

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0881550	(X3) Date Survey Completed 06/27/2023
Name of Provider or Supplier Kenny R Malott Md Inc	Street Address, City, State 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and interview with the office manger on 06/27/2023 at 11:00 AM revealed the laboratory failed to twice annually verify the accuracy of the micrographically oriented histographic surgery (MOHS) testing it performs. The laboratory performs an annual volume of 201 MOHS procedures. The findings include: 1, The office manager confirmed twice annual accuracy verifications were not done in 2022.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: The surveyor's review of equipment and maintenance records, and interview with the office manager on 06/27/2023 at 10:00 AM revealed the laboratory failed to establish and follow maintenance and function check protocols for its AVANTI Q12</p>

Cryostat SN S18071460 and Nikon Labphot 2 microscope SN 499663 in 2022. The laboratory performs an annual volume of 201 MOHS procedures. The findings include: 1. The laboratory's Preventive Maintenance of Cryostat procedure states "Goal is to have AVANTI K come out for maintenance or Pacific Pathology Lab Tech come out and maintain on a yearly basis". The office manager conformed AVANTI K and Pacific Pathology did not perform preventive maintenance on its Cryostat in 2022. 2. The office manager confirms the laboratory's quality assessment program does not include a preventive maintenance procedure for its microscope.

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:
The surveyor's review of laboratory records, and interview with the the office manager on 06/27/2023 between 10:00 and 11:00 AM revealed the laboratory director failed to ensure the quality of its MOHS histopathology services. The findings include: 1. The laboratory failed to twice annually verify the accuracy of the MOHS testing it performs. See D tag D5217. 2. The laboratory failed to establish and follow maintenance and function check protocols for its AVANTI K QS12 Cryostat SN S18071460 and Nikon Labphot 2 microscope SN 499663. See D tag D5433