**INTRODUCTION**

Rapid influenza diagnostic tests (RIDTs) continue to play an important role in clinical diagnosis given their quick turnaround time, low cost and ease of use (1). Although commercially available ridge tests cover a wide variety in their reported sensitivities, their high specificities and positive predictive values during seasons. Testing among the selected, a reliable and repeatable improved patient care by finding additional diagnostic and therapeutic interventions (providing health-concerned) (2). Furthermore, their reproducibility is a particular value in low-resource settings both in the U.S. and abroad.

Despite advantages many uncertainties exist with describing, and comparing sensitivities of RIDTs. Only a few published studies compare multiple RIDTs side by side. Levy et al. compared five of these tests at the same time (3). Distinct studies use a wide variety of sample types, protocols, and influenza viruses making it difficult to compare results across studies. Many of the studies (including those in product insert) were completed during seasons when influenza strains circulating in the general population are no longer relevant.

The purpose of this study was to assess the analytical variability of all FDA-cleared RIDTs with a set of recently circulating viruses. Additionally, we evaluated the reproducibility of RIDT results within our laboratory.

Here we show a comparison of the reactivity of each RIDT available in the US during early 2015 with 25 influenza viruses including: 4 H1N1 2009 pandemic viruses, 1 H3N2, 7 H1N1, 3 pandemic A/Mexico/4108/2009 (A/Mex09), 4 pandemic A/Hong Kong/1/2004 (A/Hkg04), 1 A/California/07/2009 (A/Cal09), 2 A/Korea/1/2009 (A/Kor09), 6 pandemic B/Yamagata/16/2006 (Yam06), 5 pandemic B/Florida/04/2006 (Fla06), 1 B/Bangladesh/5278/2006 (B/Ban06), and 1 B/Beijing/28/2007 (B/Fbe07). These viruses were selected based on the availability of NIBR stock viruses and a cross-section of both seasonal and pandemic strains.

**MATERIALS AND METHODS**

Sample Preparation:
Each of the 25 viruses (Table 1) seed this experiment were diluted in the same phosphate-buffered saline (PBS) to achieve a 1.0 x 10^8 pfu/ml (6.5; 0.905, 1.300, 3.125, 6.250, 1.250, and 0.625 pfu/ml). FluAlert, after virus dilution in saline, was tested by one dilution. In addition, we used NIBR stock virus dilution 10^-1, 10^-2, 10^-3, 10^-4, 10^-5 M, and 10^-6 M. After virus dilution in saline, we used then a different 10-fold dilution to achieve 3 different dilutions. While diluting, a sterile virus solution existing 25 -250 pfu/ml for Purdue Medical Products Co. LLC, (Lafayette, IN) was used to test the remaining viruses were used (2) as previously infected. These viruses were stored as the result of the RIDTs following the manufacturer’s test protocol for a week such as. This approach was adapted for use with the 140 RIDT liquid format as the NIBR test kits are not adapted for testing sample collection.

**RESULTS**

**DISCUSSION**

This analytical comparison study using 25 recently isolated influenza viruses (and two reconstituted influenza B viruses) and 11 FDA-approved RIDTs suggest that tests such as are similarly reactive to 2009 H1N1 pandemic viruses of A/H1N1 and A/H3N2 influenza viruses. While recent test kits appeared more reactive, only 2 test kits showed reactivity with more than three dilutions for any one influenza virus strain. This wide range was observed with influenza A for 3 test kits, and only one test kit to influenza B for 2 test kits. Replicated testing with 5 RIDTs suggests that RIDTs are generally reproducible within a half-log dilution. While all test kits used were consistent with the manufacturer’s provided controls (data not shown), some test kit lots were more variable (Fig. 1: one lot of the BinaxNOW test showed lower reactivity for almost all 25 viruses than that of the same test). Laboratories may consider preparing their own positive controls to allow detection of differences that would be observable when using the very concentrated manufacturer-provided control.

**REFERENCES**

15. Centers for Disease Control and Prevention; Vahidnia, Melool, 2012.