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Evaluation of Sofia fluorescent immunoassay analyzer for influenza A/B virus

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ABSTRACT

Background: The influenza virus causes seasonal epidemics which are associated with high morbidity and mortality. Rapid diagnostics tests (RDT) are frequently used to make a quick influenza diagnosis to confirm the clinical suspicion, despite their low sensitivity.
Objectives: Assess the performance of the Sofia Influenza A + B Fluorescence Immunoassay (Quidel, San Diego, CA).
Study design: Nasopharyngeal swabs, taken from 241 patients (influenza A ($n = 73$)/B ($n = 72$), negative samples ($n = 96$)) were analyzed using the Sofia Influenza A + B Fluorescence Immunoassay, BinaxNOW Influenza A/B antigen kit (Alere Inc., USA), Directigen EZ Flu A and B (Becton Dickinson, USA), real-time RT-PCR and an influenza virus culture.
Results: There was a significant difference between the performance of rapid antigen tests and the Sofia FIA, when compared to the RT-PCR, in the detection of influenza strain A and B. Indeed, the Sofia FIA displayed sensitivities of 82.2% and 77.8% for strains A and B respectively, whereas sensitivities of BinaxNOW Influenza A/B antigen kit, and Directigen Flu A and B were 54.8%, and 68.5% for influenza A, and 62.5%, and 52.8% for influenza B respectively. The average RT-PCR threshold cycle (C_t) (±SD) for the Sofia Influenza A + B Fluorescence Immunoassay-positive specimens was higher than those of the BinaxNOW Influenza A/B antigen and the Directigen EZ Flu A and B kit positive specimens.
Conclusion: Compared to other RDTs, the Sofia Influenza A + B Fluorescence Immunoassay is a sensitive, and rapid method for the detection and discrimination between influenza A and B.

1. Background

The influenza virus is a serious public health concern associated with high morbidity and mortality.[9] During the influenza season, various other types of respiratory viruses are prevalent and thus impede the establishment of an accurate clinical diagnosis of influenza as they must be considered in the differential diagnosis of respiratory infection.[4] Yet, the rapid and accurate diagnosis of influenza is essential for the administration of an appropriate treatment.[9]

Different diagnostic methods, such as virus isolation in cell cultures, rapid influenza antigen tests, and detection of influenza-specific RNA by real-time reverse transcriptase (RT)-polymerase chain reaction (PCR), can be used to detect the presence of influenza viruses in respiratory specimens.

The rapid influenza tests are a convenient tool for point-of-care diagnosis due to their ease of use and laboratory independence. Nowadays, there are a number of commercially available direct antigen detection assays for influenza.

Unfortunately, reported sensitivities of RDTs have varied widely from poor to acceptable in comparison with RT-PCR. QuickVue Influenza A + B test ranged from a very low sensitivity (19.7%) to an acceptable sensitivity (82%) for either influenza A or influenza B virus.[11,14] The published sensitivities of BD Directigen Flu A/B, Directigen EZ Flu A/B, BinaxNOW were 56%, 39%, 76% respectively.[15] Therefore, one cannot entirely rely on RDT results to establish a clear diagnosis.[11,14,15]

While rapid influenza diagnostic kits usually use immunochromatographic technology with gold conjugate, the Sofia Influenza A + B Fluorescence Immunoassay (Quidel, San Diego, CA) is RDT employs an advanced immunofluorescence technology with

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Table 1
Characteristics of patients presenting influenza-like symptoms.

Characteristics	Total	Influenza A	Influenza B	Negative
No. of patient	241	73	72	96
Age (mean ± SD)	27.7 ± 29.6	21.3 ± 26.2	16.8 ± 21.2	45.1 ± 27.7
Range of age	5 months–87 years	5 months–88 years	1–78 years	6 months–87 years
Male/female	136:105	38:35	44:28	54:42

europium dye that enhances its sensitivity for influenza A and B viruses.

2. Objectives

In this study, we evaluated the performance of the Sofia Influenza A + B Fluorescence Immunoassay, using frozen stored specimens which were confirmed by RT-PCR and virus culture for presence or absence of influenza A and B viruses.

