Performance of a rapid antigen test for SARS-CoV-2 in Kenya

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ABSTRACT

Testing for SARS-CoV-2 in resource-poor settings remains a considerable challenge. Gold standard nucleic acid tests are expensive and depend on availability of expensive equipment and highly trained laboratory staff. More affordable and easier rapid antigen tests are an attractive alternative. This study assessed field performance of such a test in western Kenya. We conducted a prospective multi-facility field evaluation study of NowCheck COVID-19 Ag-RDT compared to gold standard PCR. Two pairs of oropharyngeal and naso-pharyngeal swabs were collected for comparative analysis. With 997 enrolled participants the Ag-RDT had a sensitivity 71.5% (63.2-78.6) and specificity of 97.5% (96.2-98.5) at cycle threshold value <40. Highest sensitivity of 87.7% (77.2-94.5) was observed in samples with cycle threshold values ≤30. NowCheck COVID-19 Ag-RDT performed well at multiple healthcare facilities in an African field setting. Operational specificity and sensitivity were close to WHO-recommended thresholds.

1. Background

Since it was first described in December 2019 in Wuhan, Hubei Province in China, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes coronavirus disease 2019 (COVID-19) has caused a significant global public health problem(Wang et al., 2020). As of 26 November 2021 , SARS-COV-2 had resulted in 259,502,031 infections resulting in 5,183,003 deaths in over 220 countries (WHO, 2021). Preventing the spread of SARS-COV-2 is a global public health priority requiring multiple interventions such as social distancing, hand hygiene, infection protection devices, vaccination, timely and accurate diagnosis, and treatment of the sick (Botti-Lodovico et al., 2021; Gates, 2020).

Reverse transcriptase-polymerase chain reaction (RT-PCR) of nasal/oropharyngeal samples is the gold standard diagnostic method for SARS-CoV-2 (Ishige et al., 2020). Though RT-PCR has high sensitivity, it requires a robust infrastructure, well-trained staff, an elaborate

supply chain to support testing services, and it comes at a high cost (Yüce et al., 2021). In many low and middle-income countries (LMICs), there are significant gaps to support RT-PCR testing, resulting in limited access to testing. Although a typical RT-PCR assay takes an average of 4 to 6 hours, in most countries, the time to get results is much longer due to logistics, inefficient reporting systems and lack of digital data management (New guidance to expand rapid antigen testing for COVID-19 response in Africa released, 2020; Mulu et al., 2021). Furthermore, access is much more limited in hard-to-reach communities, making controlling the pandemic a problematic task. With low vaccination rates not exceeding 2% in Africa and across many low-and middle-income countries, testing remains a crucial pillar in the fight against SARS-COV-2 (Nachega et al., 2021; Sah et al., 2021). In these settings, point of care (POCT) Ag-RDTs provides a practical alternative to RT-PCR based testing.

Although Ag-RDTs may not fully replace RT-PCR testing, they offer an easy-to-use POCT method. Moreover, Ag-RDTs can easily be scaled to community settings since they do not require any equipment or well-trained laboratory staff. The quick turnaround time of 15 to 30 minutes helps in faster triage, rapid mass testing, correct patient

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placement, and, where applicable, support contact tracing (Rottenstreich et al., 2021). The low cost per test and ease of use of Ag-RDTs makes them a suitable public health tool to widely scale-up testing in LMICs even in remote communities and in high transmission zones (Ricks et al., 2021; Rottenstreich et al., 2021).

The World Health Organization (WHO) recommends using antigen test kits with a sensitivity of at least 80% and specificity of greater than 97% compared to the gold standard RT-PCR (WHO, 2020). In these settings, such Ag-RDTs provides a decent alternative to RT-PCR, hence the rapid increase in production of several such kits in the market within a short period. As of July 25, 2021, less than 20 months since the COVID-19 pandemic started, 176 listed antigen kits on the Foundation for Innovative New Diagnostics, (a global alliance for diagnostics that seeks to prioritize, partner, develop, evaluate, and support the equitable implementation of diagnostic tests) website (FIND, n.d.).

