

The recent pandemic caused by a novel human coronavirus, the SARS-CoV-2 / COVID-19 has infected 127 million people world-wide and has been responsible for more than 2.7 million deaths. In Europe a third wave is currently seen with the number of infections increasing dramatically, having profound consequences on the economy, travel and impacting on life as we use to know it. Mass immunization will undoubtedly have an impact on the spread of the virus once more than 70% of the European population has been vaccinated. Until this goal has been realized basic principles apply including washing of hands and wearing of masks. Recently advances have been made in identifying the virus in the community through the identification of the viral nucleocapsid antigen. Although the gold standard in the diagnosis of COVID-19 remains PCR testing, this type of testing requires specialized equipment and is not suitable for mass population screening. Through identification of the nucleocapsid antigen viral particles can be detected in saliva even in asymptomatic individuals during the incubation phase. After being exposed to an infected person, the virus will replicate in respiratory tract cells of an individual. During this phase, which may last 7-14 days, the individual may be asymptomatic yet already produce viral particles that are shed into the saliva and sputum. By identifying asymptomatic individuals or early infection using mass screening through the use of nucleocapsid antigen screening, will identify infected individuals early containing the spread of this infection.

Until recently the Nucleocapsid antigen test was performed by health care professionals introducing a nasal swab through the nostril to the back of the nose to obtain a specimen. The healthcare professional would then use the same swab to swab the pharynx –back of the throat- through the mouth. The sample obtained was then placed into a buffer solution, mixed and expelled onto the reading strip from which a result was shown as a band that appeared within 15 minutes.

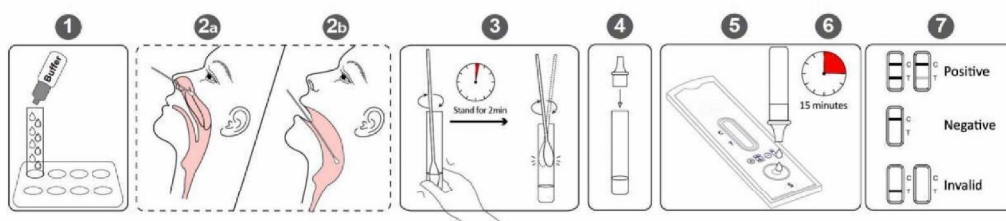


Figure 1: Rapid nucleocapsid antigen test as performed by a health care provided

The protocol for self-use of rapid antigen test kits have been adapted from the original protocol utilized by health care professionals.

First clear instructions are given in the insert to layman in how to use these tests reducing risk of injury

Second, the swab has been adapted so that it can be introduced into the nose but not sufficiently deep to cause damage to the nose or pharynx. In another variation of the same test saliva may be collected and expelled by the individual into a container from where it may be transferred to the same buffer solution referred to above. After mixing of the superficial nasal swab or saliva with the buffer solution the mixture is expelled onto the test strip in a similar way as when the test is performed by a professional.

Both these variations show results that are comparable when the test is performed by a health care practitioner.

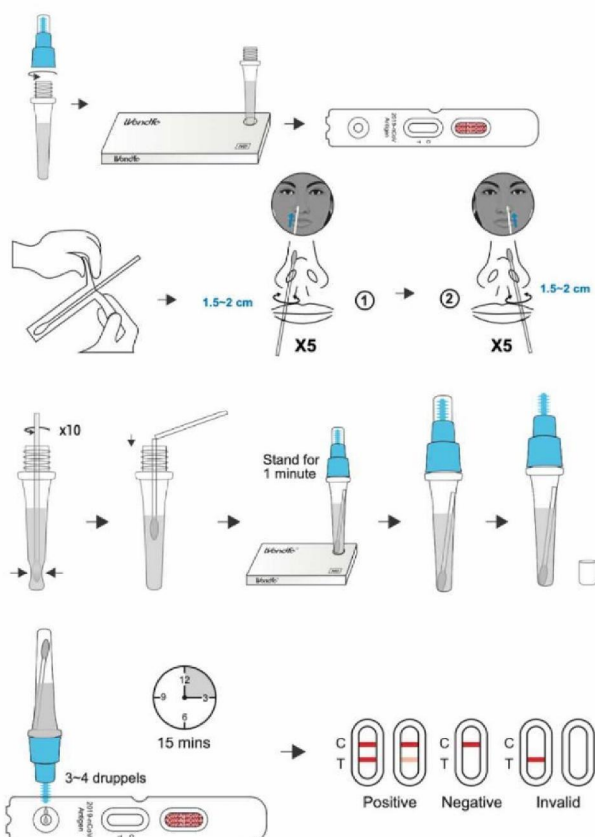


Figure 2: Rapid nucleocapsid antigen when performed by lay person

Recent published data has confirmed that antigen testing has a high diagnostic accuracy with most of the nucleocapsid antigen tests reaching a diagnostic accuracy of >95% when compared to PCR at an amplification cycle ≤ 25 . Some tests such as Wondfo even show diagnostic accuracy of >90% at PCR amplification cycles of >30

Nucleocapsid antigen self-use may allow early detection and self-isolation. The use of nucleocapsid antigen testing may be extended to schools, businesses, large gatherings such as festivals or sport events. By regular testing, for instance twice a week the diagnostic accuracy will reach 100%. This allows businesses, bars, restaurants, travel and other industries to remain productive.

The judicious use of nucleocapsid antigen testing will undoubtedly contribute and have a profound impact on the safe transition from the COVID-19 pandemic to normality if applied with, washing of hands, wearing of masks and vaccination.