UNIVERSITÉ DE GENÈVE
FACULTÉ DE MÉDECINE

Hôpitaux Universitaires Genève

To: Federal Office of Public Health FOPH

Centre for Emerging Viral Diseases

Division of Infectious Diseases

Department of Medicine

Laboratory of virology

Division of Laboratory Medicine

Diagnostic Department

Geneva, October 27th, 2020

Validation Report: SARS-CoV-2 Antigen Rapid Diagnostic Test

Please find below a summary of the results of our SARS-CoV-2 antigen rapid diagnostic test (RDT) validation for Panbio™ Covid-19 Ag Rapid Test (Abbott) and Standard Q COVID-19 Rapid Antigen Test (SD Biosensor/Roche), partly done in collaboration with the Foundation for Innovative Diagnostics (FIND), Geneva and supported by the CRIVE and The Geneva Centre for Emerging Viral Diseases. This evaluation was performed at the Hôpitaux Universitaires de Genève (HUG), Geneva, Switzerland, between Friday 9th of October to Friday 23th of October.

During the study period a total of **1064** volunteers presenting to our testing center and fulfilling the local FOPH testing criteria for SARS-CoV-2 testing were enrolled in this investigation. Volunteers were enrolled over a two-week period of time and no other specific inclusion criteria were applied; thus study participants were representative of the usual population seeking testing in our center (main testing center in Geneva). The majority were presenting with symptoms compatible with a SARS-CoV2 infection and a minority were asymptomatic but with a known positive contact or were asymptomatic healthcare workers. The overall positivity rate by RT-PCR during the study period ranged between 15% (09.10.2020) and 31% (23.10.2020).

The study was approved by the Cantonal ethics committee (Nr. 2020-02323). All study participants were enrolled by dedicated MDs and provided written informed consent.

After the reference screening, a second and contralateral nasopharyngeal swab was then performed by the same nurse to be used for the RDT, which was run by a dedicated team of laboratory technicians on site. Each study day up to 100 volunteers were enrolled. Participants were enrolled without applying any selection criteria; the logistic constraints and the team's ability to conduct high volume consecutive testing and volunteers' consents were the only constraint that defined inclusion criteria. All RDT results were read after the time indicated by the manufacturer and by two independent persons. Reference methods for comparison were cycle threshold (Ct) values of the current diagnostic routine SARS-CoV-2 RT-PCR assay (Cobas, Roche).

Results

Rapid diagnostic test validation for Panbio™ Covid-19 Ag Rapid Test (Abbott)

Number of individuals tested: **535**
Number of positives individuals by RT-PCR: **124**
Number of those positive by the rapid test: **106**
False-negatives: **18**
Number of negative individuals by RT-PCR: **411**
Number also negative by the rapid test: **411**
False-positives: **0**

Sensitivity: 85,48% (95% C.I: 78,03 – 91,16)
Specificity: 100% (95% C.I: 99,11 – 100,0)
Positive Predictive Value*: 100%
Negative Predictive Value*: 95,80% (95% C.I: 93,71 – 97,22)
*calculated based on the actual RT-PCR prevalence of the study population during the validation of this RDT of 23%

