

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2067119	(X3) Date Survey Completed 03/11/2025
Name of Provider or Supplier Pathlab Inc	Street Address, City, State 4266 Industry Dr, Ste 1, Sierra Vista, AZ	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of testing performed under the subspecialty of Cytology at least twice annually during 2024. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of the microscopic interpretation of cytology specimens at least twice annually during 2024. 2. The LD interviewed on 3/11/25 at 3:03 PM confirmed the laboratory failed to verify the accuracy of the testing indicated above at least twice annually during 2024. 3. The laboratory's reported annual test volume under the specialty of Pathology is 430.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
 Based on lack of humidity records for review from 1/02/2023 through 3/11/2025 and interview with the laboratory director (LD), (A) the laboratory failed to monitor and document the ambient humidity of the room where histopathology specimens are processed, and (B) the laboratory failed to monitor and document the temperature of the room where patient testing occurred on 20 out of 20 testing dates in September 2024. Findings include: 1. The laboratory performs the processing, gross examination and microscopic interpretation of patient specimens in the subspecialties of Histopathology and Cytology with an annual test volume of 430. The laboratory performs testing on each weekday, excluding holidays. A2. The laboratory utilizes the Tissue-Tek Prisma Plus Automatic Stainer to stain histopathology specimens. The manufacturer's environmental operating requirements for the stainer indicates an ambient humidity range of 30-85%. A3. The laboratory failed to monitor and document the ambient humidity of the room where specimen processing occurred on each testing day from 1/02/23 through the survey date on 3/11/25. A4. The LD interviewed on 3/11/25 at 3:30 PM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above. B1. The laboratory failed to monitor and document the room temperature of the laboratory on 20 out of 20 testing dates in September 2024. B2. The LD interviewed on 3/11/25 at 3:25 PM confirmed that laboratory staff failed to monitor and document the room temperature of the laboratory on each testing date during September 2024.

D5473

CONTROL PROCEDURES
 CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:
 Based on lack of Quality Control (QC) documentation, review of cytology and histopathology test reports and interview with the laboratory director (LD), the laboratory failed to document the acceptability of Hematoxylin & Eosin (H&E) and Papanicolaou staining materials each day of use, for intended reactivity and to ensure predictable staining characteristics on 2 out of 2 testing dates reviewed during the survey Findings include: 1. The laboratory performs testing under the specialty of Pathology with a reported annual test volume of 430. 2. Review of the histopathology test report for accession# S24-003401 revealed the laboratory failed to document the acceptability of the H&E stain on 1 out of 1 testing dates (9/24/24) reviewed during the survey. 3. Review of the cytopathology test report for accession# CN24-000340 revealed the laboratory failed to document the acceptability of the Papanicolaou stain on 1 out of 1 testing dates (9/25/24) reviewed during the survey. 4. The number of pathology cases read and diagnosed by the laboratory on 9/24/24 and 9/25/24 could not be determined at the time of the survey. 5. The LD interviewed on 3/11/2025 at 2: 45 PM confirmed the laboratory failed to document the H&E and Papanicolaou stain acceptability each day of use for intended reactivity and to ensure predictable staining characteristics on the testing dates indicated above.

D5805

TEST REPORT
 CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient

identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports for testing performed in the specialty of Pathology and interview with the laboratory director (LD), one out of one histopathology test report and one out of one cytology test report failed to include the name and the address of the laboratory where the testing was performed. Findings include: 1. The laboratory performs testing in the specialty of Pathology with a reported annual test volume of 430. 2. One out of one histopathology test report (S24-003401) and one out of one cytology test report (CN24-000340) was missing the laboratory name and address where the testing was performed and the final diagnosis was issued. 3. The LD interviewed on 3/11/25 at 2:10 PM confirmed that the laboratory name and address where the diagnosis was made was not indicated on the patient test reports issued by the laboratory, as indicated above.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on lack of initial training documentation for one testing personnel (TP-3) and interview with testing personnel (TP-2), the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for one testing personnel (TP-3) who performs the gross examination of cytology specimens in the specialty of Pathology. 2. TP-2 interviewed on 3/11/25 at 1:35 PM confirmed the laboratory failed to have documentation of initial training for the testing personnel indicated above. 3. The laboratory's reported annual test volume for the specialty of Pathology is 430.