

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2264866	(X3) Date Survey Completed 02/12/2025
Name of Provider or Supplier Western Pathology At Nnmc Sierra	Street Address, City, State 6500 Longley Ln, Reno, NV	
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
D5032	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to ensure that written procedures were approved, signed and dated by the Laboratory Director prior to use (refer to D5407); failed to establish and follow written policies and procedures for the reassessment of individual workload limits (refer to D5637); failed to establish and follow written policies and procedures to prorate workload limits for Technical Supervisors (refer to D5641); and failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645).</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as</p>

established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 five laboratory policies and procedures and interview with Laboratory Director/Technical Supervisor #1, 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 reporting final non-gynecologic test results. 2. During an interview on February 12, 2025 at 8:30 AM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of five laboratory policies and procedures and interview with Laboratory Director/Technical Supervisor #1, the laboratory failed to ensure that two of five written procedures were approved, signed and dated by the Laboratory Director prior to use. Findings include: 1. The Laboratory Director failed to sign and date two of five laboratory procedures in a binder titled LABORATORY PROCEDURES prior to use. Procedures include: - CYTO/HISTO PROCEDURE - ADDENDED REPORTS 2. During an interview on February 10, 2025 at 3:05 PM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.

D5637

CYTOLOGY
CFR(s): 493.1274(d)(1)(ii)

(d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview with Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies to reassess and adjust, when necessary, a maximum workload limit at least every six months for three of three Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the Technical Supervisor's workload limit would be reassessed at least every six months and adjusted when necessary. The

laboratory failed to detail the criteria used to reassess the Technical Supervisor's workload limit every six months. 2. The Survey Team requested and the laboratory failed to provide records of the reassessment of workload limits every six months for three of three Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. (See D6130) Technical Supervisors include: - Laboratory Director /Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 3. During an interview on February 10, 2025 at 2:40 PM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(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, lack of laboratory records and interview with Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures to ensure that the workload limit for three of three Technical Supervisors would be prorated when examining slides in less than eight hours. The laboratory failed to provide prorated workload limits for three of three Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Technical Supervisors when examining slides in less than an eight-hour day or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for three of three Technical Supervisors when examining slides in less than eight hours in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. (See D6130) Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 3. During an interview on February 10, 2025 at 2:40 PM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(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 review of laboratory policies and procedures and interview with Laboratory Director/Technical Supervisor #1, the laboratory failed to establish and follow written policies and procedures to ensure that the laboratory maintained records of the total number of non-gynecologic slides examined and the total number of hours the Technical Supervisors spent examining cytology slides per 24-hour period. Findings

	<p>include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and total number of hours three of three Technical Supervisors spent examining non-gynecologic slides. (See D6133) 2. During an interview on February 10, 2025 at 2:40 PM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and 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 and interview with Laboratory Director/Technical Supervisor #1, the Laboratory Director failed to ensure analytic and post-analytic quality assessment programs were established to assure the quality of cytology services. Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for an analytic and post-analytic quality assessment programs. 2. During an interview on February 10, 2025 at 3:05 PM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.</p>
<p>D6130</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> <p>(c)(2) Must establish the workload limit for each individual examining slides; (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;</p> <p>This STANDARD is not met as evidenced by: Based on lack of laboratory records and interview with Laboratory Director/Technical Supervisor #1, the Technical Supervisor failed to reassess workload limits at least every six months for the Technical Supervisors in 2023, 2024 and from January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Technical Supervisor failed to reassess workload limits at least every six months for three of three Technical Supervisors. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 2. During an interview on February 10, 2025 at 2:40 PM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.</p>
<p>D6133</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)</p> <p>(c)(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on lack of workload records and interview with Laboratory Director/Technical Supervisor #1, three of three Technical Supervisors failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period from 2023, 2024 and from January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide records of the total number of slides screened and the total number of hours three of three Technical Supervisors devoted to screening slides during each 24-hour period in 2023, 2024 and from January 1, 2025 to the date of the survey in 2025. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 2. During an interview on February 10, 2025 at 2:40 PM, these findings were confirmed with Laboratory Director/Technical Supervisor #1.

D9999

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