Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2103634	(X3) Date Survey Completed 06/19/2024
Name of Provider or Supplier Janet Vafaie Md Faad	**Street Address, City, State** 10921 Wilshire Blvd, Ste 800, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the lack of written policies and procedures manual for retention and storage applicable to dermatopathology and Mohs, review of ten (10) randomly chosen patient test records, and interview with the medical assistant (MA); the laboratory failed to have written policies in documentation and slide retention for Mohs and dermatopathology. The findings included: 1. Based on the survey conducted on June 19, 2024, at approximately 11:10 a.m., no written policies for retention of documents and slides were found. 2. The MA affirmed by interview on June 19, 2024, at approximately 11:10 a.m. that the laboratory had no retention policies for documents and slides. 3. Based on the laboratory declaration form submitted on June 19, 2024 and review of 10 randomly chosen dermatopathology test records out of 900 tests performed annually for Mohs and dermatopathology, the laboratory had no retention and storage policies.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor review of written policies and procedure manual for equipment quality control and maintenance, interview with the medical assistant (MA) and review of five (5) randomly selected patient test results for Mohs, it was determined that the laboratory missed to record the cryostat temperature during preventive maintenance (PM). The findings included: 1. Based on the survey conducted on June 19, 2024, at approximately 12:30 p.m. and review of laboratory's policies and procedures manual, the surveyor observed that on the cryostat temperature and maintenance log sheet dated 4/26/24, the cryostat temperature was missed to be recorded by the technician. 2. The MA affirmed that the temperature was missed to be recorded by the technician as mentioned on statement #1. 3. Based on the laboratory's testing declaration submitted on June 19, 2024, and review of five (5) randomly selected patient test records for Mohs, the laboratory performed 900 tests annually including dermatopathology.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's policies and procedures, and interview with the medical assistant on June 19, 2024, at approximately 12:30 p. m., the laboratory director is herein cited for deficient practice in ensuring that policies and procedures are established and maintained. Findings include: a. The policy for retention and storage was not established. See D3043 b. The policy and procedure for maintenance was not followed. See D5435