

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1073160	<b>(X3) Date Survey Completed</b>  06/09/2021
<b>Name of Provider or Supplier</b>  Pathology Laboratory, Inc, The	<b>Street Address, City, State</b>  1100 Andre Street, Suite 100, New Iberia, LA	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of 25 laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure ASCUS/SIL RATIO which stated: "The ASCUS/SIL figure is a calculated ratio: the percentage, or number, of the laboratory's ASCUS and ASC-H cases divided by the percentage, or number, or SIL (LSIL, HSIL, malignant) cases. This ratio is then compared to the benchmark data collected by the CAP's Cytopathology Resource Committee as an indicate for the under- or over- interpretation of ASCUS." "The ASCUS/SIL Ratio is calculated monthly. The results are documented in the "GYN Laboratory Statistics" spreadsheet." "If any action is required (E.g. lab's ratio is outside the 5th-95th percentile range), an "ASCUS/SIL Corrective Action" form is filled out." a. The Survey Team reviewed the ASCUS/SIL Ratio for January 2019 through December 2020. The ASCUS/SIL Ratio exceeded the CAP's 95th percentile benchmark data (3.4) for 13 of 24 months. Months include: - 03/19 - 4.6 - 06/19 - 3.6 - 10/19 - 4.9 - 11/19 - 4.6 - 02/20 - 4.0 - 04/20 - 5.0 - 05/20 - 4.5 - 06/20 - 5.0 - 07/20 - 9.7 - 08/20 - 5.8 - 09/20 - 3.7 - 10/20 - 3.7 - 11/20 - 3.6 b. The Survey Team requested and the laboratory failed to provide corrective action forms for the 13 months. c. During an interview on June 8, 2021 at 8:18 AM, Staff A stated "we have the form. They just didn't do it." d. During an interview on June 9, 2021 at 11:00 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of 25 laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for the entering and reporting of cytology test results into the laboratory information system. 2. During an interview on June 7, 2021 at 3:15 PM, these findings were confirmed with Staff A. 3. During an interview on June 9, 2021 at 11:00 AM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.

**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 and interviews it was determined that the laboratory failed to establish written policies and procedures for

	<p>an annual statistical evaluation of six of six required laboratory statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six of six required statistics. 2. During an interview on June 7, 2021 at 3:15 PM, these findings were confirmed with Staff A. 3. During an interview on June 9, 2021 at 11:00 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p><b>D5659</b></p>	<p><b>CYTOLOGY</b> 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 interviews 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 on the report. 2. During an interview on June 7, 2021 at 3:15 PM, these findings were confirmed with Staff A. 3. During an interview on June 9, 2021 at 11:00 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> 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> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. Cross refer to D5401</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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, lack of laboratory records and</p>

interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were followed to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5791

**D9999**

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