

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0645798	<b>(X3) Date Survey Completed</b>  03/11/2020
<b>Name of Provider or Supplier</b>  Etowah Pathology Associates, Llc	<b>Street Address, City, State</b>  833 Campbell Hill Street, Suite 111, Marietta, GA	
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, glass slide preparations, observation and interviews it was determined that the laboratory failed to follow written policies and procedures for specimen processing (refer to D5311); failed to ensure that written policies and procedures were approved, signed and dated by the Laboratory Director (refer to D5407); failed to maintain the dates of initial use on written policies and procedures (refer to D5409); failed to establish written policies and procedures to identify nongynecologic specimens with a high potential for cross-contamination (refer to D5619); failed to establish written policies and procedures to prorate the workload limit when examining slides in less than an 8-hour work day (refer to D5641); and failed to establish written policies and procedures to ensure that reports contain narrative descriptive nomenclature (refer to D5657). 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>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

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 follow written policies and procedures to assess the competency of one of two Technical Supervisors in 2019. Findings include: 1. The Survey Team reviewed the procedure ANATOMICAL PATHOLOGY QUALITY MANAGEMENT which stated "10% of cases of one month will be reviewed by a pathologist other than the one who initially signed out the case. This review will be performed every six month." 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for the Laboratory Director/Technical Supervisor A for 2019. 3. During an interview on March 10, 2020 at 11:13 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A.

**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 the review of laboratory policies and procedures, review of cytology slide preparations and interviews it was determined that the laboratory failed to establish written policies and procedures for specimen processing of nongynecologic specimens using the cytocentrifugation technique when cytospin preparations were deemed to be thick for 36 of 145 cases from October 2019 to the date of the survey in 2020. Findings include: 1. The procedure CENTRIFUGE SLIDE PREPARATION THEORY did not provide instruction for modification of the cytospin preparation technique when preparations were deemed to be thick and required an alternate smear preparation technique. 2. The Survey Team reviewed 145 nongynecologic cases from October 2019 to the date of the survey in 2020 that were documented in the gross description section of the final test reports as being Cytospin preparations. The Survey Team observed that 36 of 145 cases were prepared with an alternate smear preparation technique. Cases include: -MC19-193 -MC19-195 -MC19-202 -MC19-205 -MC19-208 -MC19-209 -MC19-211 -MC19-212 -MC19-215 -MC19-218 -MC20-4 -MC20-5 -MC20-6 -MC20-7 -MC20-8 -MC20-9 -MC20-10 -MC20-11 -MC20-12 -MC20-13 -MC20-14 -MC20-16 -MC20-17 -MC20-20 -MC20-21 -MC20-22 -MC20-23 -MC20-24 -MC20-25 -MC20-26 -MC20-28 -MC20-29 -MC20-31 -MC20-38 -MC20-39 -MC20-41 3. During an interview on March 10, 2020 at 2:06 PM the Laboratory Director/Technical Supervisor A stated that "Cytospin preparations are smeared out when they are too thick." 4. During an interview on March 11, 2020 at 10:05 AM these findings were confirmed by Cytopreparatory Technician A who stated that when the cytospin slides came out and the cell area was too thick, they were dipped in 95% alcohol and smeared together.

**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 17 laboratory policies and procedures and interview it was determined that the laboratory failed to ensure that 17 of 17 written policies and procedures were approved, signed and dated by the Laboratory Director prior to the initial dates of use. Findings include: 1. The Survey Team reviewed 17 procedures from the Cytology Procedure Manual. The Laboratory Director failed to approve, sign and date 17 of 17 laboratory procedures prior to the initial dates of use. Procedures include: -GUIDELINES FOR ACCEPTANCE OR REJECTION OF CYTOLOGY SPECIMENS -SPECIMEN COLLECTION AND SUBMISSION POLICY - QUALITY CONTROL/QUALITY ASSURANCE -GASTRIC & ESOPHAGEAL SLIDE AND FLUID PREPARATION PROCEDURE -PROCEDURE FOR NON-GYN SPECIMENS RECEIVED AFTER HOURS -ACCESSIONING PROCEDURE -NON-GYN CYTOLOGY STAINING PROCEDURE -DAILY EXAMINING CYTOLOGY SLIDES LOG PROCEDURE -STATISTICAL EVALUATION POLICY -WORKLOAD LIMITS -CENTRIFUGE SLIDE PREPARATION THEORY -CELL BLOCK/SMEAR PROCEDURE FOR NON-GYN PROCEDURE - SUPERFICIAL FINE NEEDLE ASPIRATION -MICROSCOPIC EVALUATION AND REPORTING PROCEDURE -CONFIDENTIALITY AND PRIVACY OF INFORMATION -CYTOLOGY INSTRUMENTS MAINTENANCE - MICROSCOPE PREVENTIVE MAINTENANCE (PM) 2. During an interview on March 10, 2020 at 11:13 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A.

