



## Short Communication

## Rapid point-of-care testing for SARS-CoV-2 in a community screening setting shows low sensitivity



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## ABSTRACT

**Objective:** With the current SARS-CoV2 outbreak, countless tests need to be performed on potential symptomatic individuals, contacts and travellers. The gold standard is a quantitative polymerase chain reaction (qPCR)–based system taking several hours to confirm positivity. For effective public health containment measures, this time span is too long. We therefore evaluated a rapid test in a high-prevalence community setting.

**Study design:** Thirty-nine randomly selected individuals at a COVID-19 screening centre were simultaneously tested via qPCR and a rapid test. Ten previously diagnosed individuals with known SARS-CoV-2 infection were also analysed.

**Methods:** The evaluated rapid test is an IgG/IgM–based test for SARS-CoV-2 with a time to result of 20 min. Two drops of blood are needed for the test performance.

**Results:** Of 49 individuals, 22 tested positive by repeated qPCR. In contrast, the rapid test detected only eight of those positive correctly (sensitivity: 36.4%). Of the 27 qPCR-negative individuals, 24 were detected correctly (specificity: 88.9%).

**Conclusion:** Given the low sensitivity, we recommend not to rely on an antibody-based rapid test for public health measures such as community screenings.

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## Background and aim

COVID-19 is rapidly spreading worldwide, and the number of cases in Europe is rising with increasing pace in several affected regions.<sup>1</sup> While there is an urgent need to contain the pandemic to protect the elderly and vulnerable population, there are several obstacles to control the spread of new infections. The vast majority of SARS-CoV-2–infected individuals appear to have only mild to moderate symptoms similar to the flu or other flu-like infections,<sup>2–6</sup> lacking defining symptoms. Thus, while we start losing the ability to trace all SARS-CoV-2–infected contacts,

identification of potentially infected individuals becomes increasingly hard.

To protect the vulnerable population, it is necessary to assess the infection status of potential contacts to patients with COVID-19 rapidly but also to approve employees to work with at-risk individuals in the hospital or nursing homes. The current gold standard for SARS-CoV-2 detection is a SARS-CoV-2–specific, quantitative real-time polymerase chain reaction (RT-qPCR) testing from a nasal or pharyngeal swab, sputum or bronchoalveolar lavage.<sup>7,8</sup> Following standard protocols, RNA needs to be extracted and the presence of viral RNA confirmed by RT-qPCR. This requires several potentially erroneous steps and several hours for sampling and evaluation. Even high-throughput laboratories require a minimum of 3–4 h from sampling to evaluation, and final information of the infection status may take up to 24 h. This bears the risk of a potential further spread of SARS-CoV-2 in the meantime and hinders widespread testing of all potential contacts. There is currently

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no rapid method to detect potentially SARS-CoV-2–positive individuals that would allow an assessment of their infection status in a reliable manner.

There is an urgent need for immediate targeted detection of infected individuals to slow the pandemic. We therefore evaluated a rapid antibody IgG/IgM–based testing system in the community setting for its ability, specificity and sensitivity to reliably identify infected individuals.

### Study design

The German Red Cross had established a COVID-19 screening centre in a high-prevalence area with more than 300 confirmed cases among 12,000 inhabitants. The cluster outbreak occurred after a carnival celebration and secondary transmissions in the families and rural community. The medical personnel at the screening site perform 150–200 throat swabs for SARS-CoV-2 diagnostics every day on symptomatic individuals.

Thirty-nine randomly selected individuals at the centre were tested simultaneously using the SARS-CoV-2 rapid test and the gold standard RT-qPCR method (Altona Diagnostics). In addition, collected and stored serum samples of 10 previously diagnosed individuals with known SARS-CoV-2 infection were analysed. All individuals accepted testing via written informed consent.