Although various kit manufacturers report the performance of their diagnostic kits, their operational performance can vary when subjected to the field or real-world conditions. Diagnostic performance of most Ag-RDTs in the market are yet to be adequately evaluated in field situations in LMIC settings. Moreover, most regulators carry out only limited, laboratory-based Ag-RDT evaluations before granting emergency use authorizations for use (Prince-Guerra et al., 2021). This study aimed at an in-depth evaluation of the field performance of BioNote NowCheck COVID-19 Ag-RDT among Kenyans suspected to have COVID-19 attending four health facilities in Kisumu County in western Kenya.

2. Materials and methods

2.1. Study design and oversight

We conducted a cross-sectional, prospective diagnostic evaluation study comparing the field-based operational performance of the NowCheck SARS-CoV-2 Ag-RDT against the gold standard RT-PCR. Four health facilities in Kisumu County participated, consisting of private hospitals, public hospitals, and faith-based hospitals, all of which were part of a public-private partnership in response to the SARS-CoV-2 pandemic in Kisumu dubbed "COVID-Dx". We obtained research and ethical approval from Jaramogi Oginga Odinga Teaching & Referral Hospital under IERC/JOOTRH/334/20 and Research License from National Commission for Science, Technology, and Innovation, license number BAHAMAS ABS/P/20/7959. We obtained informed consent for all eligible adults and assent and parental consent for eligible minors below 18 years. All study procedures were carried out according to ethical principles of the Helsinki Declaration of 1964 and good clinical practices. All study personnel were appropriately trained on infection prevention control using the Kenyan Ministry of Health guidelines and provided with personal protective equipment.

2.2. Sample collection

Trained laboratory technicians collected paired nasopharyngeal and oropharyngeal samples from eligible participants attending four healthcare facilities in Kisumu County. Eligible participants met the Ministry of Health COVID-19 case definition and provided informed consent before sample collection was undertaken. Pre- and post-test counselling services were provided as additional support for participants.

2.3. Antigen testing

The NowCheck SARS-CoV-2 Ag test is a rapid antigen chromatographic immunoassay for the qualitative detection of N protein of SARS-CoV-2 antigens (NowCheck COVID-19 Ag, n.d.). Trained health workers carried out the testing procedure according to the

manufacturer's specifications. The results were provided to patients within 15 to 30 minutes of testing while awaiting final RT-PCR results within 24 to 48 hours. The results were digitally captured onto a tablet/smartphone application (digitized Kenyan COVID-19 Case Investigation Form) and stored in a safe cloud server as described here (Smith et al., 2019), together with general information on the patients (such as age, gender and occupation). Results release, patient care and follow up was performed according to the Kenya Ministry of Health guidelines (Ministry of Health, 2020).

2.4. Reverse transcription-polymerase chain reaction (RT-PCR)

RT-PCR testing was centrally performed at Kenya Medical Research Institute. SARS-CoV-2 viral ribonucleic acid (RNA) extraction from the paired nasopharyngeal and oropharyngeal samples was manually done using MagMAX^{TM} Viral RNA Isolation Kit (Thermo Fisher Scientific, MA). Post-RNA extraction, real-time SARS-CoV-2 PCR was carried out using TaqPath^{TM} 19 kit (Thermo Fisher Scientific, MA). Three primer sets specific to different SARS-CoV-2 genomic regions (ORF1ab, N gene, S gene) were used for the RT-PCR reaction. Probes for bacteriophage MS2 were added as an RNA control to verify the efficacy of the sample preparation and the absence of inhibitors in the RT-PCR reaction. The assays were set up on the 7500 Fast Real-Time PCR Instrument (Applied Biosystems, Thermo Fisher Scientific, MA). A 5 μl template RNA from each sample's nucleic acid was used with 20 μl of the PCR master-mix.

The following thermocycling conditions were employed; 2 minutes at 25°C incubation, 10 minutes at 53°C for reverse transcription, 2 minutes at 95°C for enzyme activation and 40 cycles of 3 seconds at 95°C and 30 seconds at 60°C. Samples having exponential growth curve and Ct <40 in at least two SARS-CoV-2 targets were considered positive, while those with Ct values in only one target were inconclusive. Assays with all targets, including MS2 negative, were deemed invalid. All invalid and inconclusive assays were repeated. All test procedures were performed according to manufacturer-prescribed protocols. The antigen test results were compared with gold-standard RT-PCR results and used to compute kit field performance specifications. Table 1 below provides the breakdown of paired antigen and PCR testing across the four facilities marked A to D.

