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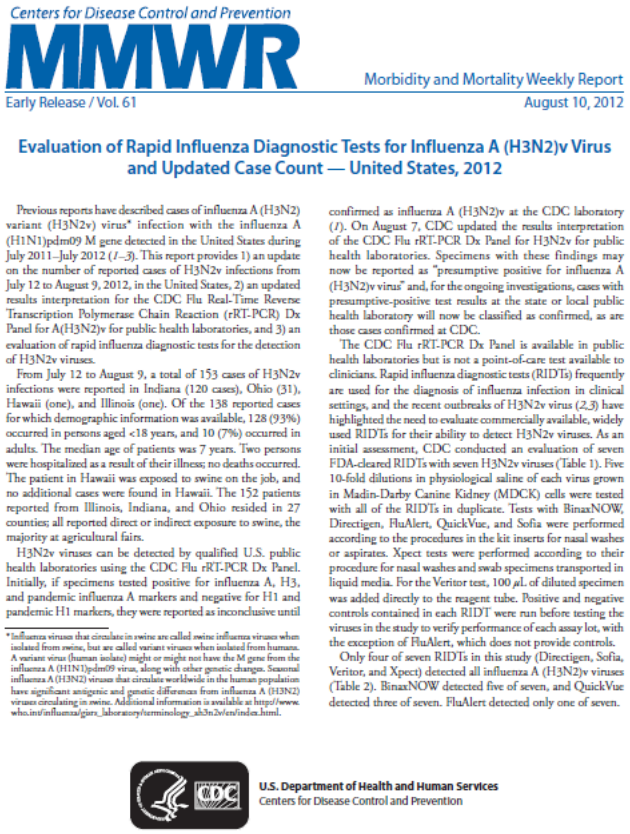
# 変異型インフルエンザ(A/H3N2v)ウイルスに対する迅速診断キットの検出性能について

BDPOC-A/H3N2-01
2012/10/1

**米国 CDC 発行の疫学週報（MMWR）に、近年分離同定された変異型インフルエンザ（A/H3N2v）ウイルスに対するインフルエンザ迅速診断キットの性能評価及び米国における 2012 年の最新の感染者数に関する報告がありました。その中に BD ベリター™ システム Flu に関する評価試験報告がありましたのでお知らせいたします。**



Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 61 August 10, 2012

**Evaluation of Rapid Influenza Diagnostic Tests for Influenza A (H3N2)v Virus and Updated Case Count — United States, 2012**

Previous reports have described cases of influenza A (H3N2) variant (H3N2v) virus* infection with the influenza A (H1N1)pdm09 M gene detected in the United States during July 2011–July 2012 (*1–3*). This report provides 1) an update on the number of reported cases of H3N2v infections from July 12 to August 9, 2012, in the United States, 2) an updated results interpretation for the CDC Flu Real-Time Reverse Transcription Polymerase Chain Reaction (rRT-PCR) Dx Panel for A(H3N2)v for public health laboratories, and 3) an evaluation of rapid influenza diagnostic tests for the detection of H3N2v viruses.

From July 12 to August 9, a total of 153 cases of H3N2v infections were reported in Indiana (120 cases), Ohio (31), Hawaii (one), and Illinois (one). Of the 138 reported cases for which demographic information was available, 128 (93%) occurred in persons aged <18 years, and 10 (7%) occurred in adults. The median age of patients was 7 years. Two persons were hospitalized as a result of their illness; no deaths occurred. The patient in Hawaii was exposed to swine on the job, and no additional cases were found in Hawaii. The 152 patients reported from Illinois, Indiana, and Ohio resided in 27 counties; all reported direct or indirect exposure to swine, the majority at agricultural fairs.

H3N2v viruses can be detected by qualified U.S. public health laboratories using the CDC Flu rRT-PCR Dx Panel. Initially, if specimens tested positive for influenza A, H3, and pandemic influenza A markers and negative for H1 and pandemic H1 markers, they were reported as inconclusive until confirmed as influenza A (H3N2)v at the CDC laboratory (*1*). On August 7, CDC updated the results interpretation of the CDC Flu rRT-PCR Dx Panel for H3N2v for public health laboratories. Specimens with these findings may now be reported as "presumptive positive for influenza A (H3N2)v virus" and, for the ongoing investigations, cases with presumptive-positive test results at the state or local public health laboratory will now be classified as confirmed, as are those cases confirmed at CDC.

The CDC Flu rRT-PCR Dx Panel is available in public health laboratories but is not a point-of-care test available to clinicians. Rapid influenza diagnostic tests (RIDTs) frequently are used for the diagnosis of influenza infection in clinical settings, and the recent outbreaks of H3N2v virus (*2,3*) have highlighted the need to evaluate commercially available, widely used RIDTs for their ability to detect H3N2v viruses. As an initial assessment, CDC conducted an evaluation of seven FDA-cleared RIDTs with seven H3N2v viruses (Table 1). Five 10-fold dilutions in physiological saline of each virus grown in Madin-Darby Canine Kidney (MDCK) cells were tested with all of the RIDTs in duplicate. Tests with BinaxNOW, Directigen, FluAlert, QuickVue, and Sofia were performed according to the procedures in the kit inserts for nasal washes or aspirates. Xpect tests were performed according to their procedure for nasal washes and swab specimens transported in liquid media. For the Veritor test, 100 µL of diluted specimen was added directly to the reagent tube. Positive and negative controls contained in each RIDT were run before testing the viruses in the study to verify performance of each assay lot, with the exception of FluAlert, which does not provide controls.

Only four of seven RIDTs in this study (Directigen, Sofia, Veritor, and Xpect) detected all influenza A (H3N2)v viruses (Table 2). BinaxNOW detected five of seven, and QuickVue detected three of seven. FluAlert detected only one of seven.

*Influenza viruses that circulate in swine are called swine influenza viruses when isolated from swine, but are called variant viruses when isolated from humans. A variant virus (human isolate) might or might not have the M gene from the influenza A (H1N1)pdm09 virus, along with other genetic changes. Seasonal influenza A (H3N2) viruses that circulate worldwide in the human population have significant antigenic and genetic differences from influenza A (H3N2) viruses circulating in swine. Additional information is available at http://www.who.int/influenza/gisrs_laboratory/terminology_ah3n2v/en/index.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

(MMWR / August 10, 2012 / Vol.61)

**本報告において、変異型インフルエンザ（A/H3N2v）ウイルスに対するインフルエンザ迅速診断キットの検出性能は分離されたウイルス株によって異なる結果が得られました。**

**BD ベリター™ システム Flu（本報告内では Veritor と記載）は本試験に用いられた 7 株全ての変異型インフルエンザ（A/H3N2v）ウイルスに対し、高い検出性能を有することが示されました。**

**本報告の全文は、以下の URL でご覧になれます。**
**http://www.cdc.gov/mmwr/pdf/wk/mm61e0810.pdf**

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