Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0856740	12/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
William J Wickwire, Md Inc	16300 Sand Cyn Ave Ste 612, 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
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 surveyor's review of the laboratory's policies and procedures manual, a review of nine (9) randomly chosen patient test records, and interviews with the supervisor and medical assistant (MA), it was determined that the laboratory failed to have an approved written policy and procedure for documentation and slide retention and storage. The findings include: 1. Based on the review of the laboratory's policies and procedures manual at approximately 12:00 p.m. on December 11, 2024, no written and approved policy and procedure was found for the retention and storage of documents and slides. 2. The deficient practice was affirmed by interviews with the supervisor and MA on December 11, 2024, at approximately 12:00 p.m., that the laboratory did not have a policy and procedure for retention and storage as mentioned in statement #1. 3. According to the laboratory's testing declaration form submitted at the time of the survey and a review of 9 randomly chosen patient test records covering the period of February 2, 2022, to September 23, 2024, the laboratory performed 516 tests annually for Mycology, Parasitology and Dermatopathology during the time the laboratory had no written and approved retention and storage policy and procedure for documentation and slides.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies & procedures, patients' test records, and interviews with the supervisor and medical assistant (MA), it was determined that the laboratory failed to establish and follow written policies and procedures to assess the quality of its preanalytical, analytical, and postanalytical systems. The findings include: 1. Based on the surveyor's review of the laboratory's policies and procedures, it was determined that the laboratory did not have any written, signed, and approved protocol for the quality assessment system established to identify problems in the preanalytical, analytical, and postanalytical systems. 2. The supervisor and MA stated in an interview on December 11, 2024, at approximately 12:00 p.m., that when errors are discovered, they are immediately corrected on files but not documented. This correction process overwrites the records of errors and potential problems, and no system was established to keep track of records for verification. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory performed approximately 516 tests annually for Mycology, Parasitology, and Dermatopathology during the time that no policies and procedures and documentation for quality assessment were established. Therefore, the quality of patient test records cannot be assured.
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 a review of the laboratory's policies and procedures, preventive maintenance (PM) documentation, five (5) randomly selected Mohs patient test records, and interviews with the supervisor and medical assistant (MA), it was determined that the laboratory failed to ensure preventive maintenance performed was monitored and documented properly prior to patient testing. The findings include: 1. Based on the review of the PM documentation called Cryostat Quality Control Log on December 11, 2024, at approximately 12:45 p.m., the lot number and expiration date for alcohol used for staining slides were rarely documented from 10/18/2022 to 6/4/2024. 2. Out of 5 patient records reviewed by the surveyor on December 11, 2024, at approximately 12:45 p.m., Patient EI24-243A had a missing PM entry to determine if the quality control slide was acceptable prior to testing. Upon review of the same log sheet, missing entries were found on 7/15/2024, 7/19/2024, 8/11/2024, 11/4/2024, and on 12/2/2024 dates; thus, the staining quality of the control slides for each Mohs day cannot be assured. 3. The supervisor and MA affirmed by interview at approximately

	12:45 p.m. on December 11, 2024, that the laboratory failed to check the log sheet for any entries missing for each patient testing day as mentioned in statements #1 and #2. 4. Based on the annual testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 500 patient tests for Mohs, including the time the missing entries for PM occurred. Thus, the quality and accuracy of patient reports cannot be assured.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of four (4) patient records for potassium hydroxide (KOH) test and interviews with the supervisor and medical assistant (MA), the laboratory is herein cited for the discrepancies in reports found. The findings include: 1. Based on the surveyor's review of 4 KOH patient test records, one out of 4 had a discrepancy in records between the patient log and the final report. a. MRN number: 92404 was recorded in the patient log as KOH positive, but on the final report it was documented as equivocal. 2. The supervisor and MA affirmed by interview on December 11, 2024, at approximately 12:45 p.m., that the results did not match from the patient log sheet and final report as mentioned in statement #1. 3. Based on the laboratory testing declaration form submitted at the time of the survey, the laboratory performed and reported 16 KOH patient tests, including the time there was a discrepancy in the report released.
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 surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, and interviews with the supervisor and medical assistant on December 11, 2024, it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. No retention policy and procedure for documentation and slides. See D3043. 2. Missing entries for preventive maintenance. See D5435.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, randomly selected patient test records, and interviews with the supervisor and medical assistant on December 11, 2024, at approximately 11:40 a.m., the laboratory director is herein cited for deficient practice for failure to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: 1. No quality assessment/assurance policy and procedure as well as documentation for the years 2022, 2023, and 2024. See D5391. 2. Discrepancy in patient result reported. See D5821.