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Title: Comparative pilot study of the BinaxNOW, Directigen EZ, ClearView and Sofia FIA rapid tests with qRT-PCR for the detection of RSV in nasal swabs

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Body: Overwhelming evidence indicates a high incidence and high medical burden for Respiratory Syncytial Virus (RSV) disease in the pediatric population, with most patients intercepted in primary care setting during the RSV epidemic season. The availability of a sensitive rapid RSV test would support the patient management and guide a potential antiviral treatment. In a pilot study we compared the performance of the 3 mostly used RSV point-of-care (POC) tests (Directigen EZ, BinaxNOW and ClearView) with the new Sofia FIA test, using qRT-PCR as a golden standard. A subset of 22 samples were selected from a total of 80 nasal midturbinate nasal swabs (Copan) collected from patients presenting with acute respiratory condition during the 2012-2013 RSV season in Belgium. The subset contained 16/22 (12 pediatric and 4 adult) RSV qRT-PCR positive samples (8 RSV-A and 8 RSV-B) with a viral load ranging from 5 to 9 $\log_{10}$ RNA copies per mL. Screening using the ClearView, BinaxNOW, Directigen EZ and Sofia FIA resulted in the identification of 1 (6.3%), 5 (31%), 5 (31%), and 9 (56%) RSV positive samples. BinaxNOW, Directigen EZ, Sofia FIA and ClearView identified 33%, 33%, 67% and 0% of the positive pediatric samples. All the POC tests identified just the adult sample with the highest viral load (8 $\log_{10}$ RNA copies/mL). The limit of detection was estimated at 5 $\log_{10}$ for Sofia FIA, 7 $\log_{10}$ for the BinaxNOW and Directigen EZ and 8 $\log_{10}$ RNA copies/ mL for the ClearView test. From the preliminary data, a 100 to 1000-fold higher sensitivity is demonstrated for Sofia FIA, clearly outperforming other commonly used RSV POC tests.