

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D2169853	(X3) Date Survey Completed 12/17/2021
Name of Provider or Supplier Ronald Moy Md	Street Address, City, State 73-4976 Kamanu St Ste 210, Kailua Kona, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with the laboratory manager on 12/17/2021 at 11:00 am, it was determined that the laboratory failed to ensure that Avantik Cryostat QS11 frozen embedding solutions were not used when they have exceeded their expiration date. The findings include: 1. Open bottles of Polarstat Plus Green solution, lot# 088371, expiration date 10/31/2021 and Polarstat Plus Red solution, lot# 088013, expiration date 10/31/2021 stored on top of the Avantik Cryostat instrument were available for testing personnel use. 2. The laboratory performed an annual volume of 600 MOHS surgeries.</p>
D6095	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with the laboratory manager on 12/17/2021 at 11:00 am, it was determined that the laboratory director failed to ensure that acceptable levels of analytical performance were maintained when Avantik Cryostat QS11 frozen embedding solutions were used when they exceeded their expiration date. See CFR 493.1252, D tag D5417.</p>