

Findings From the Field Evaluation of the Panbio™ COVID-19 Rapid Test Device for SARS-CoV-2

Kenya, March–July 2021

This preliminary report has been prepared by the [Kenya Ministry of Health \(MoH\)](#), [US Centers for Disease Control and Prevention \(CDC\) Kenya's Division of Global Health Protection](#), [Kenya Medical Research Institute \(KEMRI\) Centre for Global Health Research](#) and [Association of Public Health Laboratories \(APHL\)](#).

SUMMARY

Between March–July 2021, the field performance of the Panbio™ COVID-19 Rapid Test Device (Abbott Rapid Diagnostics, US) in detecting SARS-CoV-2 infection was evaluated in 876 symptomatic and 1,369 asymptomatic individuals at 11 sites across Kenya.

Results: The overall sensitivity of the Panbio™ COVID-19 Rapid Test Device was 46.6% (95% CI: 42.4–50.9%), specificity was 98.5% (95% CI: 97.8–99.0%), positive predictive value was 90.8% (95% CI: 86.8–93.9%) and negative predictive value was 85.0% (95% CI: 83.4–86.6%). The sensitivity of the Panbio™ COVID-19 Rapid Test Device among symptomatic individuals was 60.6% (95% CI 54.3–66.7%) and 34.7% (95% CI 29.3–40.4%) in asymptomatic individuals. The specificity was above 98% in both symptomatic and asymptomatic individuals.

Interpretation: Among those with a diagnosis of SARS-CoV-2 by reverse transcription polymerase chain reaction (RT-PCR), regardless of clinical presentation, the Panbio™ COVID-19 Rapid Test Device correctly identifies (true positives) 47 out of 100 persons with a COVID-19 infection and incorrectly classifies 53 persons as negative (false negative). Among those without SARS-CoV-2 infection by RT-PCR, the Panbio™ COVID-19 Rapid Test Device returns a true negative result in 99 out of 100 cases, and one false positive result.

BACKGROUND

Antigen rapid diagnostic tests (Ag RDTs) play a critical role in increasing access for the diagnosis of SARS-CoV-2 infections. The World Health Organization (WHO) recommends the use of Ag RDTs that have a minimum sensitivity of $\geq 80\%$ and specificity of $\geq 97\%$ where PCR is unavailable or is associated with long turnaround times. Under these conditions, the Ag RDTs may be used to respond to outbreaks and monitor disease trends in situations of widespread transmission. The WHO advises that Ag RDTs may be used in testing of asymptomatic contacts, even though they are not recommended for such use by the manufacturers.¹

The Ministry of Health (MoH) in Kenya follows the WHO's recommendations that Ag RDTs can be used in populations with a high prevalence of SARS-CoV-2 in symptomatic individuals and among contacts of confirmed COVID-19 cases. Ag RDT use is also approved by the MoH for select high-risk groups and settings, such as health care workers, outbreak investigations in congregate settings and high-risk individuals in health facilities.² Their use in low-prevalence settings is limited to symptomatic travelers at ports of entry and emergency screening in hospital settings.

The performance of the Panbio™ COVID-19 Rapid Test Device (Abbott Rapid Diagnostics, US), a type of Ag RTD, was evaluated in symptomatic and asymptomatic individuals in multiple sites across Kenya. The manufacturers report that among individuals with symptoms-onset within seven days of testing, the Panbio™ COVID-19 Rapid Test Device has a sensitivity of 91.1% (95% CI: 84.2–95.6%) and a specificity of 99.7% (95% CI: 98.6–100.0%). Among asymptomatic individuals, they report the test's sensitivity as 66.0% (95% CI: 51.2–78.8%) and specificity as 100% (95% CI: 99.2–100.0%).³

FIELD EVALUATION

Evaluation Scope: The field evaluation was conducted between March–July 2021 in 11 sites across Kenya:

- Nairobi County: Nairobi Remand Prison, Langata Women’s Prison, Tabitha Clinic
- Kiambu County: Kihara Sub-county Hospital
- Nakuru County: Nakuru Government of Kenya (GK) Prison
- Nyeri County: Nyeri Level 5 Hospital, Nyeri GK Prison
- Kisumu County: Kisumu GK Prison
- Mombasa County: Coast General Teaching and Referral Hospital
- Siaya County: Siaya County Referral Hospital, St. Elizabeth Mission Hospital

Inclusion Criteria: Trained clinical staff enrolled participants who met the case definitions for severe acute respiratory illness,^a acute respiratory illness^b or influenza-like illness.^c Asymptomatic participants were close contacts of PCR-confirmed cases of SARS-CoV-2 infection identified through contact investigation.

Data Collection: Two nasopharyngeal specimens were collected from each participant. The first specimen was tested on-site using the Panbio™ COVID-19 Rapid Test Device; the second was sent to a CDC-supported KEMRI laboratory in Nairobi or Kisumu for RT-PCR testing using the CDC dual target SARS-CoV-2 RT-PCR. Demographic and clinical presentation data were collected using a standardized questionnaire on CommCare®.

