Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2025143	**(X3) Date Survey Completed** 04/19/2023
Name of Provider or Supplier Y & Z Westwood Surgical Pathology	**Street Address, City, State** 1700 Westwood Blvd Ste 30e, Los Angeles, 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 review with the laboratory's records and interview with the laboratory director on April 19.2022, it was determined that the laboratory director , (LD), failed to verify the accuracy/peer review of any test or procedure it performed that was not listed in subpart I of this part (42 CFR part 493). The findings included: 1. The laboratory is a CLIA certified laboratory to perform histopathology services, which is not listed in the subpart I of the 42 CFR part 493, i.e. not a regulated procedure. 2. For the test procedure not listed in subpart I (not regulated), the laboratory must verify the accuracy of the test procedure twice annually. 3. The laboratory failed to verify the accuracy of its histopathology procedure in the year of 2020, 2021 and 2022 at least twice (2) annually. 4. The laboratory director affirmed April 19, 2023, that the laboratory failed to verify the accuracy of its histopathology procedure in the years of 2020, 2021, and 2022 at least twice (2) annually. 5. The laboratory's testing declaration form, signed by the laboratory Director on April 19, 2023, stated that the laboratory performs 200 tests annually in Histopathology. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 lack of a laboratory written policies and procedures manual and interview with the laboratory director (LD), it was determined that the laboratory failed to establish and follow written policies and procedures for the Histopathology lab including: Retention Policy of documents and specimens; maintenance of equipment; and verification of accuracy/peer review. The findings included: 1. On the day of the survey on April 19,2023 at approximately 11:00 a.m. the laboratory director (LD) failed to provide written policies and procedures for Histopathology test procedures performed in the laboratory. 2. Based on interview with the laboratory director and lack of policy, LD failed to establish and follow written policies and procedures for slide retention. 3. Based on interview with the laboratory director and lack of policy, LD failed to establish and follow written policies and procedures for microscope maintenance and calibration. 4. Based on interview with the laboratory director and lack of policy, LD failed to establish and follow written policies and procedures for competency assessment/peer review of the histopathology laboratory testing personnel. 5. The laboratory's testing declaration form, signed by the LD on April 19, 2023, stated that the laboratory performs 200 tests annually in Histopathology. .
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, lack of maintenance protocol, and interview with the laboratory director (LD) it was determined that the laboratory failed to establish a maintenance and calibration protocol for the NIKON ECLIPSE 55L microscope that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. At the time of the survey, April 19,2023 at approximately 12:00 p.m. an expired maintenance tag was observed on the NIKON 55L microscope. Angeles Medical Optical is the company that provided service. 2. The maintenance tag provided by Angeles Medical Optical had an expiration date of 9/30/2021 adhered to the microscope. 3. The LD confirmed the use of a contract company for microscope maintenance. 4. Record of maintenance provided by Angeles Medical was not provided at time of survey 5. A policy for microscope maintenance and calibration was requested, and not provided at time of survey. 6. The laboratory's testing declaration form, signed by the LD on April 19, 2023, stated that the laboratory performs 200 tests annually in histopathology. .
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all

	aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the lack of a laboratory written policies and procedures manual and interview with the laboratory director (LD), it was determined that the laboratory failed to have available and follow written procedures for Histopathology test procedures performed in the laboratory. The findings included: 1. On April 19,2023 at approximately 11:00 am, the laboratory director failed to provide a procedure manual that covered all aspects of the testing processes performed by the laboratory. 2. The laboratory's testing declaration form, signed by the laboratory Director on April 19, 2023, stated that the laboratory performs 200 tests annually in Histopathology. See: D5217, D5401, and D5433