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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 12D0646223 | (X3) Date Survey Completed 05/12/2025 |
| Name of Provider or Supplier Clinical Labs Of Hawaii-Kamuela | Street Address, City, State 65-1158 Mamalahoa Hwy, #27b, Kamuela, 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 |
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| D5433 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) 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. (b)(1)(ii) 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 laboratory records and an interview with the testing personnel (TP1) and technical consultant (TC1) on May 12, 2025 at 10:00 AM revealed the laboratory failed to establish a microscope maintenance protocol to ensure accurate and reliable test results. The laboratory performed an annual volume of 216 urine sediment analyses and 528 manual white blood cell differentials in 2024. The findings include: 1. TP1 stated the laboratory's Olympus microscope model BX43F, SNOG49972 was obtained from another location. Microscope records showed the last annual service was performed on August 24, 2023. The laboratory began patient testing on September 3, 2024. 2. TP1 stated the laboratory microscope is not scheduled until June 2025 for its initial maintenance by a vendor.</p> |
| D6005 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.</p> |

This STANDARD is not met as evidenced by:
The surveyor's review of laboratory records and an interview with the technical consultant (TC1) on May 12, 2025 at 10:30 AM revealed the laboratory director failed to be on-site at least once every 6 months. TC1 stated the laboratory director had not been on site prior to the laboratory opening on September 3, 2024 through 2025 present.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and 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 an interview with the testing personnel (TP1) and technical consultant (TC1) on May 12, 2025 at 10:00 AM revealed the laboratory director failed to ensure a quality program was established for the microscope used for urine sediment analyses and manual white blood cell differential testing. Refer to D tag D5433.