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

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INTENDED USE STATEMENT

The CDC sw/H1N1 (swine) Influenza Virus Real-time RT-PCR Detection Panel (RT-PCR Swine Flu Panel) and the JBAIDS are utilized 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 sw/H1 and sw/H1 primer and probe sets should not be performed unless the patient meets clinical and epidemiological criteria for testing suspected 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.

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 JBAIDS 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 to the ships. This included the renegotiation of contracts to acquire the hardware and 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.

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