

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D2305342	(X3) Date Survey Completed 04/04/2025
Name of Provider or Supplier Diagnostic Laboratory Services-Kohala Hosp	Street Address, City, State 54-383 Hospital Road, Kapaau, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: The surveyor's direct observation, and an interview with testing personnel TP#2 and technical consultant TC#3 on April 4, 2025 at 9:00 AM revealed the laboratory failed to label the hematology reagents it used to stain its manual differential slides. The laboratory stained an annual volume of 300 patient slides in 2024. The findings include: 1. 3 of 3 Coplin jars were available for use on the hematology staining counter. 1 of 3 jars contained a stain solution and the other 2 jars were empty. TP#2 stated the first jar contained Camco Quick Stain II. The stain was poured from from a stock bottle, lot #3018, expiration date 3/1/2026 although the pour off date could not be confirmed. The second and third jars used for rinsing were empty. 2. TC#3 confirmed the surveyor's direct observation that the 3 jars were not labeled with their contents, storage requirements, and expiration dates.</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</p>

are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:

The surveyor's review of laboratory records and an interview with the laboratory assistant on April 4, 2025 at 10:30 AM revealed the laboratory director failed to be on-site at least once every 6 months in 2024. The laboratory assistant stated the laboratory director on CMS Form 209 had not been on-site in 2024 through 2025 present. Testing personnel TP#2 an agency temporary employee and TC#3 hired 6 weeks prior to the survey could not confirm an on-site visit or meeting with the laboratory director.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:

The surveyor's direct observation, and an interview with testing personnel TP#2 and technical consultant TC#3 on April 4, 2025 at 9:00 AM revealed the laboratory director failed to ensure laboratory personnel performing manual differential slide testing labelled the in use staining reagent containers on the hematology counter. Refer to D tag D5415.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

The surveyor's review of testing personnel education and training records, and an interview with testing personnel TP#2 and the laboratory assistant on April 4, 2025 at 10:30 AM revealed the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education, experience, and training for the moderate complexity services offered. Refer to D tag D6064.

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

This STANDARD is not met as evidenced by:

The surveyor's review of testing personnel education and training records, and an interview with testing personnel TP#2 and the laboratory assistant on April 4, 2025 at

10:30 AM revealed the laboratory failed to ensure the laboratory assistant performing moderate complexity testing possessed a Hawaii Clinical Laboratory personnel license. The findings include: 1. The laboratory performed an annual volume of 104,045 moderate complexity tests in 2024, i.e., 1,210 Abbott GenXpert Rapid Molecular Strep, Influenza A/B, and SARS-CoV-2 tests, 3,200 Werfen ACL Tops 350 Prothrombin Time, Activated Partial Thromboplastin, Fibrinogen, and D-dimer tests, and 99,635 Sysmex XN-350 white blood cell counts, red blood cell counts, hemoglobin, hematocrit, platelet counts, and automated white blood cell differentials. 2. TP#2 stated the laboratory assistant loaded patient samples and started testing runs on Abbott GenXpert and the Sysmex XN-350 instruments. TP#2 stated the laboratory assistant performed quality control testing on the Werfen ACL Tops 350 instrument. The laboratory assistant confirmed the activities as described by TP#2. 3. The laboratory assistant does not possess a Hawaii Clinical Laboratory Personnel license as required by Hawaii administrative licensing rules.