Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D1000215	03/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hawaii Orthopaedics Inc	670 Kekuana Street, 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
D0000	Based on the results of a focused complaint survey performed at Hawaii Orthopaedics Inc dba Hilo Urgent Care Center located at 670 Kekuanaoa Street, Hilo, HI, CLIA#12D1000215, on March 25, 2025, the laboratory was found to not be in compliance with 42 CFR Part 493, Condition-level requirements. D8100 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA exempt laboratories. The surveyor's review of laboratory procedures, and an interview with the Executive Director on March 25, 2025 at 10:30 AM revealed the Hawaii Orthopaedics Inc dba Hilo Urgent Care Center laboratory located at 670 Kekuanaoa, Hilo, HI 96720 failed to meet the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Amendment of 1988 (CLIA).
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with testing personnel TP#6 on March 25, 2025 at 9:30 AM revealed the laboratory failed to follow Visby Medical Sexual Health manufacturer's instructions for performing qualitative Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis testing. The laboratory performed 372 tests in 2024. The findings include: 1. Visby Medical manufacturer instructions for Quality Control state "External controls should be run using the same step-by-step instructions in this guide. The controls must be tested with each new shipment received and once for each untrained operator." "EXTERNAL POSITIVE AND NEGATIVE CONTROLS" Natrol Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis Controls by ZeptoMetrix

	Corporation." TP#6 stated the laboratory did not run external controls. There was no evidence of external quality control reagents in the laboratory.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 (a) Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. (b) All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: The surveyor's review of laboratory procedures, and an interview with the Executive Director on March 25, 2025 at 10:30 AM revealed the Hawaii Orthopaedics Inc dba Hilo Urgent Care Center laboratory located at 670 Kekuanaoa St, Hilo HI 96720 failed to meet the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The findings include: 1. Hawaii Orthopaedics Inc dba Hilo Urgent Care Center owns and operates the Keaau Urgent Care Center laboratory located at 16-590 Old Volcano Raod, Keaau, HI 96749. The Keaau Urgent Care Center Laboratory does not possess a CLIA certificate and Hawaii Clinical Laboratory license and has performed patient testing since July 2008. The Keaau Urgent Care laboratory performed an annual volume of 12,642 waived tests in 2024 to include Abbott ID Now COVID-19 2.0 tests, Abbott ID Now Influenza A&B 2 tests, Abbott ID Now Strep A 2 tests, Abbott ID Now RSV tests, McKesson Consult Diagnostic Urine 6 parameter tests, McKesson Consult Diagnostic Urine hCG tests, Ascensia Contour glucose tests, and Visby Medical Sexual Health tests. 2. The Executive Director stated that twelve of twelve Hilo Urgent Care Center laboratory testing personnel provide staffing for the Keaau Urgent Care Center laboratory on a rotating basis. 3. The Executive Director stated the Hilo Urgent Care Center laboratory does not possess a Hawaii Clinical Laboratory license. The laboratory opened in June 2003. 4. The laboratory failed to provide copies or exact duplicates of all records and data requested during the inspection process. Refer to D tag D8103.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's

	compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the Executive Director on March 25, 2025 at 10:45 AM revealed Hawaii Orthopaedics Inc dba Hilo Urgent Care Center failed to provide copies or exact duplicates of all records and data requested during the inspection process. The findings include: 1. The Hilo Urgent Care Center laboratory employs twelve testing personnel performing waived testing on walk in patients to include Kaiser Permanente patients. The surveyor observed a new employee receiving training verbally on an Abbott ID Now instrument on March 25, 2025 at 10:15 AM. The Executive Director stated the laboratory does not document testing personnel training. The laboratory performed an annual volume of 6,493 Abbott ID Now COVID-19 2.0 tests, 10,660 Abbott ID Now Influenza A&B 2 tests, 3,282 Abbott ID Now Strep A 2 tests, 121 Abbott ID Now RSV tests, 223 McKesson Consult Diagnostic Urine 6 parameter tests (leukocytes/nitrite/blood/pH /protein/glucose), 124 McKesson Consult Diagnostic Urine hCG tests, 84 Ascensia Contour glucose tests, and 372 Visby Medical Sexual Health tests (Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis) in 2024. 2. The Hilo Urgent Care Center laboratory operates twelve Abbott ID Now instruments, serial numbers 92B5F41C, 085FE81C, 98F6401D, E4F6DC1C, 87D8F41C, 8A49K11D, 3371E61C, CD1FD91C, 763B051F, 54C6401D, C0C6F41C, B199F41C. Six instruments are located in the laboratory testing room and six are located outside of clinic rooms. The Executive Director stated the laboratory does not document operating environment temperatures and humidity levels for the six instruments outside of the clinic rooms. The Abbott ID Now Instrument User Manual lists temperature and humidity ranges as 15-30 degrees Centigrade and 10-80% respectively. The Abbott ID Now Instrument User Manual, section 1.6 Maintenance & Cleaning states "Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily". Documentation of this activity as performed by testing personnel was not kept. 3. The Executive Director stated the laboratory does not keep documentation of patient test requests, test records, and test results. The Executive Director stated that reagent quality control was performed per manufacturer instructions although documentation of this activity was not kept. There was no evidence of external quality control reagents in the laboratory. Refer to D tsg D1001.