| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 12D0646259 | 08/12/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Hawaii Dept Of Health | 2725 Waimano Home Rd, Pearl City, 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 |
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| **D0000** | Federal Surveyors from the Centers for Medicare& Medicaid Services (CMS) Survey Branch conducted a recertification survey on 8/11/2025 and 8/12/2025. The following standard level deficiencies were cited. The CMS-2567 was revised on 9/18/2025 and the tag D5451 was removed. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the laboratory's policies, manufacturer's instruction for warmmark temperature indicators, laboratory specimen temperature records, and interview with Technical Supervisor #1, the laboratory failed to follow their own procedures and take corrective action when specimens transport conditions were not within the laboratory's acceptable temperature ranges for Leptospira IgM antibody (Lepto) and Syphilis (RPR) serology for 3 of 11 daily shipments received on August 11, 2025 as evidenced by: 1. In review of the laboratory's policy, "Specimens Submission Requirement for the Syphilis Examination of Blood", stated "specimens are to be delivered to the Medical Microbiology Branch of the State Laboratory Division (SLD) at a transport temperature of 2-8 degrees. 2. In review of the laboratory's policy, "Specimens Submission Requirements for the Detection of Leptospira IgM Antibody," stated "specimens are to be delivered to the Medical Microbiology Branch of the State Laboratory Division (SLD) at a transport temperature of 2-8 degrees." 3. In review of the Warmark temperature, "Any sign of |

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| | color in the breach window after arming including light pink, pink or red is a sign of temperature excursion equal or above the time and temperature specification ... Brief runout time 2-8 degrees is 2 hours." 4. In review of the laboratory's specimen temperature records for 8/6/2025, the following three shipments were briefly out of 2-8 degrees range according to the warmark temperature indicator: a. Serum specimens received at 9:55 am b. VTM Specimens received at 9:55 am c. Blood specimens received at 9:55 am The laboratory did not take corrective action and tested the specimens for both Lepto and RPRs. 5. The following patients were tested briefly outside of the laboratory's acceptable temperature transport temperature: a. Patient #YF53335945 Lepto b. Patient # 121295 RPR c. Patient # 122184 RPR d. Patient # 122180 RPR e. Patient # 122181 RPR f. Accession # 81449 RPR g. Accession # 81448 RPR h. Accession # 81447 RPR i. Accession #81446 RPR j. Accession # 81445 RPR 6. In an interview with the Technical Supervisor #1 on 8/11/2025 at 1200 she stated that the specimens were tested and they were out of our acceptable range. 47107 II. Based on direct observation, manufacturer's instructions for transport and processing, laboratory test volume records, and confirmed in interview with the Technical Supervisor (TS)-1 according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow manufacturer's instructions for processing 14 of 14 Hologic Aptima Combo 2 Assay Tubes on 8/11/2025. Findings Included: 1. In direct observation on 8/11/2025 at 10:03 AM in the processing section, the following CT/GC Hologic Aptima specimen tubes for differing patients were shipped together in paper cups and plastic specimen bags physically touching one another for different patients: a. 1 Tube, CoC: L32186, Sample ID: 122113, MRN: 122113, Collection Date: 8/08/2025 b. 1 Tube, CoC: L32187, Sample ID/MRN: 117779, Collection Date: 8/08/2025 c. 2 Tubes, CoC: L32189, Sample ID/MRN: 122193, Collection Date: 8/08/2025 d. 2 Tubes, CoC: L32194, Sample ID/MRN: 122192, Collection Date: 8/08/2025 e. 2 Tubes, CoC: L32195, Sample ID/MRN: 119980, Collection Date: 08/08/2025 f. 1 Tube, CoC: L32199, Sample ID/MRN: 122194, Collection Date: 08/08/2025 g. 1 Tube, CoC: L32208, Sample ID/MRN: 112196, Collection Date: 08/08/2025 h. 1 Tube, CoC: L32210, Sample ID/MRN: 121405, Collection Date: 08/08/2025 i. 1 Tube, CoC: L32211, Sample ID/MRN: 122195, Collection Date: 08/08/2025 j. 1 Tube, CoC: L32212, Sample ID/MRN: 120145, Collection Date: 08/08/2025 k. 1 Tube, CoC: L32214, Sample ID/MRN: 093760, Collection Date: 08/08/2025 2. A review of manufacturers instruction for the Aptima Combo 2 Assay Panther System (502446 Rev. 009) stated the following on page 5: "Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen contains do not contact one another, and discard used materials without passing over open containers." 