### Methods

The rapid test used for evaluation is a qualitative IgG/IgM detection system to test for a current or past infection of SARS-CoV-2. The chemical coupling pad contains gold-labelled SARS-CoV-2 antigens and mouse IgG controls. There are two detection bands (T1 = IgM and T2 = IgG) on the test strip, which are coated with mouse anti-human IgM and IgG antibodies, respectively. The control band (C) is coated with a goat anti-mouse IgG antibody. After discarding the first drop of blood from a fingertip prick, two drops of blood are applied onto the rapid test chip. In addition, two drops of a provided solution are added. The test indicates positivity for IgG after 15 min and for IgM after 20 min. When a test sample is

added to the sample-loading area, the antigen forms an immune conjugate with the gold-labelled antibodies and then move to the detection zone by a capillary action. The negative conformity rate has been described to be 100% for 68 negative controls. The positive conformity rate has been described to be 70% at early stages of infection (day 4–10) and 100% at late stages of infection (day 11–24).

### Results

The study population was well balanced in terms of age (median: 46 years, interquartile range [IQR]: 28–72) and gender (24/49 female [49.0%]). The majority described symptoms including dry coughing (70.8%), fatigue (64.6%) and a runny nose (45.8%). Only five individuals had no symptoms. Twenty-two individuals were tested positive by repeated RT-qPCR, while 27 were tested negative. Positive individuals reported five symptoms in median (IQR: 3–7), while negative individuals reported only 4 (IQR: 2–5) symptoms. We were able to identify the probable date of exposure of 22 individuals (44.9%). Median time between exposure and test was 18.5 days (IQR: 15–24).

All used rapid tests were valid; 38 of 49 (77.6%) tests were negative. We saw a weak response in 7 cases and a strong response in 4 cases (Fig. 1). There was no case of a singular IgM response indicating acute or recent SARS-CoV-2 infection. The manufacturer recommends to classify weak responses as positive which was supported via receiver operating characteristics (ROC) curve analysis (Table 1). Therefore, we defined 11 tests as positive in our study. Considering the PCR results, we found eight tests to be true-positive and 3 to be false-positive, whereas 24 tests were true-negative and 14 tests were false-negative (Table 2). The test reached a sensitivity of 36.4% [95% confidence interval (CI): 17.2; 59.4] and a specificity of 88.9% [95% CI: 70.8; 97.7]. Based on a prevalence of 44.9%, the test reached a positive predictive value of 72.7% [95% CI: 39.0; 94.0] and a negative predictive value of 63.1% [95% CI: 46.0; 78.2].

There was no statistically significant correlation between rapid test results and time from potential exposure (exact test,  $p = 0.636$ ),

