Performance Evaluation of a Rapid Multiplex Point of Care SARS-CoV-2 Antigen and Flu A/B Test

Authors: Lehane, L[1]., Ellis, J[1]., Guest, P[1]., Lawson, V[1]., Loecherbach, J[1]., Young, S.[2]
1. LumiraDx Ltd, 3 More London Riverside London, SE1 2AQ, U.K **2**. TriCore Reference Laboratories, U.S.A

Lisbon, Portugal
23–26 April 2022
32nd ECCMID EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES

Background

Some symptoms of COVID-19 (fever, cough, myalgia and shortness of breath) overlap with influenza, and therefore accurate, differentiating tests that can be used at the point of care are required to confirm infection and implement correct treatment[1].

A new, rapid point of care test for SARS-CoV-2 & Flu A/B was developed and validated against PCR using single anterior nasal swab samples from clinical subjects able to aid in diagnosis and guide appropriate treatment to multiplex test for all 3 virus antigens.

Materials

Anterior nares nasal swab (Copan FLOQ® swab) samples were collected from subjects and tested on the LumiraDx SARS-CoV-2 & Flu A/B Test and reference tests (Cepheid® Influenza AB & RSV or Roche Cobas® 6800 SARS-CoV-2). Samples from subjects presenting with Influenza were collected during January 2019-March 2020, extracted into LumiraDx Extraction Buffer and frozen (188 subjects).

Subjects presenting with symptoms of COVID-19 (159) were recruited during June-September 2020. Samples were collected from sequentially enrolled subjects and swabs extracted into the LumiraDx Extraction Buffer. Samples were frozen within 1 hour of collection and stored until tested.

Results

Subject ages ranged from <1 to 90 years of age. SARS-CoV-2 analysis of symptomatic subjects up to 12 days since symptom onset demonstrated Positive Percent Agreement (PPA) 95.5% (CI: 84.9 – 98.7%) and Negative Percent Agreement (NPA) 96.0% (CI: 90.9-98.3%). At Ct < 33, the PPA was 95.5% and 100% PPA for Ct <30. Influenza A demonstrated PPA 83.3% and NPA 97.7% Influenza B analysis demonstrated PPA 80.0% and NPA 95.3%.

Conclusion

Analysis demonstrated the PPA compared to PCR of the LumiraDx SARS-CoV-2 & Flu A/B Test using anterior nasal swabs from symptomatic participants meets the minimum positive agreement of ≥80% for each analyte compared to FDA-authorised or 510k-cleared PCR test[2]. Both SARS-CoV-2 and influenza infections can present with similar symptoms, but treatment decisions are different[3]. Differentiating SARS-CoV-2 from influenza at the point of care allows clinician to optimally guide infection control and treatment decisions.

References: 1) www.CDC.org 2) www.fda.gov (6th October 2021) 3) www.Hopkins.org
Conflicts of Interest: This abstract submission was sponsored by LumiraDx UK Ltd. Dumyat Business Park, Alloa. UK. 09206123. S-COM-ART-02353 R1