3. A review of the laboratory's test volume records from 05/01/2025 to 07/31/2025 (random review) revealed 3,594 CT/GC specimens run on the Hologic Panther. 4. In an interview on 8/11/2025 at 10:05 AM in the processing area, the TS-1 confirmed the observation that the Hologic Aptima tubes for CT/GC testing were often sent in a manner where samples for several different patients were placed in the same plastic bag, or in paper cups to the laboratory. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(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:
I. Based on direct observation, review of the laboratory's temperature records, and interview with General Supervisor #3 the laboratory failed to define, monitor, and document room temperature where temperature dependent 2 of 2 reagents were stored in room 2127 as evidenced by: 1.In direct observation on 8/11/2025 at 1030 in room 2127 the laboratory had stored the following reagents that were indicated by the manufacturer of having storage temperature requirements: a. 1- box of QC slide gram stain lot# 074993, the manufacturer instructions printed on the side of the box states, "store at 20-25 degrees C." b. 1- bottle of Resolve Immersion Oil lot #153292 expiration date of 12/13/2026. The manufacturer stated on the bottle, "Store at 15-30 degrees C." 2.The laboratory could not provide any temperature records for room 2127. 3.In an interview with General Supervisor #3 on 8/11/2025 at 1031 stated that they didn't monitor or record room temperature and they move the thermometer to the MALTI room. 47107 II. Based on direct observation, manufacturer's instructions, temperature records, and interview with Technical Supervisor (TS)-2, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to define, monitor and document the temperature in the 'DIL-Alco' hallway where seven of seven temperature dependent Laboratory Response Network (LRN) reagents were stored. Findings Included: 1. In direct observation on 8/11/2025 at 8:48 AM, the following reagents were seen in storage in the DIL-Alco hallway next to the LRN laboratories: a. 4 boxes of BioFire Defense, Film Array NGDS Warrior Panels, Lot #s 301625D, Manufacturer storage temperature requirements, 18 to 30 degrees C. b. 3 boxes of Biofire Defense, Biofire Shield Control Kit for the BioFire Global Fever Special Pathogens Panel, Lot #s 305125D, Manufacturer storage temperature requirements, 18 to 30 degrees C. 2. Review of laboratory temperature records revealed no defined temperature ranges, monitored, or documented in the DIL-Alco hallway where the LRN reagents and supplies were stored. 3. In an interview on 8/11 /2025 at 8:49 AM, the TS-2 confirmed that the DIL-Alco hallway where the LRN reagents and supplies were stored, did not have defined temperature ranges and was not monitored or documented. III. Based on direct observation, manufacturer's instructions, review of temperature ranges, and interview with the General Supervisor (GS)-2 according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to define temperature ranges consistent with the manufacturer's instructions, for the -20 degree Celsius freezer where two of two temperature Invitrogen reagents were stored. Findings Included: 1) In direct observation on 8/11 /2025 at 11:36 AM in Room 2316 of the Medical Microbiology Branch (MMB)-Virology section, one Freezer (Corepoint Scientific, Serial Number # CPS 20178626-2306) was observed in use with a temperature setting of less than or equal to -20 degrees Celsius (C) [ Thermometer F11, Serial Number 240521511], and the following reagent stored within: a) Two boxes Invitrogen SuperScript III Platinum One-Step qRT-PCR System, Lot Number #3026232, Manufacturer storage temperature requirements -25 to -15 C. 2) In an interview on 8/11/2025 at 11:36 AM in Room 2316 of the Medical Microbiology Branch (MMB) - Virology section, the GS-2 confirmed the freezer temperature settings were not defined consistent to the manufacture's instructions. IV. Based on direct observation, review of laboratory policy, temperature ranges, and interview with Technical Supervisor (TS)-2 according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to define its own defined temperature ranges for storage of 2 of 2 extraction controls and