Evaluation: Performance (sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV)) of the Panbio™ COVID-19 Rapid Test Device was evaluated against the CDC RT-PCR test as a reference by clinical status, days since onset of symptoms and viral load. The performance characteristics at the operator/user level to determine its utility in the field were also evaluated.

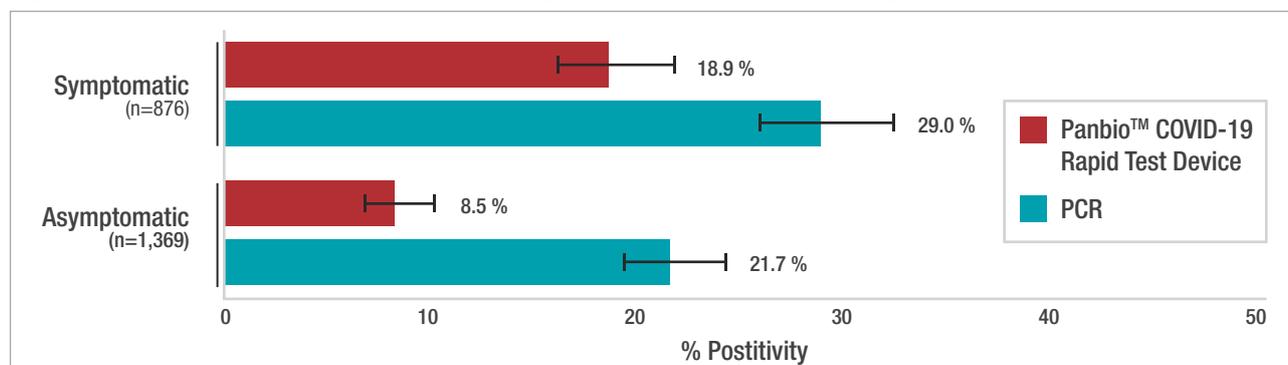
Approvals: Ethical and administrative approvals to conduct the evaluation were obtained from the KEMRI Scientific Ethics Review Unit; CDC; MoH; National Commission for Science, Technology and Innovation; the prisons department; and the county governments of Nakuru, Nyeri, Mombasa, Kiambu and Siaya. Informed consent was obtained from all enrolled participants.

RESULTS

Nasopharyngeal samples were collected and tested from 2,245 individuals, comprised of 876 (39%) symptomatic participants and 1,369 (61%) asymptomatic contacts of confirmed COVID-19 cases. The median age was 31 years (inter-quartile range: 23–40 years) and 1,369 (60.9%) were male.

To evaluate the device’s field characteristics, 17 surveillance officers (SOs) were interviewed: 10 (59%) clinicians and seven (41%) laboratory staff. All SOs reported that it was easy to perform the test and the manufacturers’ instructions were clear and easy to follow. The main challenge the SOs noted when performing the test was difficulty in dispensing a sample onto the test device from the extraction tube when samples were collected from individuals with thick mucus (reported by four (23.5%) SOs).

Figure 1: SARS-CoV-2 positivity with 95% CI by testing method and clinical status among participants.



a Defined as an acute respiratory illness with a history of fever or measured fever of $\geq 38^{\circ}\text{C}$ and cough requiring hospitalization, with onset within the past 10 days.

