

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0931555	(X3) Date Survey Completed 09/03/2021
Name of Provider or Supplier Patti K M Endo, Md	Street Address, City, State 1830 Wells St Suite 102, Wailuku, 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
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: Based on a review of laboratory maintenance records and an interview with the Laboratory Director on 09/03/2021 at 12:00 p.m., it was determined that the laboratory failed to establish a maintenance protocol that ensures the equipment test system performance necessary for accurate and reliable test results. The findings include: 1. The laboratory performs potassium hydroxide (KOH) preparation testing and histopathology biopsy slide readings on its Nikon Labophot2 microscope SN 446172. The microscope maintenance protocol includes annual preventive maintenance service activities by a commercial vendor. The Laboratory Director confirmed that the last annual service was performed on 06/21/2016. 2. The laboratory performed 9 KOH preparation tests and 748 biopsy slide readings in 2020.</p>
D6094	<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>

This STANDARD is not met as evidenced by:
Based on a review of laboratory maintenance records and an interview with the Laboratory Director on 09/03/2021 at 12:00 p.m., it was determined that the quality assessment program established by the laboratory failed to assure the quality of laboratory services provided and to identify failures in quality as they occur. Annual preventive maintenance service was not performed on the Nikon Labophot2 microscope since 06/21/2016. See D5433.