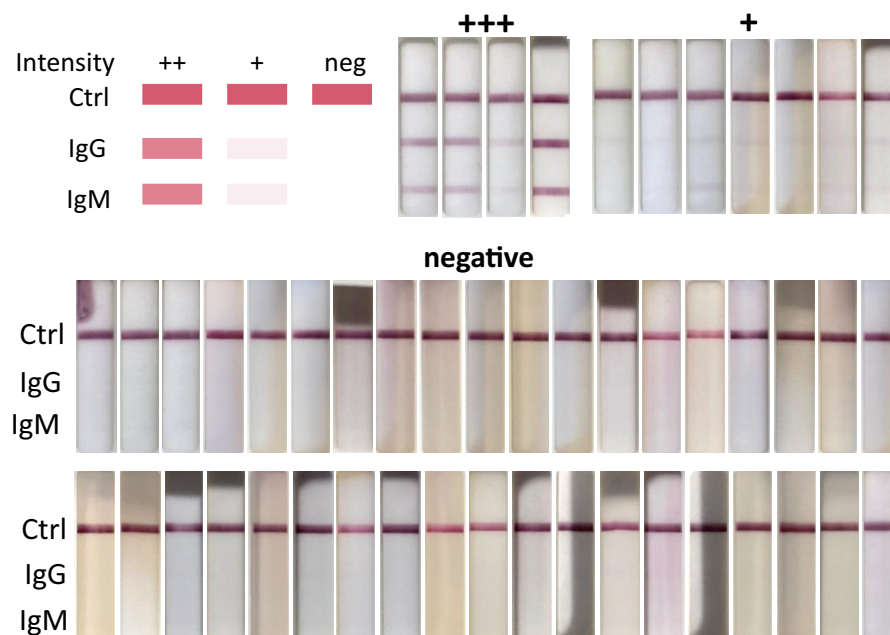


Fig. 1. Documentation of the 49 test results and their valuation. +++: Strong positive; +: positive; neg: negative; Ctrl: control.

**Table 1**

Possible cut-off points for SARS-CoV-2—positive test results.

Cut-off point	Sensitivity	Specificity	Correctly classified	LR+	LR-
Weak and strong bands	36.36%	88.89%	65.31%	3.2727	0.7159
Strong bands only	18.18%	100.00%	63.27%		0.8182

ROC = 0.64 [95% CI: 0.52; 0.76].

Weak and strong is superior; the manufacturer's recommendation is also to interpret weak results as positive.

LR+: positive likelihood ratio; LR-: negative likelihood ratio; ROC: receiver operating characteristics; CI: confidence interval.

**Table 2**

Comparison of SARS-CoV-2 RT-qPCR—positive samples and positive rapid tests

PCR	Rapid test		Total	
	Positive	negative		
positive	8	14	22	Sens: 8/22 = 36.4% [17.2; 59.3]
negative	3	24	27	Spec: 24/27 = 88.9% [70.8; 97.7]
Total	11	38	49	
	PPV: 8/11 = 72.7% [39.0; 94.0]	NPV: 24/38 = 63.2% [46.0; 78.2]		

Weak and strong responses were counted as positive.

Sens: sensitivity; Spec: specificity; PPV: positive predictive value; NPV: negative predictive value; RT-qPCR: real-time quantitative polymerase chain reaction.

Square brackets give the 95% confidence intervals.

presence of symptoms (exact test,  $p = 0.689$ ), age (exact test,  $p = 0.145$ ) or gender (exact test,  $p = 0.531$ ).

## Conclusion

The SARS-CoV-2 outbreak in 2019/2020 followed an unprecedented international response to contain the pandemic. High transmission rates and the vast majority presenting with only mild to moderate unspecific symptoms complicate the ability to contain the virus.<sup>9</sup> Moreover, laboratory methods to detect SARS-CoV-2 infection rely on RT-qPCR testing that require longer time for sample handling, preparation and diagnosis. While rapid point-of-care testing is critically needed, the current evaluation of an antibody-based system demonstrates only low sensitivity and is therefore not recommendable to detect potential infections as a stand-alone test. Indeed, studies demonstrated that seroconversion occurred sequentially for IgM and then IgG with a median time of 11 and 14 days, respectively. The presence of antibodies was <40% among patients in the first 7 days of illness and then rapidly increased to 100% at day 15 after onset of symptoms, which appear to be too late from a public health perspective.<sup>10</sup>

In this real-life study setting at a community SARS-CoV-2 testing site after a cluster outbreak, we investigated the superiority of an antibody-based rapid test in comparison with the current SARS-CoV-2 RT-qPCR gold standard. We tested screened persons of an official screening centre that we had selected by chance. This is a scenario that already occurs and will more often occur in all European Union (EU) member states within the next months.

The rapid test was substantially inferior to the RT-qPCR testing and should therefore neither be used for individual risk assessment nor for decisions on public health measures. As there is an urgent need for a sufficient rapid testing system for SARS-CoV-2, an antigen-based system may therefore be more appropriate. We recommend accelerating the development and evaluation of effective point-of-care testing systems.

## Author statements

### Ethical approval

The study has been approved by the local institutional review board in March 2020 (085/20).

### Funding

None declared.

### Competing interests

None declared.

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