

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2042078	(X3) Date Survey Completed 04/17/2019
Name of Provider or Supplier Cunningham Pathology	Street Address, City, State 2010 Brookwood Medical Center Drive, Birmingham, AL	
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	<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 policies and procedures, record review and interviews, it was determined that the laboratory failed to establish written policies and procedures for the comparison of gynecologic cytology reports to histopathology reports to determine the causes of discrepancies (refer to D5623); failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years from patients with a current high grade lesion (refer to D5625); failed to establish written policies and procedures for the evaluation and comparison of six of six annual laboratory statistics and failed to document two of six required annual statistics (refer to D5629); failed to establish written policies and procedures to ensure that unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report (refer to D5659). 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.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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</p>

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 records and interviews it was determined that the laboratory failed to ensure that nine of nine Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test, according to the manufacturer's instructions. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, CYTYC Part Number 70354-001, states "the evaluation of microscopic slides produced with the THINPREP 2000 System should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by CYTYC Corporation or by organizations or individuals designated by CYTYC Corporation." a. The Survey Team requested and the laboratory failed to provide the training records for nine of nine Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H -Technical Supervisor I 2. During an interview on 04/16/2019 at 12:15 PM with the Operations Manager and at 1:00 PM with the Cytology Supervisor, when asked if the ThinPrep morphology training records existed, both stated that the training records for the nine Technical Supervisors could not be located. 3. During an interview on 04/17/2019 at 11:30 AM, the Laboratory Manager confirmed that the Hologic morphology training records for the Technical Supervisors were not available.

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 and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the cytology diagnosis and the histopathology diagnosis were compared to determine the causes of any discrepancies. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. 2. These findings were confirmed by the Laboratory Director/Technical Supervisor A during an interview on 04/16/2019 at 4:15 PM and by the Laboratory Manager and the Cytology Supervisor during an interview on 04/17/2019 at 11:30 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 and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current High Grade Lesion (HSIL) or Malignancy was performed. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or Malignancy. 2. These findings were confirmed by the Laboratory Director/Technical Supervisor A during an interview on 04/16/2019 at 4:15 PM and the Laboratory Manager and the Cytology Supervisor on 04/17/2019 at 11:30 AM.

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 the evaluation and comparison of six of six laboratory statistics and failed to document two 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 to describe the laboratory's process for an annual statistical evaluation of six of six required annual statistics. 2. The Survey Team requested, and the laboratory failed to provide records of two of six required annual statistics for 2017 and 2018. - Gynecologic cases where cytology and histology are discrepant; and - Gynecologic cases where any rescreen of a normal or negative specimen results in

	<p>reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. 3. These findings were confirmed by the Laboratory Director/Technical Supervisor A during an interview on 04/16/2019 at 4:15 PM and by the Laboratory Manager and the Cytology Supervisor during an interview on 04/17/2019 at 11:30 AM.</p>
<p>D5655</p>	<p>CYTOLOGY 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 interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. These findings were confirmed by the Laboratory Director/Technical Supervisor A during an interview on 04/16/2019 at 4:15 PM and the Laboratory Manager and the Cytology Supervisor on 04/17/2019 at 11:30 AM.</p>
<p>D5659</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(6)</p> <p>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.</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 corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to ensure that corrected reports indicated the basis for the correction. 2. These findings were confirmed by the Laboratory Director/Technical Supervisor A during an interview on 04/16/2019 at 4:15 PM and by the Laboratory Manager and the Cytology Supervisor during an interview on 04/17/2019 at 11:30 AM.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p>

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 provide a written policy or procedure to describe the laboratory's cytology quality assessment program in gynecologic and non-gynecologic cytology. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to describe the laboratory's cytology quality assessment program in gynecologic and non-gynecologic cytology. 2. These findings were confirmed by the Laboratory Director/Technical Supervisor A during an interview on 04/16/2019 at 4:15 PM and by the Laboratory Manager and the Cytology Supervisor during an interview on 04/17/2019 at 11:30 AM.

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, record review 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 that quality assessment programs were established to assure the quality of laboratory services (refer to D6094) and failed to ensure appropriate training according to the manufacturer's instructions for nine Technical Supervisors (refer to D6102). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on review of 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

	<p>Laboratory Director were performed. Cross refer to D5623, D5625, D5629, D5655 and D5659</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures 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. Cross refer to and D5791</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, lack of records and interviews it was determined that the Laboratory Director failed to ensure appropriate training according to the manufacturer's instructions. Nine of nine Technical Supervisors had not received the appropriate training to evaluate the Hologic ThinPrep Pap Test. Cross Refer to D5411</p>
D9999	<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>