Rapid antigen tests (RAT) are used to screen patients with suspected influenza virus infection and provide results in a timely manner. RAT can also help to reduce unnecessary diagnostic testing, to facilitate antiviral treatment, and to decrease inappropriate use of antibiotics (4). However, the clinical sensitivity of RAT was poor for 2009 H1N1 influenza virus, showing an accuracy from 11.1% to 51% (2–5). Drexler et al. have suggested that the viral concentrations in clinical samples influence the outcome of RAT (2). Thus, the collection time of the samples may be an important factor for the accuracy of RAT.

Retrospectively, we tested 637 clinical samples from 637 different patients. Samples were collected during the pandemic 2009 H1N1 influenza season by nasopharyngeal swab and were kept frozen at −80°C until use. The 120 controls were taken from H1N1-negative febrile subjects.

The 2009 H1N1 influenza virus was confirmed by real-time reverse transcription-PCR. A standard curve of control RNA transcripts was constructed in parallel with the detection of viral M segment RNA in clinical samples. Using this standard curve, we calculated the log_{10} viral copy number from the cycle threshold \((C_T)\). The cutoff value of \(C_T\) was set at 37 for H1N1 influenza diagnosis. All processes were conducted by following the Centers for Disease Control protocol for H1N1. The RAT was done by using the SD Bioline influenza A/B/H1N1) pandemic test kit (Standard Diagnostics, Yongin, South Korea). The RAT has four lines, for the detection of 2009 H1N1, influenza A, influenza B, and controls, and distinguishes between seasonal influenza virus and 2009 H1N1 influenza virus (1). Samples were classified when they were collected by the number of hours elapsed after the first symptoms appeared. They were classified into ≤24 h (D1), 24 to 48 h (D2), 48 to 72 h (D3), 72 to 96 h (D4), and 96 to ≤168 h (D5). We calculated the sensitivity and specificity of the RAT. Data analysis was performed using SPSS, version 16.0. The analysis of variance (ANOVA) test and Tukey’s post hoc test were used to calculate the mean log_{10} viral copy numbers. The study protocol was approved by the Institutional Review Board of the Chonbuk National University Hospital. The mean age of the subjects was 23.4 ± 12.81 (median, 18.0; range, 13 to 82; male, 51.0%). The control patients had a mean age of 34.6 ± 20.8 (median, 27.0; range, 8 to 82; male, 54.3%). The overall sensitivity and specificity of the RAT were 75.6% and 99.3%, respectively. The sensitivity of the RAT at D1, D2, D3, D4, and D5 was 75.0%, 76.8%, 79.9%, 77.4%, and 67.3%, respectively (Fig. 1). The log_{10} virus copy number at D1, D2, D3, D4, and D5 was 76.8%, 79.9%, 77.4%, and 67.3%, respectively (Fig. 1). The log_{10} virus copy number at D1, D2, D3, D4, and D5 was 76.8%, 79.9%, 77.4%, and 67.3%, respectively (Fig. 1). The log_{10} virus copy number at D5 showed a significant difference by Tukey’s post hoc test.

FIG. 1. 2009 H1N1 influenza viral loads and time-dependent sensitivity of RAT in clinical samples. The viral loads are presented as log_{10} of M segment copy number/1 ml of viral transport medium. An ANOVA test was used to compare the mean log_{10} viral copy numbers in specimens from patients with different collection times \((P = 0.025)\). “a” indicates a significant difference of the viral load between 48 and 72 h versus 96 to 168 h by using Tukey’s post hoc test \((P = 0.026)\). The sensitivity of the RAT is presented as a percentage.

### REFERENCES


**Chang-Seop Lee**
Department of Internal Medicine
Chonbuk National University Medical School
San 2-20 Geumam-Dong, Deokjin-Gu
Jeonju, Jeonbuk, South Korea

**Ju-Hyung Lee**
Department of Preventive Medicine
Chonbuk National University Medical School
San 2-20 Geumam-Dong, Deokjin-Gu
Jeonju, Jeonbuk, South Korea

**Cheon-Hyeon Kim**
Division of Zoonoses
Jeollabukdo Institute of Health & Environmental Research
Jeonbuk, South Korea

*Phone: 82-63-250-2391
Fax: 82-63-254-1609
E-mail: lcsmd@jbnu.ac.kr

*Published ahead of print on 19 January 2011.*