

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0619009	(X3) Date Survey Completed 06/17/2026
Name of Provider or Supplier Clinical Labs Of Hawaii-Hilo Benioff Medical Cntr	Street Address, City, State 1190 Waianuenue Avenue, Hilo, 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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: The surveyor's review of 2 of 2 laboratory quality assurance procedures, laboratory reports, and interview with the general supervisor, revealed the laboratory failed to monitor its corrected inpatient reports and failed to verify the accuracy of manually transcribed reports during 2025 and 2026. The findings include: 1. The Laboratory Quality Management Program, Quality Assurance Aims procedure states "Quality Indicators F. Proper Correction of Reports 1. Assess proper correction of results and notification of correction to requesting physician or nursing unit; 2. Reports are generated daily by Information Systems". No documentation was presented for review to indicate daily laboratory reports were generated for Hilo Benioff Medical Center corrected inpatient results. A Laboratory Information Systems (LIS) 2026 summary of daily corrected reports was printed on 6/17/2026 at 10:30 AM. The general supervisor interviewed on 6/17/2026 at 10:35 AM stated 9 of 9 corrected reports on this summary were outpatient reports and confirmed the laboratory did not monitor its corrected inpatient reports. 2. The laboratory Error Prevention and Detection Policy states "III. Report Review: Departmental Logs: The laboratory staff on the dayshift in the core lab is responsible for reviewing the departmental logs for those tests not interfaced with the computer. The staff will review AT LEAST 10% of the logs for apparent data entry errors, unusual results, and flagged results which may require further investigation". No documentation was presented for review to indicate laboratory staff generated and reviewed 10% of department logs for tests not interfaced with the laboratory LIS for data entry errors or unusual results. 3. An inpatient corrected <i>Angiostrongylus cantonensis</i> (rat lung worm disease) RTPCR report on cerebral

spinal fluid (CSF) accession number 112564 collected 3/10/2026 at 15:15 PM was generated by the LIS department on 6/17/2026 at 10:58 AM. The Hawaii Department of Health (DOH) Disease Investigation Branch 3/18/2026 Angiostrongylus cantonensis RTPCR report on the specimen stated "Interpretation: No Angiostrongylus cantonensis Nucleic Acid Detected". The report was corrected on 3 /19/2026 at 11:36 AM to state "Angiostrongylus cantonensis Nucleic Acid Detected". The general supervisor interviewed on 6/172026 at 11:05 AM stated Clinical Labs of Hawaii CLIA# 12D0664165 Client Service employees are responsible for manually transcribing DOH test results into the LIS. The general supervisor confirmed reports transcribed by Clinical Labs of Hawaii Client Service employees were not verified for accuracy by Clinical Labs of Hawaii Hilo Benioff Medical Center laboratory staff.

D6083

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

This STANDARD is not met as evidenced by:
The surveyor's review of laboratory quality assurance procedures, laboratory reports, and interview with the general supervisor on 6/17/2026 between 9:00 AM and 11:50 AM revealed the laboratory director failed to ensure the laboratory quality management program was maintained to monitor the quality its test reporting. The findings include: 1. The laboratory failed to monitor its corrected inpatient reports. No documentation was presented for review to indicate the laboratory followed its Laboratory Quality Management Program Quality Assurance Aims procedure. 2. The laboratory failed to verify the accuracy of manually transcribed reports to include performing a review of department logs for non-interfaced LIS data entry errors and unusual results which may require further investigation. No documentation was presented for review to indicate the laboratory followed its Error Prevention and Detection Policy. 3. See D tag D5891