# **Technical Briefing**

# Fortress Diagnostics

## Influenza and COVID-19 Antigen Combo Rapid Test

#### The need for rapid diagnosis of COVID-19 and Influenza

"If you could distinguish early on whether it's COVID or Flu that would be a massive improvement, so it has to be the next frontier"

Axel Heitmueller, previous Director of Strategy and Innovation at NHS Test and Trace

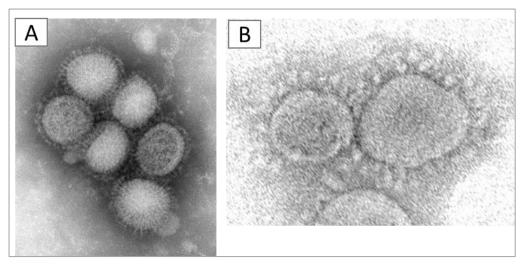
Not only has the COVID-19 pandemic had a profound impact on the way that humans interact, it has also had an impact on the seasonality of other respiratory viruses.

The incidence of influenza and other winter-associated respiratory viruses was significantly lower than usual during winter 2020/21 compared with previous winter seasons. This is likely due to measures that were in place to prevent spread of SARS-CoV-2, such as social distancing, wearing masks and improved hand hygiene.

As COVID-19 restrictions have now been lifted in the UK, public health and infectious disease experts are expecting more influenza to be circulating alongside SARS-CoV-2 in the coming 2021/22 winter season.

What does this mean for clinical practice? Influenza and SARS-CoV-2 are both highly contagious viruses that can cause serious illness in at risk populations. Clinical symptoms are similar between these viruses (and other acute respiratory infections) and accurate diagnosis is needed to make informed decisions about patient management and for the prevention of transmission to others.

Electron microscopic images of the [A] H1N1 influenza virus and [B] SARS-CoV-2 virus.



[A] Image source: https://www.cdc.gov/h1n1flu/images/B00528\_H1N1\_flu\_med.jpg

[B] Image credit: Hannah A. Bullock and Azaibi Tamin. Image source: https://phil.cdc.gov/, Image ID#: 23641.

#### Description

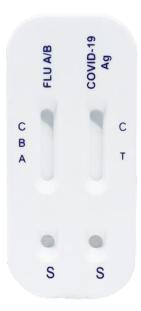
The Influenza and COVID-19 Antigen Combo Rapid Test from Fortress Diagnostics (Co. Antrim, Northern Ireland) is a lateral flow assay that detects the presence of SARS-CoV-2, Influenza A and/or Influenza B direct from nasal swabs within 10 minutes.

The Combo Rapid Test single use cassettes are easy to use and have easy to interpret results without the need for expensive equipment or extensive training.

#### How Influenza and COVID-19 Antigen Combo Rapid Test works

The Influenza and COVID-19 Antigen Combo Rapid Test is a visual, multiplex lateral flow immunochromatographic assay. Each single use cassette offers rapid, qualitative detection, and differentiation, of SARS-CoV-2, Influenza A and/or Influenza B direct from nasal swabs.

The Influenza and COVID-19 Antigen Combo Rapid Test detects the nucleoprotein antigen of each of the viruses included in the test.



#### Key benefits

- Quality product (CE marked/MHRA registered)
- 3 in 1 test: SARS-CoV-2, Influenza A and Influenza B
- Detection of a conserved viral antigen (nucleocapsid protein)
- Detects current SARS-CoV-2 variants and commonly circulating strains of Influenza A and B
- Nasal swab patient-friendly, easily accessible sample type
- Rapid, easy-to-interpret results
- Minimal training required
- No additional equipment needed
- Immediate patient management decisions
- Informed decision making
- Prevent transmission protect staff (if used in a work environment) and positive patients can take precautions to protect others
- Improved antimicrobial stewardship antibiotics will not treat COVID-19 or influenza infections

#### Frequently asked questions

#### Does the Influenza and COVID-19 Antigen Combo Rapid Test detect SARS-CoV-2 variants?

Yes, the Influenza and COVID-19 Antigen Combo Rapid Test does detect current SARS-CoV-2 variants.

The ribonucleoprotein of SARS-CoV-2 is entirely encased within the viral envelope (Figure 1), meaning that it is not exposed to the same selective pressures, such as avoiding the immune system and maximising cell entry, as the SARS-CoV-2 surface proteins. The circulating variants of concern of SARS-CoV-2 are characterised by mutations in the gene encoding the surface spike protein; however, this combo antigen test detects the distinct nucleocapsid protein that is common to all variants.

#### Does the Influenza and COVID-19 Antigen Combo Rapid Test detect different circulating influenza strains?

Yes, the Influenza and COVID-19 Antigen Combo Rapid Test does detect different circulating influenza strains.

The ribonucleoprotein of influenza viruses is entirely encased within the viral envelope (Figure 2). While mutations do occur in this genetic region of the virus, this genetic region is much more conserved than the regions encoding the surface proteins haemagglutinin (H) and neuraminidase (N) surface proteins, which is where most mutational shift/drift change occurs.

The Influenza and COVID-19 Antigen Combo Rapid Test is proven to detect 31 Influenza A subtypes, including subtypes of H1N1, H2N2, H3N2, H5N1, H5N3 (see Product Insert for the full list) and all nine Influenza B strains.

Figure 1. Simplified structure of the SARS-CoV-2 virus, showing the main features of a SARS-CoV-2 virus, including the surface protein spike glycoprotein (green) and the conserved inner coil of ribonucleoprotein (yellow coil that is completely internalised within the viral particle).

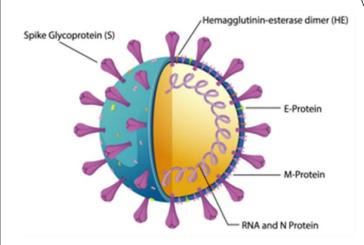
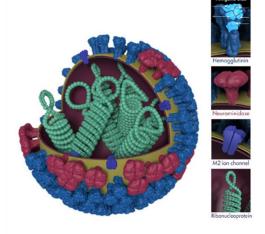


Figure 2. Simplified structure of an influenza A virus, showing the main features of an influenza A virus, including the surface proteins hemagglutinin (dark blue external structure) and neuraminidase (dark red external structure) and the conserved inner ribonucleoprotein (green coil) within the viral particle.



Modified from https://www.freepik.com/free-vector/diagram-corona-virus-particle-structure 11252089.htm | Image source: https://www.cdc.gov/flu/resource-center/freeresources/graphics/images.htm

"Well-evaluated and accurate point-of-care testing (POCT) for influenza and other respiratory viruses could be deployed in hospitals, primary care settings, care homes and community pharmacies to aid rapid diagnosis of highly transmissible respiratory viruses."

The Academy of Medical Sciences report (15 July 2021): COVID-19: Preparing for the future - Looking ahead to winter 2021/22 and beyond

### Pricing and ordering

For order enquiries, please email enquires@unahealth.co.uk