3. Study design

3.1. Field samples collection and preparation

Nasopharyngeal swabs from 241 patients presenting influenza-like symptoms were collected at Seoul's Korea University Guro Hospital, from December 2011 to February 2012. The sampling time was less than 48 h post onset of illness for all patients. Individuals' ages ranged between 5 months and 88 years old (mean ± SD: 27.7 ± 29.6), with a total of 136 males and 105 females (Table 1).

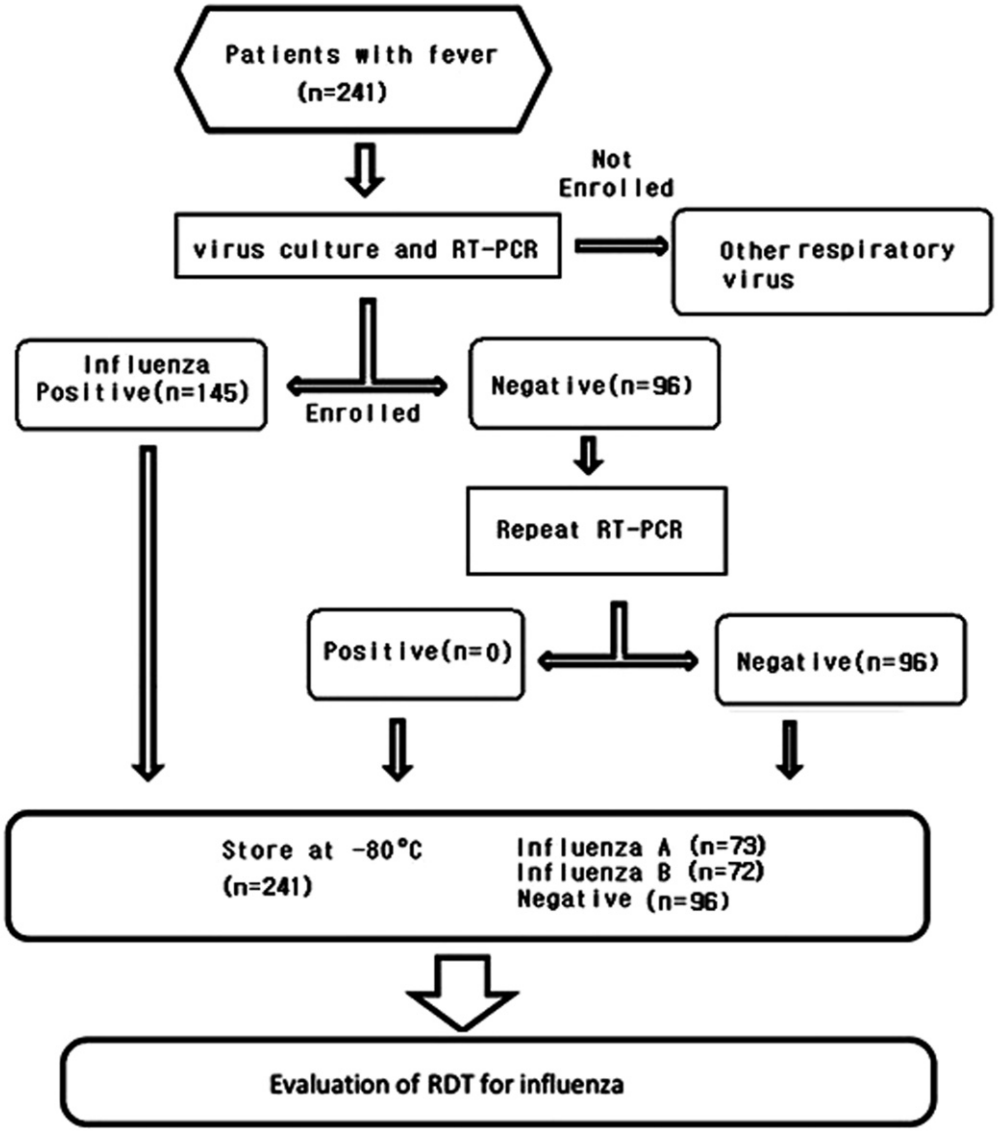

Fig. 1. Flow diagram of sample selection profile in the evaluation: rapid influenza tests, virus culture, and PCR were performed.