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FALSE POSITIVE ABBOT PANBIO™ COVID-19 ANTIGEN RAPID TESTS

Govender Kreshalen[1&2], Mafuyeka Rendani[1&2], Mayaphi Simnikiwe[1&2]

[1]Department of Medical Virology, University of Pretoria

Background:

Rapid diagnostic test (RDT) kits have enabled the point-of-care diagnosis of SARS-CoV-2, the causative agent of COVID-19. The Panbio™ Covid-19 Ag Rapid Test (Abbot) detects SARS-CoV-2 antigen using immunochromatographic methods and is approved SAHPRA. We describe two cases of false positive Panbio™ Covid-19 Ag Rapid Test for patients who attended a tertiary hospital. Abbot Panbio™ COVID-19 Ag Rapid Test Device used by hospitals in Tshwane is validated for nasopharyngeal sample; CE and WHO approval for the qualitative detection of SARS-CoV-2 including the testing of both symptomatic and asymptomatic individuals (CE). According to the manufacturer's package insert, Panbio has a sensitivity of 98.1% and specificity of 99.8%

Field evaluation[1,2] has shown that sensitivity ranges from 62.5% to 96%

Case Description:

Case 1 - 54-year-old female with hypertension and hypothyroidism on treatment, well controlled. Admitted to a hospital in Tshwane for elective surgery on 08 Feb 2021 for possible total abdominal hysterectomy with lymph node dissection → ? Endometrial cancer. Hospital policy to have a COVID-19 test prior to admission → cohorting

Patient was asymptomatic and clinically stable on admission, no epidemiological risk

- Patient had a nasopharyngeal swab taken on the 08 Feb 2021
- Tested on Panbio™ according to manufacturer's instructions → positive result
- The same nasopharyngeal sample tested in RT-PCR at National Health Laboratory Services Tshwane Academic Division Virology → negative
- A separate sample was tested using molecular methods at a private laboratory → negative

Case 2 - 9-year-old male with no comorbidities. Admitted with suspected acute appendicitis. No other symptoms suggested of COVID-19, no epidemiological risk. Nasopharyngeal sample taken and tested on Panbio™ according to manufacturer's instructions: returned a positive result

- Same sample subsequently tested negative on RT-PCR
- Patient was managed conservatively

Discussion:

- Suboptimal test performance may have serious implications for inpatient management as uninfected patients could be exposed to SARS-CoV-2 if admitted to a designated COVID-19 ward as part of containment strategies[3]
- Clinical context and prevalence affects antigen-based test performance

Clinical context and prevalence[4]:

- Positive predictive value is affected by prevalence
- Prevalence 5% → PPV of 90% → 1 in 6 positive tests are false positives
- Prevalence of 0.5% → PPV 28% → 9 in 10 positive results will be false positives
- Both patients tested during periods of lower prevalence (after the second wave)

Conclusion:

- Pre-test probability of results and prevalence should always be taken into consideration when interpreting the SARS-CoV-2 Panbio™ Covid-19 Ag Rapid Test
- For patients requiring hospitalisation in low prevalence settings and where rapid test results and symptomatology are incongruent, molecular based confirmatory testing is more appropriate as false positive rapid test results may hinder medical care
- The implication of false positive results on care may be catastrophic for both the patient and managing team

References:

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