Performance of a novel diagnostic assay for rapid SARS-CoV-2 antigen detection in nasopharynx samples

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Elmoussaoui Sara. Performance of a novel diagnostic assay for rapid SARS-CoV-2 antigen detection in nasopharynx samples. J Clinic Micro Infec 2021;4(5):1-3.

Among the laboratory testing methods developed for identifying patients with infection due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) — the agent of coronavirus disease 2019 (COVID-19) — viral RNA amplification using real-time PCR (RT-PCR) is to date the standard method in many clinical virology laboratories [1]. However, RT-PCR-based assays are labour intensive and, when not completely automated, take hours to yield results. Conversely, rapid antigen detection assays—intrinsically less laborious and requiring a few minutes to results—have the potential to satisfy the pressing demand for an early SARS-CoV-2 infection diagnosis [[2], [3], [4]].

Here, we evaluated the performance of the Panbio™ COVID-19 Ag rapid Test Device, an assay detecting SARS-CoV-2 nucleoprotein antigen, on nasopharynx swab samples. It contains a membrane strip, which is pre-coated with immobilized anti-SARS-CoV-2 antibody on the test line and mouse monoclonal anti-chicken IgY on the control line. Two types of conjugates (human IgG specific to SARS-CoV-2 Ag gold conjugate binds to the nucleocapsid protein) and chicken IgY gold conjugate) move upward on the membrane chromatographically and react with anti-SARS-CoV-2 antibody and pre-coated mouse monoclonal anti-chicken IgY respectively after a 15min incubation.

Clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was determined by testing symptomatic and asymptomatic subjects for SARS-CoV-2 antigen(Ag). Clinical specimens were determined to be positive or negative using an FDA EUA RT-PCR reference method. However, the limit of detection of Panbio™ COVID-19 Ag Rapid Test Device was confirmed to detect 2.5X101.8 TCID50/ml of SARS-CoV-2 which was isolated from a COVID-19 confirmed patient in Korea.

Then, we tested 218 samples (67 positive and 151 negative), previously characterized with the Gene Finder COVID-19 Plus RealAmp Kit or Eurobio Scientific kit 2019 nCoV, in the virology laboratory of the Mohammed V military training hospital. Tests were performed within 24 hr after collection on samples kept at 4°C until testing, according to the Abott manufacturer's recommendations. The median RT-PCR cycle threshold (Ct) value of positive samples was 31.3 (range, 15.3–39.7). Secondly, we compared the results obtained with the Panbio™ COVID-19 Ag Rapid Test Device with those from any of mentioned RT-PCR assays (**Table 1**). Among negative samples, the Panbio™ COVID-19 Ag Rapid Test Device detected 147 of 151 samples as negative, resulting in a negative per cent agreement of 97.3% (95% confidence interval (CI), 98.8–100%). Repeat Panbio™ COVID-19 Ag Rapid Test Device testing was performed on four false-positive samples, and again three were positive. Among positive samples, the Panbio™ COVID-19 Ag Rapid Test Device detected only 30 of 67 samples, resulting in a positive per cent agreement of 44.7% (95% CI, 85.5–95.5). According to RT-PCR Ct values, the sample per cent positivity of the Panbio™ COVID-19 Ag Rapid Test Device ranged from 100.0% (5/5; Ct, <18), 93.8% (15/16; Ct, ≥18–<25), 42.0% (23/55; Ct, ≥25–<35) to 21.0% (6/28; Ct, ≥35). Assuming samples as from individuals diagnosed (n = 67) or not diagnosed (n = 151) with COVID-19, positive and negative predictive values were 82.2% (49/53; 95% CI, 81.8–97.9) and 79.8% (251/306; 95% CI, 77.3–86.2), respectively. At 10% SARS-CoV-2 infection prevalence, anticipated positive and negative predictive values were 76.9% (95% CI, 55.3–90.0) and 94.4% (95% CI, 93.3–95.3), respectively.

Table 1: (a) This value corresponds to the assay's sensitivity assuming all 67 samples being from individuals diagnosed with COVID-19.

(b) This value corresponds to the assay's specificity assuming all 151 samples being from individuals not diagnosed with COVID-19.

Our study shows that the Panbio™ COVID-19 Ag Rapid Test Device had a good specificity for SARS-CoV-2 detection in nasopharynx swab samples but had a good sensitivity only for samples with Ct values lower than 25 (corresponding to higher viral loads). Thus, we believe that the Panbio™ COVID-19 Ag Rapid Test Device might be reliably used in the early phases of acute SARS-CoV-2 infection, e.g. within the first days after infection when Ct values are likely to still be below 25. This would be consistent with the viral load kinetics within the first days of SARS-CoV-2 infection, showing that nasopharynx swab samples obtained on day 7 may be persistently positive (Ct values, 23–24) for SARS-CoV-2 [5]. However, considering the current epidemiological scenario, a non-negligible proportion of symptomatic or, most commonly, asymptomatic patients, whose nasopharynx swab samples display Ct values of ≥25–<35 or ≥35, might be negative with Panbio™ COVID-19 Ag Rapid Test Device (or similar) assays. This scenario would also encompass "new" patients who begin their SARS-CoV-2 infection course with a low viral load (resulting in Ct values of ≥35). In the light of these observations, it is presently difficult to envisage the correct, fruitful and safe use of these assays unless they are integrated in laboratory diagnostic algorithms based on both molecular and serological testing for SARS-CoV-2 infection.

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Citation: *Sara E (2021) Performance of a novel diagnostic assay for rapid SARS-CoV-2 antigen detection in nasopharynx samples. J Clinic Micro Infec. 4(5).*

Received date: *July 05, 2021*; **Accepted date:** *October 12, 2021*; **Published date:** *October 22, 2021*

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