**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 17 laboratory policies and procedures and interview it was determined that the laboratory failed to maintain the date of initial use for 17 of 17 written policies and procedures. Findings include: 1. The laboratory failed to maintain the initial date of use for 17 of 17 procedures. Procedures include: -GUIDELINES FOR ACCEPTANCE OR REJECTION OF CYTOLOGY SPECIMENS -SPECIMEN COLLECTION AND SUBMISSION POLICY -QUALITY CONTROL/QUALITY ASSURANCE -GASTRIC & ESOPHAGEAL SLIDE AND FLUID PREPARATION PROCEDURE -PROCEDURE FOR NON-GYN SPECIMENS RECEIVED AFTER HOURS -ACCESSIONING PROCEDURE -NON-GYN CYTOLOGY STAINING PROCEDURE -DAILY EXAMINING CYTOLOGY SLIDES LOG PROCEDURE - STATISTICAL EVALUATION POLICY -WORKLOAD LIMITS -CENTRIFUGE SLIDE PREPARATION THEORY -CELL BLOCK/SMEAR PROCEDURE FOR NON-GYN PROCEDURE -SUPERFICIAL FINE NEEDLE ASPIRATION - MICROSCOPIC EVALUATION AND REPORTING PROCEDURE - CONFIDENTIALITY AND PRIVACY OF INFORMATION -CYTOLOGY INSTRUMENTS MAINTENANCE -MICROSCOPE PREVENTIVE MAINTENANCE (PM) 2. During an interview on March 10, 2020 at 11:13 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A.

<p><b>D5619</b></p>	<p>CYTOLOGY CFR(s): 493.1274(b)(3)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, direct observation and interview it was determined that the laboratory failed to establish written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. 2. During an observation and interview on March 10, 2020 at 1:15 PM these findings were confirmed by Cytopreparatory Technician A who stated "There is no way to know if a case is malignant." 3. During an interview on March 10, 2020 at 2:30 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.</p>
<p><b>D5641</b></p>	<p>CYTOLOGY CFR(s): 493.1274(d)(2)(ii)</p> <p>(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;</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 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 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 and procedures to determine how to prorate the workload limit for two of two Technical Supervisors when time was spent on duties other than slide examination or when examining slides in less than an 8-hour workday. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 2. During an interview on March 10, 2020 at 11:13 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A.</p>
<p><b>D5657</b></p>	<p>CYTOLOGY CFR(s): 493.1274(e)(5)</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.

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 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 nongynecologic cytology test results. 2. During an interview on March 10, 2020 at 11:13 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor A. 3. During an interview on March 11, 2020 at 9:35 AM, these findings were confirmed by Technical Supervisor B.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, glass slides 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 written policies and procedures were established and followed to assess, monitor and maintain the competency of two of two Cytopreparatory Technicians and one of two Technical Supervisors (refer to D6103); and failed to ensure that an approved procedure manual was available to all personnel (refer to D6106). 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 reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	<p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, cytology slide preparations, observation 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 D5311, D5409, D5619, D5641 and D5657</p>
<p><b>D6103</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the Laboratory Director failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of two of two Cytopreparatory Technicians and failed to ensure that written policies and procedures were followed to assess, monitor, and maintain the competency of one of two Technical Supervisors. 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 two of two Cytopreparatory Technicians. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for two of two Cytopreparatory Technicians for 2018, 2019 and to the date of the survey in 2020. Cytopreparatory Technicians include: -Cytopreparatory Technician A - Cytopreparatory Technician B 3. During an interview on March 10, 2020 at 11:13 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</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 Director failed to ensure that an approved procedure manual was available to all personnel for cytology test processes. Cross refer to D5407</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</p>

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