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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 12D2134265 | (X3) Date Survey Completed 10/06/2023 |
| Name of Provider or Supplier Amy Reisenauer Md Llc | Street Address, City, State 1300 North Holocono St Suite 215, 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: Based on a review of laboratory records and an interview with the histology technician on 10/6/2023 at 10:30 AM, it was revealed that the laboratory failed to twice annually verify the accuracy of the potassium hydroxide (KOH) testing it performs. The laboratory performs 50 KOH tests annually. The findings include: 1. KOH Exam Result reports were available for 8/19/2021 and 8/23/2022, however, the identity of the testing service and the individual taking the exam was not provided on these reports. A second KOH accuracy check for 2021 and 2022 was not performed. 2. KOH accuracy checks for 2023 were not performed as of this survey date.</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> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the histology technician on 10/6/2023 at 10:30 AM, it was revealed that the laboratory director failed to ensure its quality assessment program was maintained to verify the accuracy of its potassium hydroxide (KOH) testing at least twice annually. See D tag D5217.</p> |