

June 2009: New Press Release From Inverness Medical

Inverness Medical Innovations launches the new FDA cleared
C. DIFF QUIK CHEK COMPLETE® rapid test

Waltham, MA – Inverness Medical Innovations, Inc. (NYSE:IMA), a global leader in enabling individuals to take charge of their health at home through the merger of rapid diagnostics and health management, announced today that it will begin marketing and distributing the new

C. DIFF QUIK CHEK COMPLETE® rapid test as an in vitro diagnostic aid for *Clostridium difficile* associated disease (CDAD). This follows TECHLAB®, Inc.'s recent clearance from the Federal Drug Administration (FDA) to manufacture the product for Inverness. *C. difficile* is responsible for the most common form of hospital-acquired diarrhea and antibiotic-associated colitis. *C. difficile* is highly infectious and a significant danger to the health of immunocompromised or elderly patients. The infection can be life-threatening when not caught in time to allow for appropriate therapy to combat the disease and thereby reduce morbidity associated with CDAD. The new rapid test yields results within 30 minutes and detects all strains of *C. difficile*, including the highly virulent strain BINAP1/027 which is causing outbreaks of increasing severity and mortality across Europe and North America. Collective scientific data suggests that the incidence of *C. difficile* infection (CDI) has recently increased in East Asia and the Middle East, further highlighting the disease as a global epidemic. In US Hospitals alone, current annual spending is estimated at \$40 million in testing aimed at diagnosing CDAD patients in order to provide appropriate therapy and control the spread of the disease. While primarily a hospital-acquired disease, *C. difficile* infection is increasingly occurring in community outpatient settings. This is causing a major problem for hospital and community care environments because the number of patients at risk for *C. difficile* infection is substantial. At present, the incidence of infection has reached epidemic proportions. Recently-released results from the "National Prevalence Study of *Clostridium difficile* in US Healthcare Facilities" indicate that the rate of infection, or colonization, is 6.5 to 20 times greater than previous estimates. The *C. DIFF QUIK CHEK COMPLETE*® test offered by Inverness Medical is the only device that simultaneously detects both *C. difficile* glutamate dehydrogenase (GDH) and *C. difficile* toxins A and B in one simple assay. It can be used for screening while also confirming the presence of toxigenic *C. difficile* strains. The test provides results in less than 30 minutes from fecal samples, enabling rapid diagnosis and initiation of appropriate patient management. With use of a *C. difficile* rapid test, patients can be effectively isolated at an earlier stage of illness, reducing the risk of cross contamination and widespread outbreaks.

The *C. difficile* antigen glutamate dehydrogenase (GDH) used in the test is common to all strains of *C. difficile* and has been identified as an excellent screening marker for the infection. The new

C. DIFF QUIK CHEK COMPLETE® test, developed and manufactured by TECHLAB®, Inc. in Blacksburg, VA, provides a more complete picture of the patient's disease state within one single test format with quicker time to results and higher negative predictive value (less false negative results) when compared to alternative existing testing methods.