Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2227171	12/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Western Pathology, Inc	1 Technology Dr Ste C-523, Irvine, CA	

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	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) 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. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedure, five (5) randomly selected patient test records, and interview with the laboratory's director of operations (DO), laboratory manager (LM), and testing personnel (TP); the laboratory was found not in compliance to have a written and approved policy and procedure for all the processed and stains performed in the laboratory. The findings included: 1. Based on the surveyor's request for special stains procedures, the laboratory failed to provide CLIA compliant standard operation procedures for all the stains performed in the laboratory. 2. The reliability of the laboratory to have an effective and complete laboratory procedures for special stains to follow and ensure compliance with federal CLIA regulations could not be assured during this survey. 3. The DO, LM, and TP affirmed by an interview on December 30, 2025, at 11:30 a.m. that the laboratory failed to have CLIA compliant protocols and procedures for all the histopathology and special stains prepared in the laboratory. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 10,000 histopathology and oral pathology stains including special stains during the time the laboratory lacked CLIA compliant written and approved special stains protocols.
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 the laboratory's policies and procedures manuals and interview with the director of operations (DO) and laboratory manager (LM) on December 30, 2025, the laboratory failed to have all laboratory procedures signed, reviewed, and dated by the laboratory director. The findings included: 1. It was the practice of the laboratory to perform histopathology stains including special stains such as immunohistochemistry (IHC) stains. 2. On December 30, 2025, at approximately 11: 30 a.m., the DO and LM confirmed that the laboratory director did not provide approved, signed, and dated special stains procedure manuals to reflect the current practice offered by the laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on December 15, 2025, stated that the laboratory performed approximately 10,000 histopathology stains including IHC stains without approved protocols and procedures.
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 surveyor's review of laboratory personnel report (CLIA) Form CMS -209 and interview with the director of operations and the laboratory manager on December 30, 2025, the laboratory director failed to ensure that all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered. See findings: D6170.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, survey findings and an interviews on December 30, 2025, the laboratory director is herein cited for failure to ensure that a CLIA compliant, approved, signed, and dated, procedure manual that accurately reflects current laboratory practices is available for all personnel. See D5401 and D5407.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is

	required; and This STANDARD is not met as evidenced by: Based on interviews with the laboratory director of operations (D) and the laboratory manager (LM) and review of testing personnel qualification records on December 30, 2025, at approximately 11:00 a.m., the laboratory personnel performing gross examination (macro) failed to meet qualification requirements. Findings included: 1. It was the practice of the laboratory for gross examinations to be performed by non-certified/licensed personnel without supervision of a licensed medical doctor or qualified personnel. According to the DO and LM, gross examinations (macro) were performed by their non-certified/licensed personnel since 2023. 2. Based on the review of the laboratory's submitted "Laboratory Personnel Report (CLIA)," Form CMS-209, signed by the laboratory director on December 15, 2025, and testing personnel qualifications information provided by the Do and LM, apart from the laboratory director declared as the only testing personnel listed on the Form CMS-209, there were three (3) histology technicians whom did not possess the qualifications for testing personnel, high complexity testing. 3.The DO and LM confirmed by interview on December 30, 2025, at approximately 11:15 a.m. that non-licensed personnel were performing gross examinations (macro) as stated in # 2. 4. According to the laboratory's annual volume declaration, the laboratory performed 10,000 tests for histopathology. Therefore, the quality and accuracy of the patients' test results rendered by the laboratory cannot be assured.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified

	laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: The laboratory director is cited herein for failing to follow CLIA regulation 493.1489 "testing personnel qualification" .See D6170