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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 12D0646234 | (X3) Date Survey Completed 08/06/2019 |
| Name of Provider or Supplier Clinical Labs Of Hawaii-Kau Hospital | Street Address, City, State 1 Kamani St, Pahala, 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 |
|---------------------------|---|
| D5775 | <p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on an interview with the Technical Consultant and Testing Personnel on 8/6 /2019, the lab failed to have a system that twice a year evaluates and defines the relationship between two Abbott iStat analyzers used to perform the same tests. Findings include: a) The technical consultant and testing personnel confirmed that the laboratory maintained two Abbott iStat analyzers for patient testing of Arterial Blood Gases, Prothrombin Time, and Lactate. The technical consultant and testing personnel also confirmed that no system was in place that twice a year evaluates and defines the relationship between the two Abbott iStat analyzers used to perform the arterial blood gas, prothrombin time, and lactate tests. b) The laboratory performs 3 arterial blood gas tests, 38 lactate tests, and 168 prothrombin time tests annually.</p> |