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| | stock cultures for Laboratory Response Network (LRN) testing. Findings Included: 1) In direct observation, on 8/12/2025 at 11:34 AM in the Biological Response Section (BRS), room 2206, the following freezers and contents within were seen: a) one New Brunswick Ultralow Freezer, Model Number Innova #U535-86, Serial Number #F35DQ430194 was seen with a temperature range of -85 to -65 degrees Celsius (C) [No correction Factor as of 12/5/24], and Angiostrongylus cantonensis extra controls stored within. b) one PhCbi Ultralow Freezer, Model Number MDF #DU502VHA-PA, Serial Number #24060104 was seen with a temperature range of -85 to -65 C (Correction Factor +1 as of 1/10/25), and stock cultures (mumps) stored within." 2) Review of the laboratory section's policy titled "Laboratory Preparedness and Response Branch (LPRB) Biological Reponse Section (BRS) Specimen Management Standard Operating Procedure (SOP) Amplification of Angiostrongylus cantonensis" stated the following: "A. Preparation of Extraction Controls: 1. Human Speciment Control (HSC) - A549 Cells: 1.1 Order a batch of A549 cells. 1.2 Upon receipt freeze tubes or flasks that cells were grown in at -70 C.. 1.5. Aliquot into usable volumes for one-time use. Freeze aliquots at -70 C ..." 3) Review of the section's policy titled "Laboratory Preparedness and Response Branch (LPRB) Biological Reponse Section (BRS) Standard Operating Procedure Real Time (TaqMan) RT-PCR Assay for Detection of Mumps Virus RNA in Clinical Samples" stated the following: "4. Reagent Control (RC): 4.1 Aliquot VTM or PBS into usable volumes for on-time use. Freeze aliquots at -70 C. 5. Human Specimen Control (HSC) - A549 Cells: 5.1 Order a batch of A549 cells. 5.2 Upon receipt freeze tubes or flasks that cells were grown in at -70 C.. 5.5. Aliquot into usable volumes for one-time use. Freeze aliquots at -70 C ..." 4) In an interview on 8/12/2025 at 11:36 AM in Room 2206 of the LRN BRS laboratory, the TS-2 confirmed the freezer temperature settings were not defined consistent to the laboratory's defined criteria of essential for proper storage of reagents and specimens, according the SOP. V. Based on direct observation, review of manufacturer's instructions, and interview with the General Supervisor (GS)-2 according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow manufacturer's instructions for storage for one of one boxes of reagents. Findings Included: 1) In direct observation on 8/11/2025 at 11:36 AM in Room 2316 of the Medical Microbiology Branch (MMB)- Virology section, one Freezer (Corepoint Scientific, Serial Number # CPS 20178626-2306) was observed in use with a temperature setting of less than or equal to -20 degrees Celsius (C) [ Thermometer F11, Serial Number 240521511], and the following reagent stored within: a) One box CDC Influenza Virus Real-Time RT-PCR Panel, Panel Lot #230801, Exp. Date 2026-11-28, Manufacturer storage temperature requirements 2-8 C. 2) In an interview on 8/11/2025 at 11:36 AM in Room 2316 of the MMB-virology section, the GS-2 confirmed the CDC reagent was stored improperly in the wrong area (freezer instead of 2-8 C refrigerator), and not in accordance with manufacturer storage condition requirements. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on direct observation, review of the laboratory inventory, and interview with General Supervisor #3, the laboratory failed to document the expiration date of frozen ATCC stock strains of 31 of 31 reviewed as evidenced by: 1. In direct observation on 8-11-2025 at 1327 the following E.coli stock strain was not labeled with an expiration date: E.coli ATCC #25922. None of the ATCC strain had an expiration date. 2.In review of the laboratory inventory worksheet, the laboratory did not have expiration dates listed for the 31 bacteria listed in their inventory. 3. In interview with General Supervisor #3 on 8-11-2025 at 1327 she stated that none of the bacteria strains had an expiration date labeled on them and the frozen vials were good indefinitely. