Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0881550	05/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kenny R Malott Md Inc	375 Huku Lii Place, Ste 201, Kihei, HI	

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: The surveyor's review of laboratory records and an interview with the office manager on 5/21/2025 at 11:30 AM revealed the laboratory failed to at least twice annually verify the accuracy of the micrographically oriented histographic surgery (MOHS) microscopic examinations it performed. The office manager confirmed twice annual accuracy verifications were not done in 2024. The laboratory examined 358 patient sample blocks in 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: The surveyor's review of laboratory records, direct observation, and an interview with the office manager on 5/21/2025 at 11:00 AM revealed the laboratory failed to

	monitor and document room temperatures to ensure proper storage of its MOHS histology stains and reagents. The laboratory performed microscopic examinations on 233 patient sample blocks in 2023, 358 blocks in 2024, and 73 blocks in 2025 to date. The findings include: 1. Leica Surgipath manufacturer storage temperature ranges for Reagent Alcohol 100%, Hematoxylin Gill III Stain, SelecTech Blue Buffer Concentrate 8, and SelecTech Eosin Phloxine 515 is 15 degrees to 30 degrees Centigrade. 2. The laboratory documented 2023 and 2024 room temperature readings on the Cryostat Maintenance Log. The acceptable room temperature range on the log was 20 degrees to -30 degrees Centigrade. Room temperatures were not documented on the following testing dates: July 2023 4 of 4 testing days (July 3-4 patients, July 11-3 patients, July 18-4 patients, July 24-3 patients) October 2023 1 of 6 testing days (October 31-four patients) December 2023 2 of 6 testing days (December 12-5 patients, December 19-6 patients) April 2024 1 of 6 testing days (April 16-5 patients) May 2024 1 of 6 testing days (May 14-4 patients) July 2024 1 of 4 testing days (July 2-4 patients) August 2024 2 of 6 testing days (August 26-3 patients, August 27-4 patients) October 2024 1 of 9 testing days (October 22-4 patients December 2024 1 of 6 testing days (December 31-3 patients) 3. The laboratory documented 2025 room temperature readings on the Lab Room Temperature Log. The acceptable room temperature range on the log is 10 degrees to 33 degrees Centigrade. Room temperature was not documented for May 2, 2025 when MOHS procedures were performed on five patients. 4. The surveyor observed the laboratory room temperature reading of 66 degrees Fahrenheit (18.9 degrees Centigrade) on its temperature monitoring device. The laboratory room temperature for the day was documented on the Lab Room Temperature Log as 22 degrees Centigrade. The office manager and tech processing patient specimen blocks stated the laboratory could not adjust the room temperature.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: The surveyor's review of laboratory procedures and direct observation of the laboratory Hematoxylin and Eosin manual staining counter on 5/21/2025 at 10:30 AM revealed the laboratory failed to label 14 of 14 stain and reagent containers with storage requirements, and preparation and expiration dates. The laboratory processed 233 patient specimen blocks in 2023, 358 blocks in 2024, and 73 blocks in 2025 to date. The findings include: 1. The laboratory MOHS H&E STAIN PROTOCOL states, "Staining from left to right in auto-stain" Location 1 Alcohol 100% Change Weekly Location 2 50% Alcohol Change Weekly Location 3 Running Water Constant Rotation Location 4 Running Water Constant Rotation Location 5 Hematoxylin Change Every 2 Weeks Location 6 Running Water Constant Rotation Location 7 Bluing Change Weekly Location 8 Running Water Constant Rotation Location 9 Eosin Change Every 2 Weeks Location 10 95% Alcohol Change Daily Location 11 100% Alcohol Change Daily Location 12 100% Alcohol Rotate Weekly Location 13 100% Alcohol Rotate Weekly Location 14 Cleaning Agent Rotate As Needed The tech processing patient sample blocks for staining stated the ThermoScientific Linistat

	Slide Stainer (auto-stain) was not in use. A protocol for manual staining was not available for review. 2. 14 of 14 containers in use on the manual staining counter were labeled only with the name of the "Agent" it contained.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) 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. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the office manager on 5/21/2025 at 11:00 AM revealed the laboratory failed to perform maintenance on two of two microscopes used for MOHS micrographic surgery (MOHS) microscopic examinations, and failed to document the maintenance performed on its fume hood. The findings include: 1. The laboratory Preventative Maintenance of Cryostat and Microscope procedure states "Have Avantik, Pacific Pathology Lab Tech, or ... come out for maintenance on a biannual basis". The office manager confirmed microscope maintenance was not performed on the laboratory's Amscope SN101574-24 and Nikon Labophot-2 SN449663 in 2023 and 2024. The laboratory performed MOHS microscopic examinations on 233 patient sample blocks in 2023 and 358 blocks in 2024. 2. Documentation of annual vendor performed maintenance on the laboratory fume hood MicroAir VM-500 no serial number for 2023, 2024, and 2025 was not available for surveyor review.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records, direct observation, and an interview with the office manager on 5/21/2025 at 11:00 AM revealed the laboratory failed to establish a control procedure to monitor the accuracy and precision of the MOHS microscopic examinations it performed. The findings include: 1. The laboratory failed to monitor and document room temperatures to ensure proper storage of its histology stains and reagents. See D tag D5413. 2. The laboratory failed to label 14 of 14 stain and reagent containers with the storage requirements, and preparation and expiration dates of its contents. See D tag D5415. 3. The laboratory failed to perform maintenance on two of two microscopes used for MOHS microscopic examinations and failed to document the maintenance performed on its fume hood. D tag D5433. 4.

	The laboratory failed to document the intended reacitivity of its Leica Surgipath Hematoxylin and Surgipath SeleTech Eosin Phloxine 515 stains each day of use. D tag D5473.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the office manager on 5/21/2025 at 11:15 AM revealed the laboratory failed to document the intended reacitivity of its Leica Surgipath Hematoxylin and Surgipath SeleTech Eosin Phloxine 515 stains each day of use to ensure predicatable staining for the MOHS microscopic examinations it perfromed. The findings include: 1. Hematoylin and Eosin stain reactivity was not documented for 27 testing days between September 16, 2024 to December 31, 2024. September 16, 17, 23, 30 October 1, 7, 8, 14, 15, 21, 22, 28, 29 November 4, 5, 11, 12, 18, 19, 25, 26 December 2, 3, 9, 10, 30, 31 2. The laboratory examined 358 patient sample blocks in 2024.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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: The surveyor's review of laboratory procedures and an interview with the office manager on 5/21/2025 between 11:00 AM and 12:15 PM revealed the laboratory director failed to ensure quality control and quality assessment programs were established and maintained to ensure the quality of the laboratory services it provided and to identify failures in quality as they occur. The findings include: 1. The laboratory failed in 2024 to at least twice annually verify the accuracy of the micrographically oriented histographic surgery (MOHS) microscopic examinations it performed. See D tag D5217. 2. The laboratory failed to establish a control procedure to monitor the accuracy and precision of the MOHS microscopic examinations it performed. See D tag D5441. 3. The Kenny R Malott MD Inc MOHS Daily Quality Assessment Program states "Update and have Dr/Lab Director sign and date Monthly Logs". 2023 and 2024 Cryostat Maintenance Logs were not signed and dated by the laboratory director. 2025 Lab Room Temperature Logs were not signed and dated by the laboratory director. See D tag D5413. The laboratory director initialed Hematoxylin and Eosin stain reactivity logs for 27 testing days although stain reactivity results were not documented on the form. See D tag D5473.