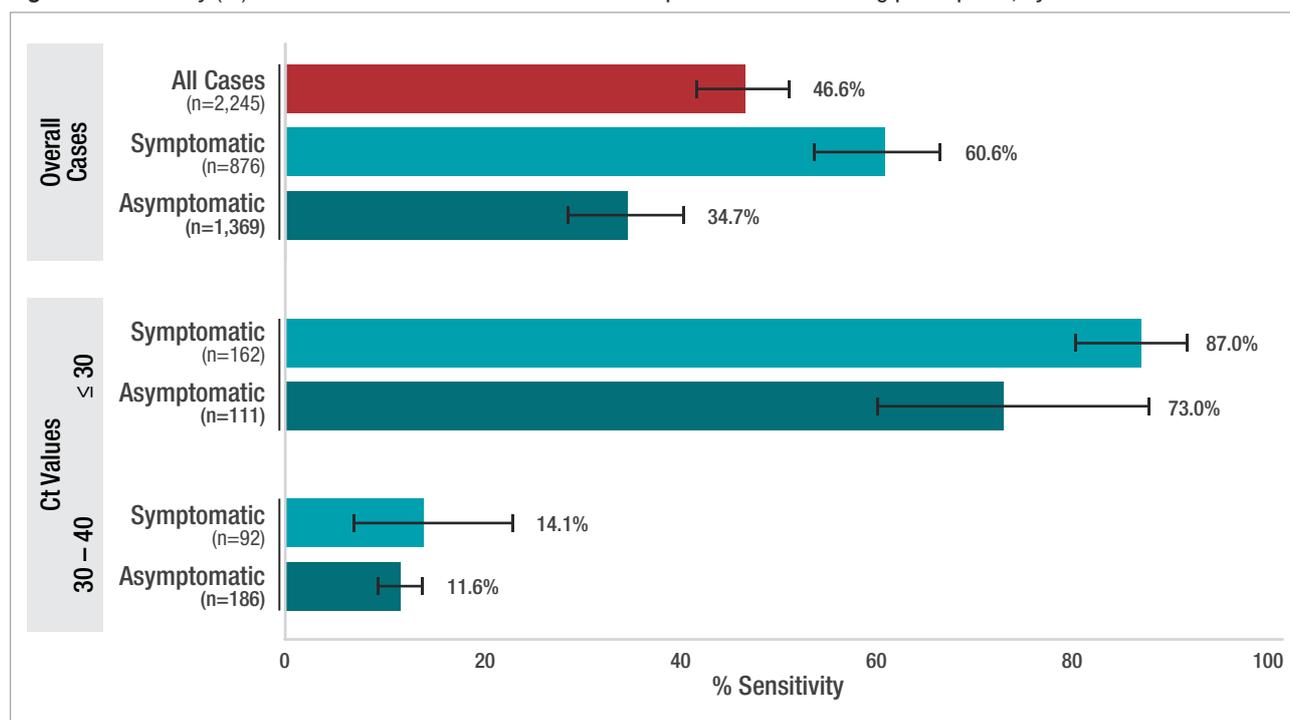
b Defined as cough OR difficulty in breathing OR sore throat OR Coryza with acute onset (<2 weeks).

c Defined as acute respiratory illness with a measured temperature of $\geq 38^{\circ}\text{C}$ and cough, with onset within the past 10 days.

Table 1: Performance of Panbio™ COVID-19 Rapid Test Device by clinical status and days since onset of symptoms.

Variable	Total Number	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
All cases	2,245	46.6 % (42.4 – 50.9)	98.5 % (97.8 – 99.0)	90.8 % (86.8 – 93.9)	85.0 % (83.4 – 86.6)
Symptomatic Cases	876 (39%)	60.6 % (54.3 – 66.7)	98.1 % (96.7 – 99.0)	92.8 % (87.7 – 96.2)	85.9 % (83.1 – 88.4)
Asymptomatic Cases	1,369 (61%)	34.7 % (29.3 – 40.4)	98.7 % (97.8 – 99.3)	88.0 % (80.7 – 93.3)	84.5 % (82.4 – 86.5)
Days Post-onset of Symptoms (Symptomatic Individuals Only, n=876)					
<5 days	594 (67.8%)	67.1 % (59.2 – 74.3)	98.2 % (96.4 – 99.2)	93.0 % (86.6 – 96.9)	89.2 % (86.0 – 91.8)
5 – <7 days	125 (14.2%)	44.4 % (27.9 – 61.9)	87.8 % (92.1 – 99.7)	88.9 % (65.3 – 98.6)	81.3 % (72.6 – 88.2)
7 – <14 days	157 (17.9%)	53.3 % (40.0 – 66.3)	97.9 % (92.7 – 99.7)	94.1 % (80.3 – 99.3)	77.2 % (68.8 – 84.3)

Figure 2: Sensitivity (%) with 95% CI of the Panbio™ COVID-19 Rapid Test Device among participants, by clinical status.



CONCLUSIONS

- The Panbio™ COVID-19 Rapid Test Device performance was only within an acceptable sensitivity (87.0%) when used among individuals with current respiratory symptoms and high viral load as determined by Ct values of <30.
- The kit may be useful as a rapid screening tool for the detection of SARS-CoV-2 for symptomatic patients in health facilities and other high-risk settings with limited access to RT-PCR. All symptomatic individuals with a negative Ag RDT test should be re-tested by RT-PCR.
- The low sensitivity (35%) among asymptomatic contacts of confirmed cases may limit its use for surveillance and screening.
- Performance characteristics indicated that the Panbio™ COVID-19 Rapid Test Device was easy to use, reading results was simple and can therefore be used in primary care health settings with minimal training.

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CONTACTS

For more information, contact:

Kenya MoH

- Dr. Rashid Aman
amanra54@gmail.com
- Dr. John Kiiru
kyirow@gmail.com
- Dr. Linda Makayotto
makayotto@gmail.com

CDC

- Dr. Amy Herman-Roloff
bjy2@cdc.gov
- Dr. Elizabeth Hunsperger
enh4@cdc.gov
- Dr. Peninah Munyua
ikg2@cdc.gov

KEMRI

- Dr Godfrey Bigogo
gbigogo@kemricdc.org

APHL Kenya

- Dr. Irungu Karuga (now MoH staff)
ikarugah@gmail.com
- Edwin Ochieng
Edwin.Ochieng@ken.aphl.org