

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0857182	(X3) Date Survey Completed 12/02/2020
Name of Provider or Supplier Southwest Pathology, Inc	Street Address, City, State 8803 S 101st E Ave, Suite 360, Tulsa, OK	
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
D5209	<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> <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 assess the competency of three of three Technical Supervisors in 2018, 2019 and to the date of the survey in 2020. 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 diagnostic competency of three of three Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for three of three Technical Supervisors who performed microscopic evaluations in 2018, 2019 and to the date of the survey in 2020. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</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 written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the general laboratory systems. Cross refer to D5209 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the general laboratory system. 2. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A 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, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation of three of three annual laboratory statistics. 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 three of three required statistics: a) Cytology cases examined; b) Specimens processed by specimen type; c) Patient cases reported by diagnosis to include unsatisfactory. 2. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5655

CYTOLOGY
CFR(s): 493.1274(e)(4)

(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.

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 non-gynecologic specimens or slides were identified and reported as unsatisfactory in 2018, 2019 and 2020 to survey date. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that non-gynecologic slide preparations were identified and

reported as unsatisfactory. 2. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5659

CYTOLOGY
CFR(s): 493.1274(e)(6)

(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.

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 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 for issuing a corrected report. 2. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A 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, 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 identified during the evaluation and reporting of cytology specimens. Cross refer to D5629, D5655 and D5659 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the analytical laboratory system. 2. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

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 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 identified in the cytology postanalytic systems. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing

	<p>mechanism to assess the evaluation of cytology test results and reporting of the results. 2. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR 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 interview 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 ensure that quality assessment programs were established and maintained (refer to D6094); and failed to ensure written policies and procedures were established to assess the competency of three of three Technical Supervisors (refer to D6103). 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>D6094</p>	<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, laboratory records and interview it was determined that the Laboratory Director failed to establish written quality assessment policies and procedures for a quality assessment program to monitor, assess and correct problems identified throughout the laboratory. Cross refer to D5291, D5791 and D5891 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality assessment policies and procedures of the laboratory services during all phases of specimen evaluation and interpretation. 2. During an interview on December 2, 2020 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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>

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 written policies and procedures were established to assess, monitor and maintain the competency of Laboratory Director/Technical Supervisor A, Technical Supervisor B and Technical Supervisor C in 2018, 2019 and 2020 to survey date. Cross refer to D5209

D9999

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