

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2144056	(X3) Date Survey Completed 12/18/2024
Name of Provider or Supplier Pathnet Llc	Street Address, City, State 5100 Talley Road, Ste 300, Little Rock, AR	
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
D5401	<p>PROCEDURE MANUAL 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 35 laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow two written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure CYTOPATHOLOGY GYN CORRELATIONS, which stated: "Pap tests with concurrent HPV tests will be correlated monthly and discordant cases will be reviewed." a. The Survey Team reviewed laboratory records titled PAP/HPV CORRELATIONS 2023. The records failed to document the date the cases were correlated and discordant cases were reviewed. b. The Survey Team reviewed laboratory records titled HPV CORRELATIONS 2024. The records documented the correlations were correlated and discordant cases reviewed in December 2024. (The day of the month was illegible.) c. The Laboratory failed to correlate Pap tests with concurrent HPV tests and review discordant cases monthly. Refer to D5787 2. The laboratory failed to follow the procedure DPS VALIDATION AND MAINTENANCE, which stated: "At least 60 cases are required for one application or use (FFPE H&E, frozen sections, Hematology, Cytology) that represent the spectrum of specimen types that the evaluating pathologist will be signing out." a. During an interview on December 16, 2024 at 8:30 AM, the Cytology Manager stated all cytology slides were digitally imaged on the Aperio GT450 #2 (SN# 12401) Slide Scanner. b. The Survey Team reviewed validation records titled VALIDATION: LEICA APERIO GT450 #2 (SN# 12401) SLIDE SCANNER. The records documented that nine cytology cases were reviewed as part of the validation study. c.</p>

During an interview on December 18, 2024 at 9:35 AM, the Quality Assurance Specialist confirmed the laboratory failed to include 60 cytology cases to validate the Leica Aperio GT450 #2 (SN# 12401) Slide Scanner. 3. During an interview on December 18, 2024 at 11:30 AM, these findings were confirmed with the Cytology Manager and Quality Assurance Specialist.

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 35 laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for two laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process to reprocess gynecologic cytology specimens with glacial acetic acid. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process to filter Hologic ThinPrep Pap Tests prior to specimen processing. a. During an interview on December 17, 2024 at 11:10 AM, Staff A stated that at times the Cytotechnologists requested Hologic ThinPrep Pap PreservCyt Solution Vials to be filtered and a slide prepared from the filtered fluid. A paper tea bag was cut and placed in a 50 mL conical tube. The Hologic PreservCyt Vial was poured through the paper tea bag. PreservCyt Solution was added to the conical tube to bring the volume to 20 mL. The fluid in the conical tube was then added to an empty PreservCyt Solution Vial and a Hologic ThinPrep slide was prepared. 3. During an interview on December 17, 2024 at 3:35 PM, these findings were confirmed with the Cytology Manager.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

A. Based on review of the HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL, observation and interviews the laboratory failed to follow the manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 5000 Processor. Findings include: 1. The HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL states: "Specimens must be centrifuged and washed in CytoLyt Solution and transferred to PreservCyt Solution prior to being processed on the ThinPrep 5000 Processor." "Addition of CytoLyt Solution to cell pellets is required to wash the sample." "A CytoLyt Solution Wash consists of the following process: Adding 30 mL of CytoLyt Solution to a cell pellet" "When a sample is collected in CytoLyt Solution at a ratio less than 30 parts CytoLyt Solution to 1 part sample, this is considered a Collection Step and not a Wash Step. For example, if one collects 15 mL of a sample and adds 30 mL of CytoLyt Solution to this sample, then the CytoLyt: sample ratio is only 2 to 1 and this is considered a sample collection step and still requires a CytoLyt Solution Wash." 2. During an observation of nongynecologic specimen processing on December 17, 2024 at 11:10 AM, Staff A added 10 mL of CytoLyt Solution to the cell pellet in a centrifuge tube. The specimen was centrifuged for 5 minutes and decanted, and the cell pellet added to a Hologic ThinPrep PreservCyt Solution Vial. a. The Survey Team asked Staff A why 10 mL of CytoLyt Solution was added instead of 30 mL. Staff A stated "that is how I was trained." b. The laboratory failed to follow the manufacturer's instructions when processing nongynecologic specimens. The laboratory failed to perform a CytoLyt wash on nongynecologic specimens during specimen processing. 3. During an interview on December 17, 2024 at 3:35 PM, these findings were confirmed with the Cytology Manager. B. Based on interviews and review of the HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL the laboratory failed to follow the manufacturer's instructions for processing gynecologic cytology specimens using the Hologic ThinPrep 5000 Processor. Findings include: 1. During an interview on December 17, 2024 at 11:10 AM, Staff A stated that at times the Cytotechnologists requested Hologic ThinPrep PreservCyt Solution Vials to be filtered and a second slide prepared from the filtered fluid. A paper tea bag was cut and placed in a 50 mL conical tube. The Hologic PreservCyt Solution Vial was poured through the paper tea bag. The paper tea bag was discarded and PreservCyt Solution was added to the conical tube to bring the volume to 20 mL. The fluid in the conical tube was transferred to an empty PreservCyt Solution Vial and a Hologic ThinPrep slide was prepared. 2. The HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL does not contain instructions to filter Hologic ThinPrep PreservCyt Solution Vials prior to specimen processing. a. The laboratory failed to follow the manufacturer's instructions when processing gynecologic specimens. 3. During an interview on December 17, 2024 at 3:35 PM, these findings were confirmed with the Cytology Manager.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on review of the HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL and interviews the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of processing cytology specimens. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified procedure, reportable range of test results or any other performance characteristic was adequate to provide accurate diagnostic interpretations. Refer to D5411

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 with the Cytology Manager the laboratory failed to establish written policies and procedures to ensure workload limits would be prorated for individuals when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for individuals when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. During an interview on December 16, 2024 at 4:00 PM, these findings were confirmed with the Cytology Manager.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the Cytology Manager the

laboratory failed to maintain records of the date the correlative review (microscopic evaluation and reporting of interpretive results) of prior negative gynecologic cases with positive HPV results was performed and the identity of the personnel performing the review. Findings include: 1. The Survey Team reviewed laboratory records titled PAP/HPV CORRELATIONS 2023. a. The records failed to document the date the correlative review of prior negative gynecologic cases with positive HPV results was performed for 22 of 22 cases. Cases include: -PNG-23-00002 -PNG-23-00021 -PNG-23-00022 -PNG-23-00035 -PNG-23-00065 -PNG-23-00070 -PNG-23-00078 -PNG-23-00086 -PNG-23-00157 -PNG-23-00188 -PNG-23-00198 -PNG-23-00199 -PNG-23-00224 -PNG-23-00234 -PNG-23-00286 -PNG-23-00290 -PNG-23-00317 -PNG-23-00328 -PNG-23-00386 -PNG-23-00403 -PNG-23-00458 -PNG-23-00466 b. The records failed to document the identity of the personnel performing the correlative review for eight of 22 cases. Cases include: -PNG-23-00198 -PNG-23-00199 -PNG-23-00224 -PNG-23-00234 -PNG-23-00286 -PNG-23-00290 -PNG-23-00317 -PNG-23-00328 2. During an interview on December 17, 2024 at 3:35 PM, these findings were confirmed with the Cytology Manager.

D9999

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