H1N1 Diagnostic Capability via the Joint Biological Agent Identification Diagnostic System (JBAIDS)

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ABSTRACT

The H1N1 influenza pandemic of 2009 directly impacted the missions of the USS RONALD REAGAN (CVN 76) and the USS BATAAN (LHD 5) and other Navy ships. As new outbreaks were anticipated and no vaccine was available, by August 2009, VADM Gortney requested the accelerated fielding of JBAIDS to provide ship medical personnel the H1N1diagnostic capability on forward deployed ships.

The H1N1 diagnostic assay, provided by the Centers for Disease Control (CDC), was adapted and tested for use on the JBAIDS, receiving the Food and Drug Administration (FDA) authorization for emergency use in August 2009. JBAIDS is the program of record to meet the need for confirmatory testing of possible contamination by biological warfare agents aboard ship. Aboard ship, hand-held assays for presumptive testing of biological warfare agents from environmental samples are utilized to provide a quick-look result in minutes, but do not have the accuracy needed to justify the medical treatment of sailors. JBAIDS utilizes polymerase chain reaction (PCR) technology, which is more accurate than the antigen-antibody based technology utilized in the hand-held assays. JBAIDS provides confirmatory identification in a matter of a few hours. For legal and forensic purposes, a sample can also be sent away to a definitive lab. This thorough identification can take weeks, which is too long to begin implementation of protective measures for the warfighter aboard ship. With contamination or infection by known biological agents, specific symptoms can be anticipated, appropriate medication for prophylaxis or treatment can be identified, likely course of illness or contamination can be anticipated, and the appropriate protective posture can be implemented.

Since the initiation of the accelerated fielding of JBAIDS, an effective vaccine for H1N1 has been produced and administered. This has allayed many of the fears of the effects of H1N1 globally; however, the rapid mobilization of getting the H1N1 diagnostic capability to the ships has put into place an infrastructure for the next pandemic. We know the paths to take for getting a new medical diagnostic capability to the Fleet, and should this or another strain mutate or a new biological threat present itself, Naval Surface Warfare Center stands ready.

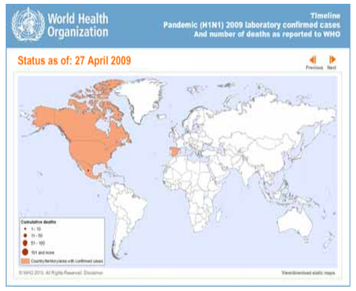
INTRODUCTION

Because of the close quarters of a shipboard environment, a respiratory illness such as influenza spreads rapidly and renders personnel unable to perform their normal duties. As a result, scheduled exercises may be cancelled or deployments may be postponed until the situation is mitigated.

The Office of the Joint Project Manager for Chem/Bio Medical Systems provided H1N1 support equipment to supplement the JBAIDS package and assisted in the acceleration process to field JBAIDS to the ships.

While the modification and testing of the H1N1 assay for use on the JBAIDS platform was underway during the spring of 2009, personnel at Naval Surface Warfare Center Dahlgren Division (NSWCDD) responded to the possibility of accelerating the fielding by addressing the shortest time possible to get the H1N1 diagnostic capability with JBAIDS to the ships. This included the renegotiation of contracts to acquire the hardware and perishable consumables in a shorter time frame, the surge in training by the JBAIDS schoolhouse to accommodate additional Navy JBAIDS operators, the surge in provision of operator support, and the accelerated install process (with all the coordination and work needed to formally install a system aboard ship). After all time requirements for the different aspects of fielding were identified, the JBAIDS fielding schedule was compressed from three years to nine months.

Progression of H1N1 Pandemic



INTENDED USE STATEMENT

The CDC swH1N1 (swine) Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) on the JBAIDS instrument is intended for use in real-time RT-PCR assays on a JBAIDS instrument in conjunction with clinical and epidemiological information:

- For the qualitative detection of influenza virus type A viral RNA in nasopharyngeal swabs (NPS) from patients with signs and symptoms of respiratory infection or viral culture.
- For the identification of the 2009 H1N1 Influenza virus from viral RNA in nasopharyngeal swabs (NPS) from patients with signs and symptoms of respiratory infection and from viral culture in conjunction with clinical and epidemiological risk factors.

Testing with the swine influenza swInfA and swH1 primer and probe sets should not be performed unless the patient meets clinical and epidemiologic criteria for testing suspect specimens. The identification of 2009 H1N1 influenza virus should be performed along with clinical and epidemiological assessment.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by JBAIDS instructors or designees prior to use. Use of this device is limited to designated Department of Defense (DoD) laboratories equipped with the JBAIDS instruments.

EMERGENCY USE AUTHORIZATION (EUA)

- An Emergency Use Authorization (EUA) may be issued by the Food and Drug Administration (FDA) to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies with specified agents.
- The EUA use of the swine influenza H1N1 test capability on JBAIDS is limited to qualified Department of Defense (DoD) laboratories.

JBAIDS

H1N1 Training Program

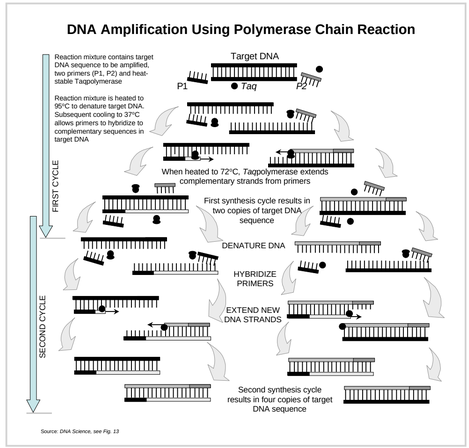
Certification for the operator is achieved with 85% score on written exam and successful run (all controls correct) on lab exam

JBAIDS

Confirmatory Test

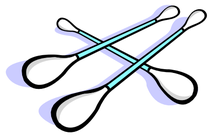
- DNA or RNA is extracted from the specimen and combined with cocktail to allow for DNA amplification and detection
- DNA + cocktail combination is loaded onto instrument and produces positive or negative results for the specimen

DNA Amplification using PCR

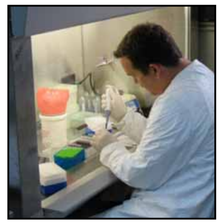


H1N1 SAMPLE PROCESS

Nasopharyngeal Swab



Sample Prep and Reaction Prep



JBAIDS Analysis

NSWCDD ROLE

- Acquisition Engineering Agent (AEA) and Technical Direction Agent (TDA), In-Service Engineering Agent (ISEA)
- Alteration Installation Team (AIT)
  - Standard Operation Verification Test (SOVT)
- Waterfront Team
  - Readiness Assist Visit (RAV)

SUMMARY

- The JBAIDS can be utilized for both biological warfare agents and for naturally occurring biological pathogens of interest.
- The JBAIDS analyzer and software can be updated as new assays are developed.
- The infrastructure is in place for the rapid deployment of new JBAIDS assays to meet emerging detection needs.
- Two-year assay kit stability testing is in progress.

ACKNOWLEDGEMENTS

This effort is supported by the Joint Program Manager Chemical Biological Medical Systems (JPM CBMS) and Naval Sea Systems Command (NAVSEA).

We would like to thank Idaho Technology Inc., BDRD and AMEDD for technical support and training.