

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1006255	<b>(X3) Date Survey Completed</b>  07/13/2021
<b>Name of Provider or Supplier</b>  Andrew L Simon Md Facs Pa	<b>Street Address, City, State</b>  459 Jack Martin Blvd Suite 3, Brick, NJ	
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>D5629</b>	<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, 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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Office Manager (OM), the laboratory failed to establish a written procedure which included number of cytology cases examined, specimens processed by type and patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) from 8/15/18 to the date of the survey. The OM confirmed on 7/13/21 at 12:30 pm the laboratory did not have the above procedure.</p>
<b>D5643</b>	<p>CYTOLOGY CFR(s): 493.1274(d)(2)(iii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over</p>

one-half or less of the total available slide may be counted as one-half slide; and (d)(2) (iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to establish workload limits for personnel reading nongynecology slides from 8/15/18 to the date of the survey. The OM confirmed on 7/13/21 at 12:30 pm that workload limits were not established.

**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 surveyor review of the Procedure Manual and interview with the Office Manager (OM), the laboratory failed to establish a procedure for maintaining records of the total number of slides reviewed in 24 hours from 8/15/18 to the date of the survey. The OM confirmed on 7/13/21 at 12:30 pm that the above mentioned procedure was not established.

**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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Office Manager (OM), the Laboratory Director failed to establish the work load limit for examining slides and to reassess the work load limit every six months on the day of the survey. The OM confirmed on 7/13/21 at 12:30 pm that work load limits were not established.