5787

**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, laboratory records 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 in the

	<p>postanalytic phases of cytology testing. 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 correct problems identified in the post analytic phases of testing. 2. During an interview on April 10, 2019 at 1:10 PM, Technical Supervisor B confirmed these findings.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION 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 have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure quality assessment programs were established (refer to D6094) and failed to ensure that prior to testing patients' specimens, Technical Supervisor's had the appropriate training for ThinPrep Pap Tests. 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.</p>
<p><b>D6079</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5403, D5411, D5473, D5645, D5655, D5657, D5787</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p>

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 D5791 and D5891

**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 laboratory records and interview, it was determined that the Laboratory Director failed to ensure that two of two Technical Supervisors that performed Hologic ThinPrep Pap Test evaluations during 2017, 2018, and to the date of the survey in 2019, had received the appropriate morphology training and certification. Cross refer to D5411

**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 18 consecutive negative gynecologic cases/slides from January 2017 through March 2019 and confirmation by Technical Supervisor B on April 11, 2019, it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. S17-02573 08/23/2017 ThinPrep Pap Test  
LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM  
DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL  
SUPERVISOR B DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion

**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.

	<p>This STANDARD is not met as evidenced by:  Based on review of laboratory procedures, lack of 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 2017, 2018 and to the date of the survey in 2019. Cross refer to D5633 and D5637</p>
<p><b>D6133</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(c)(6)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  Based on review of laboratory procedures, lack of laboratory records and interview, it was determined that two of two Technical Supervisors failed to document the number slides evaluated and the number of hours spent examining slides during each 24-hour period in 2017, 2018 and to the date of the survey in 2019. Cross refer to D5645</p>
<p><b>D9999</b></p>	<p>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.</p>