2.5. Statistical analysis

Analyses were performed using STATA-15 (StataCorp LLC, TX) and Microsoft Excel (Microsoft, Redmond, WA). We used descriptive statistics to describe the general information of study participants. Continuous data were summarized and presented in means, standard deviation (SD), median, and range as applicable. Categorical data were summarized in percentages, and a significance value of 0.05 in statistic tests was considered. Ag-RDT sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, positive predictive value, negative predictive value, and accuracy were calculated using MedCalc online software calculator (Schoonjans, n.d.), grouped according to Ct values using the following cut-offs: 25, 30, 35 and 40

3. Results

3.1. Demographic characteristics

From 28 December 2020 and 31 March 2021, 997 eligible participants were enrolled in the study across four health facilities. The median age was 37 years (interquartile range, 28−49 years). Their demographic characteristics are summarized in Table 1. The distribution of antigen and RT-PCR testing across the four participating health facilities in Kisumu County are summarized in Table 2 below.

Table 1
Demographic characteristics of study participants.

Variable	n (%)	95%CI
Sex		
Male	536(53.8)	
Female	461(46.2)	
Occupation		
Informal workers	367(36.8)	33.86−39.86
Formal workers (non-healthcare)	276(27.7)	24.98−30.55
Students	163(16.4)	14.17−18.78
Healthcare workers	124(12.4)	10.52−14.64
Unemployed	42(4.2)	3.12−5.65
Children (<14 y)	25(2.5)	1.69−3.69
Symptoms		
Cough	738(16.1)	15.08−17.22
Headache	598(13.1)	12.12−14.07
Sore throat	596(13.0)	12.07−14.03
General weakness	548(12.0)	11.06−12.94
Nausea/vomiting	508(11.1)	10.22−12.04
History of fever/chills	426(9.3)	8.50−10.18
Runny nose	409(8.9)	8.14−9.80
Diarrhoea	271(5.9)	5.27−6.64
Pain-muscular/abdominal/chest/joint	253(5.5)	4.90−6.22
Irritability/confusion	138(3.0)	2.55−3.55
Shortness of breath	80(1.8)	1.40−2.17
Other	8(0.2)	0.08−0.34
Asymptomatic	3(0.1)	0.02−0.20

3.2. Performance characteristics

When compared against RT-PCR as the gold standard, the kit sensitivity and specificity showed variable performance across varying Ct values (Table 3). The lowest sensitivity, 71.5% (63.2−78.6), was reported at Ct value <40, while the lowest specificity of 89.5% (87.4−91.4) was noted at the lowest Ct values. We observed the best Ag-RDT performance when the Ct values were ≤35 with a sensitivity of 84.5% (76.00%−90.9%) and specificity of 95.3% (93.7−96.6). At this cut-off, the diagnostic accuracy was 94.2% (92.5−95.6). The highest sensitivity of 87.7% (77.2−94.5) was observed in samples with Ct values ≤30, corresponding with samples with higher viral loads. At Ct value <40, kit sensitivity dropped to 71.5% (63.2−78.6) with a specificity matching that of RT-PCT at 97.5% (96.2−98.5).

4. Discussion

Testing is essential for controlling SARS-COV-2 infection, allowing early identification and isolation of cases to slow down transmission, and providing timely clinical management to those affected and protecting health systems operations through triaging at admissions (Taleghani and Taghipour, 2021). In most LMICs, access to RT-PCR testing capacity is limited to a few specialized centres resulting in significant delays in testing (Kobia and Gitaka, 2020; Mina et al., 2020). Ag-RDTs presents a suitable testing method with several advantages. These include low cost per test, availability as point-of-care, easy to use, does not require electricity, specialized skills or special equipment. The lower cost per test and ease of rolling out to remote communities may offer opportunities to rapidly scale up to meet the high demand for testing, contributing to effective control of the COVID-19 pandemic(Peeling et al., 2021; WHO, 2020).

