Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0860800	03/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Straub Medical Center Poct	888 S King Street, Honolulu, 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
D0000	An on-site validation survey was conducted on March 09, 2026 with the following standard level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, competency assessment documentation and interview with Technical Consultant (TC) #1, according to the Centers for Medicare and Medicaid Services (CMS) 209 Form, the laboratory failed to establish and follow a policy for consultant competency assessment for three of three Technical Consultants (TC). Findings Included: 1) Review of the laboratories policy titled 'Hawaii Pacific Health Straub Benioff Medical Center POCT Quality Assurance' did not state written policies or procedures to assess consultant competency. 2) The laboratory was asked to provide documentation of consultant competency assessment for three TCs. No documentation was provided. 3) In an interview on 3/09/2026 at 11: 45 AM in the conference room, TC#1 confirmed the laboratory did not have an established policy to perform competency assessments for the consultant roles, and did not have consultant competencies on file.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Proficiency Testing (PT) records, and interview with Technical Consultant (TC) #1, according to the Centers for Medicare and Medicaid Services, the laboratory failed to document corrective action when PT results were unacceptable or unsatisfactory for 2 of 12 PT events reviewed in the specialties of Chemistry and Hematology, between 2024 and 2025. Findings Included: 1) Review of the laboratory's policy titled 'Hawaii Pacific Health Straub Benioff Medical Center POCT Quality Assurance' stated the following on page 10 of 19: "IX. Proficiency Testing Program H.Evaluation of PT Test Results, 5. Documenting Investigation and Corrective Action Plan of Action: a. Documenting the investigation step by step. b. Design a Corrective Plan of Action(s) on findings to prevent recurrence. c. Present investigation with summary indicating the root cause of the problem and Plan of Action to the POCT Medical Director for his/her review and signature. d. Complete investigation within 14 days from the arrival of the test results ..." 2) Review of the laboratory PT records revealed failures for the following events, with no substantiating documentation of the corrective action: a. College of American Pathologists (CAP) Event: SO-A 2024, Kit ID: 37774994, Instrument: Rapidpoint 500e, Date: 2/27/2024, Analyte(s): Total Hemoglobin (tHb), Result(s): No result (Not analyzed) b. American Proficiency Institute (CAP) Event: Chemistry Core - 1st Event, Instrument: iSTAT, Date: 1/23/2024, Analyte(s): pCo2, pH, pO2, Result(s): pCO2 (51), pH (7.18), pO2 (129). 3) In an interview on 3/9/2026 at 1:00 PM in the conference room, TC #1 confirmed he did not have the substantiating documentation of the corrective action counseling and instructional re-training provided to testing personnel who performed the PT for the two PT event failures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer instructions, laboratory policies, temperature records, and interview with Technical Consultant (TC) #1, according to the Centers for Medicare and Medicaid Services (CMS) Form 209, the laboratory failed to define room temperature ranges consistent with manufacturer instructions of storage requirements for five of five boxes of i-STAT EG7+ and ACT Cartridges, and one of one box of RAPIDPoint 500 Wash/Waste Cartridge. Findings Included: 1) During a laboratory tour on 3/9/2026 at 9:30AM, the following reagents were observed stored on the shelves of the Cath lab and Intensive Care Unit (ICU) North Point of Care Testing (POCT) areas: a. One Box of i-STAT EG7+ Cartridges (Lot Number N25243), Manufacturer Storage Temperature Requirements 18 to 30 degrees Celsius. b. Four Boxes of i-STAT ACT Cartridges (Lot Numbers R25319A, R26028), Manufacturer Storage Temperature Requirements 18 to 30 degrees Celsius. c. One Box of RAPIDPoint 500 Systems (Lot Number WW/01526), Manufacturer Storage Temperature Requirements 2 to 25 degrees Celsius. 2) Review of the laboratories

	policy titled 'Hawaii Pacific Health Straub Benioff Medical Center POCT Quality Assurance' stated the following on page 4 of 19: "Definitions - Room Temperature: 15 to 30 degrees Celsius." In addition, the following was stated in Appendix A of the policy: "I-STAT - all reagents, Storage/Special Handling: Room temperature ACT (ACT Plus), Storage/Special Handling: Room temperature ACT (HMS Plus), Storage /Special Handling: Room temperature Blood Gas and Co-oximetry (Rapidpoint), Storage/Special Handling: Room temperature" 3) Review of the SensoScientific Continuous Temperature Monitoring records revealed the following allowable temperature ranges set, before alerting, for the Catheter Lab and ICU North locations where the laboratory performed testing and stored reagents: a. Hospital 2nd Floor, Catheter Lab, Node A0B3 - Acceptable Temperature range 17 to 23 degrees Celsius b. Hospital 2nd Floor, ICU North, Node A4A1 - Acceptable Temperature range 15 to 40 degrees Celsius 4) In an interview on 3/9/2026 at 9:30AM in the conference room, TC#1 confirmed the laboratory did not define temperature ranges in the policy and in the SensoScientific temperature monitoring system in accordance with manufacturer instructions.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, delegation of responsibilities and duties, and interview with Technical Consultant (TC) #1, according to the Centers for Medicare and Medicaid Services (CMS)-209 Form, the Laboratory Director failed to specify, in writing, the responsibilities and duties of each consultant listed on the CMS-209 Form for three of three consultants. Findings Included: 1) Review of the laboratories 'Hawaii Pacific Health Straub Benioff Medical Center POCT Quality Assurance' stated the following on page 5 of 19: "III. Responsibilities/Designated Duties, A. Ultimate responsibility of the entire program falls under the guidance of the POCT Medical Director, to include approval of testing sites, tests to be performed and testing personnel." 2) The laboratory was unable to provide a delegation of responsibilities/duties for each TC listed on the CMS 209 Form. 3) In an interview at 1:00 PM in the conference room, TC #1 confirmed the findings the laboratory director did not specify, in writing, the responsibilities and duties for each consultant.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) Form 209, policies and procedures, personnel competency records, and interview with Technical Consultant (TC) #1, according to the CMS Form 209,

	TC #1 failed to ensure documentation of annual competency for 96 of 96 Testing Personnel (TP). Findings Included: 1) Review of the laboratory's CMS Form 209 revealed 96 TPs performing moderate complexity testing. 2) Review of the laboratory's policy titled 'Hawaii Pacific Health Straub Benioff Medical Center POCT Quality Assurance Policy and Procedure' revealed elements regarding the evaluation of competency of testing personnel but did not include documenting competency assessment as required under 493.1413. 3) Review of the laboratory's competency records revealed evaluation cover sheets with six required elements for competency assessment for each testing personnel, but no substantiating documentation provided of the competency assessment activities performed. In addition, the laboratory had a spreadsheet to track what/when competencies were completed, and due, but no supporting documentation. 4) In an interview at 1:00PM in the conference room, TC #1 confirmed the findings the laboratory did not include documentation of the six-element competency assessment requirements performed to support the TP evaluation.