

Post-Market Surveillance for the Performance of Influenza A Rapid Test In Vitro Diagnostic Devices

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ABSTRACT

Influenza, commonly referred to as the flu, is an infectious disease that affects birds and mammals. Influenza spreads around the world in seasonal epidemics, resulting in thousands of deaths of people every year, up to millions in some pandemic years. In April 2009, an A (H1N1) influenza virus of swine lineage was detected in humans in the USA, and in just over a month has infected over 10,000 people in more than 40 countries. The type A viruses are the most virulent among all influenza types and cause severe disease. There are primarily two influenza A virus subtypes (H3N2 and H1N1) infecting humans worldwide during the past several decades.

For the patient's well being and for the prevention of virus spread throughout the community, an early influenza diagnosis is required. Influenza A rapid test in-vitro diagnostic devices are the fastest diagnostic tools for the detection of influenza viruses currently. However, the Influenza rapid test in-vitro diagnostic devices were categorized into class 1 (low risk) medical devices in Taiwan. The registration and approval procedures for class 1 medical device imports in Taiwan are not as strict as that for other classes.

We have evaluated the performance of several widely available influenza rapid test in-vitro diagnostic devices in Taiwan. Swine lineage A (H1N1) and the human seasonal influenza strain (H3N2) were cultured, and the cultured viruses and influenza hemagglutinin (HA) were diluted to specific infectivity titres. Viral and HA dilutions were assayed using the rapid test in-vitro diagnostic devices. The study indicated that most of the products detected virus or HA only when they were presented at high concentrations. Early diagnosis of infection can assist in the rapid management. However, the tests are not as sensitive as PCR assays and as such, negative results should be verified by a laboratory test.

Key words: influenza virus, rapid test in vitro diagnostics, post-market surveillance