

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0881550	(X3) Date Survey Completed 12/21/2021
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and an interview with the office manager on 12/21/2021 at 1:00 PM, it was determined that the laboratory failed to ensure that its MOHs procedures were approved, signed and dated by the laboratory director before use. The findings include: 1. The following procedures were not approved, signed and dated by the laboratory director: a. Protocol for MOHs Lab b. Cryostat Use Protocol c. MOHs H & E Stain Protocol revised 02/05/2019 d. MOHs Relaxing and Inking Instructions 01/29/2019 e. MOHs Linear Stainer 01/29/2019 f. MOHs Manual Stainer 01/29/2019 g. Preventive Maintenance of the Cryostat h. MOHS Daily Quality Assessment Program 2. The laboratory performed 2140 MOHs biopsies in 2020 and 1601 MOHs biopsies in 2021.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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. (g)</p>

	<p>The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of temperature monitoring logs and an interview with the testing personnel on 12/21/2021 at 1:30 PM, it was determined that the laboratory failed to monitor over time the accuracy and precision of its MOHs test performance that may be influenced by changes in environmental conditions. The findings include: 1. Monthly room temperature logs for 2020 and 2021 were not reviewed for variances that may affect test system performance 2. The laboratory performed 2140 MOHs biopsies in 2020 and 1601 MOHs biopsies in 2021.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory quality assessment program, temperature monitoring logs and an interview with the testing personnel on 12/21/2021 at 1:30 PM, it was determined that the laboratory director failed to ensure that its quality assessment program was maintained to assure the quality of services it provided and to identify failures in quality as they occur. The findings include: 1. The laboratory MOHs Daily Quality Assessment Program procedure stated "Update and have Dr/Lab Director sign and date monthly logs" 2. Monthly room temperature logs for 2020 and 2021 were not reviewed for variances that may affect test system performance. See CFR 493.1256(s)(b)(c)(g), D tag D5441.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and an interview with the office manager on 12/21/2021 at 1:00 PM, it was determined that the laboratory director failed to ensure that approved MOHs procedures were available to testing personnel responsible for any aspect of its testing processes. See CFR 493.1251(d), D tag D5407.</p>