

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311996	(X3) Date Survey Completed 04/04/2018
Name of Provider or Supplier Associated Pathologists, Llc	Street Address, City, State 990 Oak Ridge Turnpike, Oak Ridge, TN	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</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 failed to establish a maintenance protocol for one of one cytology slide preparation machines from 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the "Hologic ThinPrep 2000" cytology specimen slide preparation machine would be cleaned and maintained. 2. The survey team requested and the laboratory failed to provide maintenance records for the "Hologic ThinPrep 2000" from 2016, 2017 and to the date of the survey in 2018. 3. During an interview on 04/05/2018 at 10:05 AM, the Laboratory Director/Technical Supervisor confirmed that there were no maintenance records for the "Hologic Thin Prep 2000" machine.</p>
D5629	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(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,</p>

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 interview, it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required statistics for nongynecologic cytology specimens in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical laboratory evaluation of three required statistics for the nongynecologic specimens: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis, to include unsatisfactory. 2. During an interview on 04/03/2018 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings and stated that the laboratory had the statistics in the computer but did not have a procedure for an evaluation of the statistics.

D5631

CYTOLOGY

CFR(s): 493.1274(c)(6)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interview, it was determined that the laboratory failed to establish written policies and procedures for a program to evaluate the case reviews of the Laboratory Director /Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 against the laboratory's overall statistical values in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures for a program to evaluate the case reviews of the Laboratory Director/Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 against the laboratory's overall statistical values. 2. The Survey Team requested and the laboratory failed to provide records for comparative reviews to evaluate the case reviews of the Laboratory Director/Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 against the laboratory's overall statistical values. 3. During an interview on 04/03/2018 at 10:00 AM, the Laboratory Director /Technical Supervisor confirmed these findings.

D5641

CYTOLOGY

CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing

workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for the Laboratory Director/Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 when examining slides in less than an 8-hour workday, would be prorated using a period of eight hours to determine the number of slides that may be examined in each day for 2016, 2017 and 2018 to the date of the survey. 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 the Laboratory Director/Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 when examining slides in less than an 8-hour workday or with activities other than primary examinations of cytology slides. 2. During an interview on 04/03/2018 at 11:35 AM the Laboratory Director/Technical Supervisor 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 and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory would maintain records for the Laboratory Director /Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 of the number of hours devoted to examining slides in 2016, 2017 and 2018 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory would maintain records of the total number of hours devoted to examining slides during each 24-hour period for the Laboratory Director/Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2. 2. The Survey Team requested and the laboratory failed to provide records of the total number of hours devoted to examining slides during each 24-hour period for the Laboratory Director/Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 in 2016, 2017 and to the date of the survey in 2018. 3. During an interview on 04/03/2018 at 11:35 AM the Laboratory Director/Technical Supervisor confirmed these findings.

D6133

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(c)(6)

In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2),

if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

This STANDARD is not met as evidenced by:

Based on interview and lack of laboratory records it was determined that the Laboratory Director/Technical Supervisor, Technical Supervisor #1 and Technical Supervisor #2 failed to document the number of hours devoted to screening slides during each 24-hour period for any date in 2016, 2017 or 2018 to the date of the survey. Cross refer to D5645

D9999

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