AMPATHCHAT no. 76

THE COVID-19 ANTIGEN TESTING SOLUTION

Dr Marieke Brauer, Clinical Virologist

INTRODUCTION

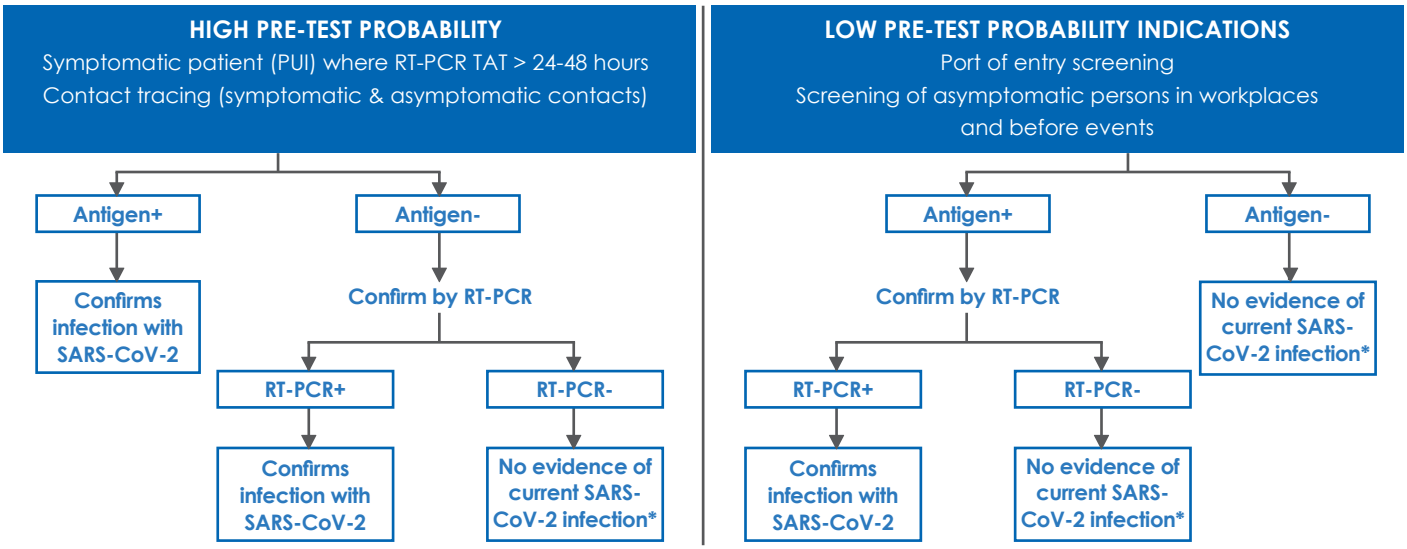
Diagnostic testing plays a critical role in the strategy to prevent COVID-19. While nucleic acid amplification tests such as the reverse transcriptase polymerase chain reaction (RT-PCR) remain the gold standard reference method to detect SARS-CoV-2 (the virus that causes COVID-19), these assays are generally expensive and usually require laboratory facilities, mostly with longer turnaround times. There is an ever-growing need for faster and more cost-effective diagnostic tests that can be performed near the individual being tested.

COVID-19 antigen tests have been designed to detect SARS-CoV-2 proteins produced by the virus in respiratory secretions. The majority of antigen tests have been formulated as rapid diagnostic test devices, intended for near-patient use. Although COVID-19 antigen tests do offer several advantages, these tests are less sensitive than the SARS-CoV-2 RT-PCR tests, with a greater possibility of false negative results. Antigen tests are most likely to detect SARS-CoV-2 from 2 days prior to, and 5 to 7 days after the onset of symptoms, when the amount of virus is at its highest level. In an attempt to meet the growing demand, over two hundred tests for SARS-CoV-2 antigen detection have been brought to market, with variable performance in their ability to accurately detect SARS-CoV-2. For this reason, the World Health Organization (WHO) has recommended minimum performance criteria of ≥ 80% sensitivity and ≥ 97% specificity for rapid antigen test devices, compared to a nucleic acid amplification test in suspected COVID-19 cases.

ANTIGEN TESTING ALGORITHMS

The pre-test probability is an important factor to be considered when interpreting SARS-CoV-2 antigen test results, as this will affect the positive and negative predictive values of these tests. The recommendations for confirmatory testing by RT-PCR will vary accordingly, as follows:

- High pre-test probability (high prevalence settings), e.g. symptomatic person in a setting with established community transmission: The positive predictive value (PPV) is high, which means that a positive result can be managed as a true positive, while a negative result should prompt confirmatory testing by RT-PCR.
- Low pre-test probability (low prevalence settings), e.g. screening of an asymptomatic person with no known exposure: In this instance the negative predictive value (NPV) would be higher, and such negative results need no confirmation. The risk of false positive results exists despite good specificity. Confirmation of positive results by RT-PCR is recommended.



THE ANTIGEN TESTING PROCESS

SARS-CoV-2 Antigen tests are performed on respiratory specimens similar to those required for RT-PCR tests. As such, regulatory requirements for the collection of specimens include observing appropriate infection prevention and control measures (IPC) to protect health care workers from potentially infectious individuals. In order to ensure reliability of test results, it is critical to observe correct storage of kits, specimen handling, testing of quality control specimens and correct result interpretation by trained and competent personnel. Although personnel who perform specimen collection need to wear appropriate personal protective equipment (PPE), the virus will be inactivated once it is placed in the buffer tube supplied with the antigen test kit, thereby eliminating the need for advanced biohazard laboratory equipment.

REPORTING OF SARS-COV-2 ANTIGEN RESULTS

As stipulated by the Department of Health, it is a requirement that all SARS-CoV-2 antigen test results, whether positive or negative, are reported to the National Institute of Communicable Diseases (NICD) when performed by any facility outside the National Health Laboratory service (NHLS). Furthermore, as COVID-19 is a notifiable medical condition, all positive results should be reported by the attending clinicians to the NICD as part of Notifiable Medical Conditions surveillance (NMC-SS).

AMPATH ANTIGEN TESTING SOLUTION

Ampath laboratories are ISO 15189:2012 accredited, and offer competent personnel trained to collect appropriate specimens at our countrywide depots, on-site at work places or at alternate venues. COVID-19 antigen testing can be performed according to customer needs whether on- or off-site. All antigen assays in use within Ampath have been South African Health Products Regulatory Authority (SAHPRA) approved and have passed internal validation in accordance with WHO specifications. Antigen testing can be offered with or without automatic confirmation by SARS-CoV-2 RT-PCR (on- or off-site), typically recommended to confirm any positive antigen test results when used in low pre-test probability scenarios. All positive and negative antigen results are automatically reported to the NICD. Ampath also provides the option of electronic test ordering and electronic test reporting.

PUBLISH: 5 NOVEMBER 2021

REFERENCES

1. World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection: Interim guidance [updated 6 October 2021]. Available from: https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays

2. Department of Health, Republic of South Africa. Guide to antigen testing for SARS-CoV-2 in South Africa [updated 21 July 2021]. Available from: https://www.nicd.ac.za/wp-content/uploads/2021/08/GUIDE-TO-ANTIGEN-TESTING-FOR-SARS-COV-2-IN-SOUTH-AFRICA_V4_06.07.2021-DR-NDJEKA.pdf

3. National Pathology Group. SARS-CoV-2 Antigen Test Protocol and Guidance. 21 December 2020.