In its preliminary guidance on using SARS-CoV-2 rapid antigen kits, the WHO recommends using kits with a sensitivity of ≥ 80% and specificity greater than 97% WHO, 2020). In this study, we sought to evaluate the field performance of the NowCheck SARS-CoV-2 antigen kit in a field context, comparing it with the manufacturer's reported sensitivity and specificity of 89.2% and 97.3%, respectively. In this field evaluation, the BioNote NowCheck kit shows an excellent sensitivity of 84.5% (76.0%−90.7%) and specificity 95.30% (93.7%−96.6%) when Ct value ≤35 was used. The sensitivity dropped to 71.5% (63.2−78.6) and specificity increased to 97.5% (96.2−98.5) when using a Ct value of ≤40. The highest sensitivity was in samples with a Ct value ≤30, corresponding to a higher viral load. At Ct values ≤30, the sensitivity was 87.7% (77.2−94.5) and specificity at 92.3% (90.4−93.9).

Studies from around the world evaluating various rapid diagnostic antigen kits show mixed findings (Jonathan et al., 2020). Reported sensitivities vary from as low as 30.2% for Coris COVID-19 Ag Respi-Strip(Scohy et al., 2020) to 64% for the Alltest lateral flow immunoassay (Pérez-García et al., 2020) to kits with reported sensitivities higher than 80% such as Orient Gene, Deepblue, Abbott and Innova SARS-CoV-2 Antigen Rapid(Peto et al., 2021). In a field evaluation study by Eliseo et al., similar to our study in a primary health centre, the Panbio Ag-RDT kit showed a sensitivity of 79.6% and specificity of 100%(Torres et al., 2021). Again, in a similar field evaluation of Standard Q Ag-RDT in Uganda, Nalumansi et al. (Nalumansi et al., 2021) noted a less than optimal performance with a sensitivity of 70% and specificity of 92%. The authors noted better performance at lower Ct

Table 2
Distribution of antigen and PCR testing across facilities in Kisumu County.

Facility	Ag-RDT results per Facility			SARS CoV 2 RT-PCR		
	Negative	Positive	Total RDTS	Negative	Positive	Total RT-PCR
Facility A	106	45	151	104	47	151
Facility B	644	72	716	627	89	716
Facility C	71	10	81	71	10	81
Facility D	47	2	49	43	6	49
Totals	868	129	997	845	152	997

Table 3
Performance characteristics of NowCheck COVID-19 Ag-RDT across grouped PCR Ct values.

	Ct ≤25	Ct ≤30	Ct ≤35	Ct ≤40
Sensitivity	87.5% (71.0−96.5)	87.7% (77.2−94.5)	84.5% (76.0 − 90.85)	71.5% (63.2−78.6)
Specificity	89.5% (87.4−91.4)	92.3% (90.4−93.9)	95.30% (93.7 − 96.59)	97.5% (96.2−98.5)
Positive Likelihood Ratio	8.4(6.7−10.5)	11.4(8.9−14.4)	17.98 (13.2 to 24.4)	28.81(18.7−44.5)
Negative Likelihood Ratio	0.14(0.1−0.4)	0.13(0.1−0.3)	0.16 (0.1 − 0.3)	0.29(0.2−0.4)
Positive Predictive Value	21.7% (18.1−25.8)	44.2% (38.4−50.2)	67.4% (60.4 −73.79)	83.7% (76.9−88.1)
Negative Predictive Value	99.5% (98.9−99.8)	99.1% (98.3−99.5)	98.16% (97.1 − 98.8)	95.1% (93.7−96.1)
Accuracy	89.5% (87.5−91.3)	91.9% (90.1−93.6)	94.18% (92.5 to 95.6)	93.6% (91.9−95.0)

values $\leq$29 with sensitivity exceeding 92%. The same finding was confirmed by Nahal et al. (Eshghifar et al., 2021), who evaluated seven different rapid antigen kits and noted better performance at higher viral load, with an optimal Ct value of $\leq$25.

