Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2050266	06/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Newport Harbor Pathology	1 Hoag Dr, Newport Beach, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on interview with the Laboratory Director of Operations and review of laboratory's Proficiency Testing (PT) records on June 13, 2025, it was determined that the Laboratory failed to ensure that the accuracy of the histopathology and non-gynecologic cytology tests were verified at least twice annually in 2023 and 2024. The findings included: 1. It was the practice of the laboratory that pathologists examine histopathology and non-gynecologic cytology slides, which are not listed in subpart I of 42 CFR part 493. For test procedure not listed in subpart I, the laboratory must verify the accuracy of the test procedure at least twice annually by each Testing Personnel (TP) in 2023 and 2024. 2. On June 13, 2025, at approximately 12:30 pm, the Laboratory Director of Operation affirmed that the laboratory did not verify the accuracy of the test procedure at least twice annually for each Testing Personnel (TP). a) The laboratory did not have records of twice- annual verification of accuracy for the histopathology testing for eight of ten testing personnel in 2023. b) The laboratory did not have records of twice- annual verification of accuracy for the histopathology testing for seven of ten testing personnel in 2024 c) The laboratory did not have records of twice- annual verification of accuracy for non-gynecologic cytology tests for ten of ten testing personnel in 2024. 3. The laboratory's testing declaration form, signed by the laboratory director on May 30, 2025, stated that the laboratory performed approximately 26000 histopathology and 30 non-gynecologic cytology tests annually. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients.
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 interview with Laboratory Director of Operations and review of laboratory's policy and procedure manuals on June 13, 2025, it was determined that the laboratory failed to maintain policy and procedure manuals for non-gynecologic cytology examination. The findings included: 1. It was the practice of the laboratory to perform non-gynecologic cytology on- site. 2. On June 13, 2025, at approximately 1:00 p.m., the Laboratory Director of Operations was not able to retrieve the policy and procedure manuals for the non-gynecologic cytology testing. 3. The laboratory's testing declaration form, signed by the laboratory director on May 30, 2025, stated that the laboratory performed approximately 30 non-gynecologic cytology tests annually. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients.
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 policies and procedures manuals and interview with the Laboratory Director of Operations on June 13, 2025, it was determined that the laboratory director failed to approve, sign, and date procedures and changes in procedures. The findings included: 1. It was the practice of the laboratory to perform histopathology and cytology testing. 2. On June 13, 2025, at approximately 1:00 pm, the Laboratory Director of Operations affirmed that she signed and dated the recently updated written procedures. 3. The laboratory's testing declaration form, signed by the laboratory director on May 30, 2025, stated that the laboratory performed approximately 26,030 tests annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: Based on interview with Laboratory Director of Operations, review of policies and procedures manuals and Proficiency Testing records on June 13, 2025, the laboratory Director (LD) failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings included: 1. The LD failed to ensure the accuracy of the test procedures were verified at least twice annually. See D5217. 2. The LD failed to ensure the written procedure manual for cytology testing was available at the laboratory. See D5401.