Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2056387	08/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Brenda Latowsky Md Pllc	20201 N Scottsdale Healthcare Dr Ste 260, Scottsdale, AZ	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of temperature records for review from June 25, 2024 and interview with the facility personnel, the laboratory failed to monitor and document the room temperature where dermatopathology reagents are utilized and stored and failed to monitor and document the temperature of the cryostat used in conjunction with Mohs testing. Findings include: 1. The laboratory processes specimens and interprets dermatopathology slides in conjunction with Mohs surgery, with an approximate annual test volume of 464. 2. No documentation of the room temperature was presented for review from June 25, 2024, to indicate the laboratory monitored and documented the temperature of the room where dermatopathology reagents are utilized and stored each day of Mohs testing. 3. No documentation of the cryostat temperature was presented for review from June 25, 2024, to indicate the laboratory monitored and documented the temperature of the cryostat used on each day of Mohs testing. 4. A total of 13 patients were tested on June 25, 2024. 5. The facility personnel interviewed on August 15, 2024 at 10:30 AM confirmed that the laboratory failed to monitor and document the cryostat temperature and the room temperature of the laboratory where reagents are stored and used on June 25, 2024.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for one out of four testing dates reviewed during the survey and interview with the facility personnel, the laboratory failed to document the acceptability of Hematoxylin & Eosin (H&E) staining materials each day of use, for intended reactivity to ensure predictable staining characteristics. Findings include: 1. No documentation of the H&E stain acceptability was presented for review for Mohs testing that occurred on July 18, 2023. 2. A total of 6 Mohs cases were performed on the date indicated above. 3. The facility personnel interviewed on August 15, 2024 at 10:45 AM confirmed the laboratory failed to document the H&E stain acceptability on the testing date indicated above, for intended reactivity to ensure predictable staining characteristics.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of tissue pathology reports and interview with the facility personnel, the qualified individual who performed the examination and made the diagnosis failed to sign the Mohs test report for one out of four test reports reviewed during the survey. Findings include: 1. The laboratory performs Mohs testing in the subspecialty of Histopathology, with an approximate annual test volume of 464. 2. One out of four Mohs test reports (ZMS23-0013) reviewed in the Electronic Health Record (EHR) failed to include the electronic signature of the individual who performed the examination and made the diagnosis. 3. The facility personnel interviewed on August 15, 2024 at 9:50 AM confirmed the tissue pathology report indicated above was not signed by the individual who performed the examination and made the diagnosis.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of Mohs test reports and Mohs maps maintained in the Electronic Health Record (EHR) and interview with the facility personnel, one out of four Mohs test reports and the corresponding Mohs map reviewed in the EHR failed to include the correct case number. Findings include: 1. The laboratory performs Mohs testing under the subspecialty of Histopathology, with an annual test volume of 464. It is the practice of the laboratory to assign a unique case number to each Mohs case, and the unique case number is manually transcribed on the test report and Mohs map maintained in the EHR. 2. One out of four Mohs test reports and the corresponding Mohs map maintained in the EHR failed to include the correct case number. The Mohs map and Mohs test report maintained in the EHR listed the case number as OMS22-0218. The Mohs log and Mohs slides listed the case number as OMS24-0218. 3. The facility personnel interviewed on 8/15/24 at 10:10 AM confirmed the Mohs operative report and Mohs map maintained in the EHR for the patient indicated above failed to include the correct Mohs case number, and confirmed the testing was performed in 2024, not 2022.