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of manufacturer's instructions, laboratory maintenance records (5/1/2025 - 7/31/2025), test volume records, and interview with the General Supervisor (GS)-2 according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow the operator's manual for the Hologic Panther System daily mag wash maintenance and cleaning for two of two Hologic Panther Analyzers. Findings Included: 1) In direct observation on 8/11/2025 at 11:38 AM in the virology section, two Hologic Panther Analyzers were observed in use (Serial Numbers #03743, 00421). 2) A review of manufacturer's instructions (AW-20220-001 Rev. 001) for the Hologic Panther revealed the following maintenance requirements for the mag wash cleaning: "As part of system maintenance, it is required that this task be performed after each testing day. For example, if processing test orders on Monday-Friday, schedule the Mag Wash Clean task to be run after working hours on Monday-Friday." 3) A review of the laboratory's onboard Panther Fusion Maintenance Log Reports from May 1, 2025, to July 31, 2025, revealed Mag Wash interval settings set to be completed midday at 13:09 and 15:34 and not at the end of each day testing was performed (Serial Numbers #03743, 00421). 4) A review of the laboratory's test volume records from 05/01/2025 to 07/31/2025 (Random review) revealed 1,671 CT/GC specimens run on the Hologic Panther Serial Number #03743, and 1,923 CT/GC specimens run on the Hologic Panther Serial Number #00421. 5) In an interview on 8/11/2025 at 10:05 AM in the virology section, the GS-2 confirmed the Mag Wash settings were not set to be performed in accordance with the manufacturer's instructions at the end of each testing day. Word Key: CT/GC - Chlamydia/Gonorrhea |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, and interview with Technical supervisor |

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| | #1, the laboratory failed to have a policy for twice a year evaluates and define the relationship between two real-time PCR ABI 7500 instruments used for testing Bordetella pertussis as evidenced by: 1. In review of the laboratory's policies, the laboratory did not have a department policy for twice a year evaluation of two real-time PCR ABI 7500 instruments for Bordetella pertussis. They could not provide a policy. 2. In interview with General Supervisor #3 on 8/11/2025 at 1429 stated they don't have a policy like the other branch for a twice a year verification. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the temperature records, laboratory policies, and interview with the General Supervisor (GS)-2, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to document corrective actions when the refrigerator was recorded outside the acceptable range in the MMB (Medical Microbiology Branch) - Virology section for 5 of 19 months reviewed from January 2024 to July 2025 (random review). Findings Included: 1) In direct observation on 8/11/2025 at 11:50 AM in the virology section, one refrigerator (Serial Number #1161327201200601, Thermometer Serial Number 230190951) was observed in use with a range of 2 to 8 degrees Celsius (C). 2) Review of the laboratory's refrigerator temperature records titled, "Medical Microbiology Branch Freezer & Refrigerator Temperature Chart, Equipment 1161327201200601, Thermometer Serial Number 230190951" revealed an acceptable temperature range of 2 to 8 C. For the following months and dates, the temperature was out of acceptable range with no documented corrective action: a) January 2024: 1/2/24 - 8.9 C 1/23/24 - 9.2 C b) February 2024: 2/2/24 - 9.3 C c) November 2024: 11/1/24 - 8.2 C 11/2/24 - 8.2 C 11/28/24 - 8.9 C d) December 2024: 12/8/24 - 8.9 C 12/13/24 - 8.9 C 12/28/24 - 10.0 C 12/29/24 - 10.0 C e) May 2025: 5/5/25 - 9.5 C 3) Review of the MMB-Virology laboratory section's policies revealed no instructions to document corrective actions for temperature deviations outside of the laboratory's verified or established specifications for the refrigerator or freezers. 4) In an interview on 8/11/2025 at 11:54 AM, the GS-2 confirmed the laboratory section did not document corrective actions for when temperatures deviated outside of established ranges. |