To our knowledge, this is the first study in Kenya to extensively evaluate the field performance of an affordable COVID-19 Ag-RDT kit. The Ag-RDT kit showed excellent sensitivity and specificity compared to the gold standard, despite the challenges of the real-world environment. Such challenges included variability in sample collection practices among laboratory technicians across different healthcare facilities. Rapid turnover of healthcare staff requiring regular retraining. Growing stigma and fear due to curfews, lockdowns and stringent quarantine measures contributed to laboratory staff hesitation to collect samples (to the level of requesting 'danger allowances'). Shipment of samples to the central laboratory through motorbikes experienced cooling challenges. Patients became increasingly critical to getting tested, given the limited perspectives offered when testing positive. Stock-outs of reagents and kits for RT-PCR occurred, as well as (temporary) breakdowns of crucial laboratory equipment.

In general, the Ag-RDT kit proved easy to use, requiring minimal training time. Patients' discomfort during sample taking was reportedly minimal, and they appreciated an earlier (preliminary) COVID-19 test result. Patients and health workers considered the immediate availability of pre-and post-test counselling services of good value in nudging subsequent patient behaviour, including quarantining, support of contact tracing and hospitalization of those in need. This study provides a proof of concept that rapid antigen kits can easily be rolled out to the community level to support the quick point-of-care diagnosis that allows rapid patient triage, quarantining and hospital placement. In areas with limited access to RT-PCR testing and high patient flow, Ag-RDTs can be scaled up to remote locations, support quick turnaround times for test results with minimal training requirements. Rapid testing can help quick and effective contact tracing at the POCT, supporting efforts to contain SARS CoV-2 spread within the community.

Though helpful, the limitations of these kits should be noted by the users. Some studies have suggested low sensitivity in screening asymptomatic patients (Eshghifar et al., 2021; Peña et al., 2021; Torres et al., 2021). Various authors have cited lower sensitivity in patients with low viral load (high Ct values on RT-PCR); hence RT-PCR testing should continue to be offered where clinical suspicion is high (Ebrahimi et al., 2021; Nalumansi et al., 2021; Peeling et al., 2021). The users should follow manufacturers laid down testing procedures to avoid potentially misleading false-negative or false-positive results.

5. Conclusion

In this study, we carried out a field evaluation of a rapid antigen test for COVID-19 across four healthcare facilities in western Kenya. The performance of the kit almost met the WHO cut-off specifications in detecting COVID-19 when compared to the current gold standard method. We note that The BioNote NowCheck rapid antigen test is a realistic testing option for usage in Africa in the fight against the COVID-19 pandemic.

Authors' contributions

SON: Data curation; Formal analysis; Investigation; Methodology; Visualization; Writing - original draft; Writing - review & editing; **KO**: Investigation; Project administration; Supervision; Validation; Writing - review & editing: **SVD**: Data curation; Formal analysis; Investigation; Methodology; Writing - review & editing; **EA**: Methodology; Validation; Visualization; Roles/Writing - original draft; Writing - review & editing; **MO**: Investigation; Methodology; Project administration; Validation; Roles/Writing - original draft; Writing -

review & editing; **IAO**: Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Roles/Writing - original draft; Writing - review & editing; **AK**: Data curation; Formal analysis; Software; Supervision; Validation; Visualization; Writing - review & editing; **NH**: Conceptualization; Funding acquisition; Project administration; Resources; Supervision; Roles/ Writing - original draft; Writing - review & editing; **EM**: Investigation; Methodology; Project administration; Resources; Software; Supervision; Writing - review & editing; **RA**: Investigation; Methodology; Project administration; Validation; Roles/Writing - original draft; Writing - review & editing; **HCB**: Conceptualization; Funding acquisition; Investigation; Methodology; Project administration; Resources; Writing - review & editing; **FO**: Conceptualization; Funding acquisition; Investigation; Methodology; Project administration; Resources; Writing - review & editing; **AO**: Conceptualization; Funding acquisition; Investigation; Methodology; Project administration; Resources; Supervision; Validation; Visualization; Writing - review & editing; **SK**: Conceptualization; Funding acquisition; Investigation; Methodology; Project administration; Resources; Supervision; Writing - review & editing; **TFR**: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Supervision; Writing - review & editing.

Declaration of competing interest

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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