A Prospective, Multicenter Study to Evaluate the Performance of a Novel Home Diagnostic Kit for Detection of Influenza A and B

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Rationale: Seasonal epidemics caused by the influenza virus are associated with high morbidity and mortality. Rapid influenza diagnostic tests (RIDTs) are designed to yield a rapid diagnosis, important for early treatment and implementation of control measures, but their use is restricted to point of care (POC) settings. GSK is developing with Ellume, an influenza test for consumer use. A prospective study was conducted across 25 sites in the USA to evaluate the performance of the Theraflu Home FluTest (THFT), a novel RIDT, for detection of Influenza A and B. Methods: The study enrolled 1012 subjects between December 2018 and April 2019. Nasal swabs were self-collected or taken by caregivers from subjects ≥2 years old with influenza-like symptoms and analyzed using the THFT. Key performance values were based on comparison with three reference methods: nucleic acid amplification testing, shell viral culture and a RT-PCR consensus comparator. Data were generated using the per protocol population of the prospective study and an archived sample population for Influenza B due to a very low prevalence during study conduct. A user questionnaire assessed the ease of use of THFT using a five-point Likert scale (from 1=strongly disagree to 5=strongly agree). Results: For Influenza A, the THFT compared with the consensus result, demonstrated a positive agreement of 87.7% (95% confidence limits (CL) 83.6%, 90.9%) and negative agreement of 98.0% (CL 96.6%, 98.9%). For Influenza B, the THFT compared with the consensus result, demonstrated a specificity of 97.9% (CL 96.8%, 98.7%). Due to a small sample size of Influenza B subjects (maximum 12 subjects), a further analysis using 89 archived samples for Influenza B demonstrated a sensitivity versus consensus result of 86.3% (CL 74.3%, 93.2%). Five subjects in the safety data set experienced an adverse event related to nasal swabbing. None were assessed as serious, all were graded as mild in severity and recovered. In the usability questionnaire ≥95% of subjects agreed or strongly agreed that the test was easy to use and they would feel confident using the test at home; 88% of subjects agreed or strongly agreed the nose swab was easy to do. Conclusion: The THFT demonstrated good sensitivity and specificity for Influenza A and B viruses. There were no safety concerns. Users found the THFT easy to use and would feel confident doing so at home. The THFT should expand opportunities as an aid to rapid influenza detection and management beyond POC settings.

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