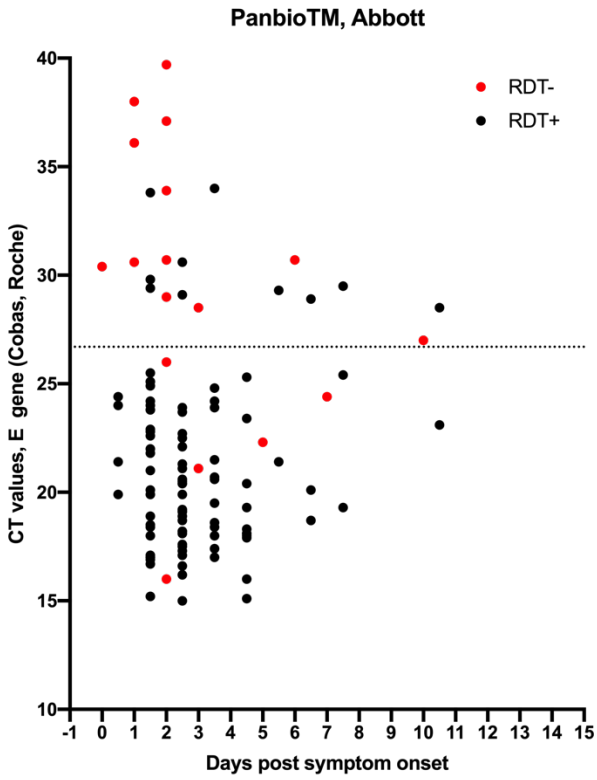

Figure 1. Ct values and RDT results by days post symptom onset for 114 symptomatic, RT-PCR positive individuals tested with the Panbio™ Covid-19 Ag Rapid Test (Abbott) for whom date of symptom onset was known. Black dots – Antigen RDT positive, red dots – Antigen RDT negative. Dotted line: CT value of 26,7 which corresponds to a viral load of $1x10^6$ SARS-CoV-2 RNA copies/mL (considered threshold for presence of culturable virus)

Out of the 114 PCR-positive individuals for whom days post symptom onset was known, 86 (75,4%) had symptoms for 0-4 days (less than 96h) and did not have any

comorbidities as defined by the current criteria of the FOPH[1]. In this subgroup, sensitivity of the rapid antigen test was 87,21% (C.I 95% 78,27 – 93,44) and negative predictive value was 97,39% (95% C.I 95,56 – 98,48).

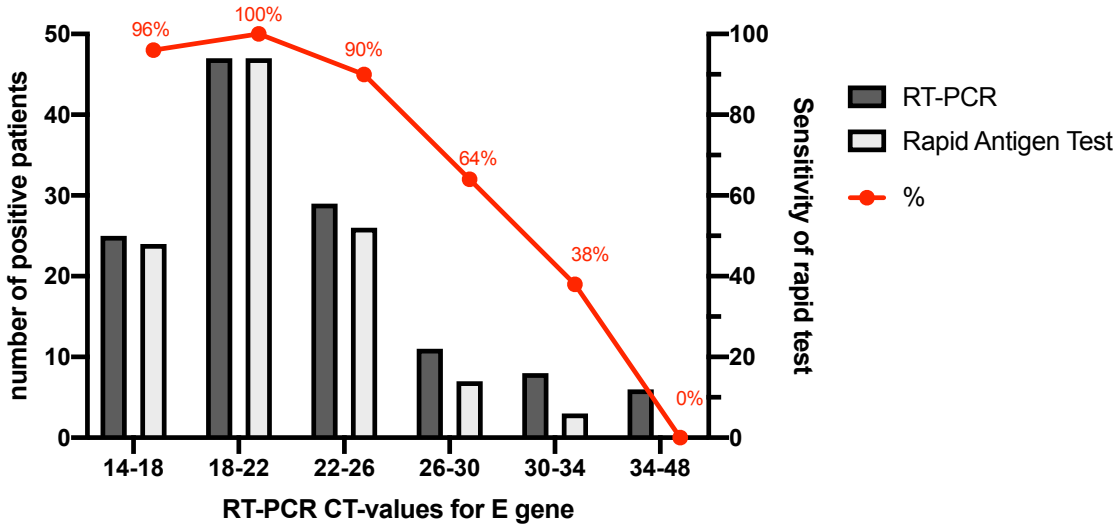

Figure 2. Sensitivity of the Panbio™ Covid-19 Ag Rapid Test (Abbott) depending on CT-values of the RT-PCR. The dark grey bars represent the number of patients positive by RT-PCR. The light grey bars represent the number of patients positive with the rapid test. The red line represents the sensitivity (%) of the RDT per group.

Rapid diagnostic test validation for Standard Q COVID-19 Rapid Antigen Test (SD Biosensor/Roche)

Number of individuals tested: **529**
Number of positives individuals by RT-PCR: **191**
Number of those positive by the rapid test: **170**
False-negatives: **21**
Number of negative individuals by RT-PCR: **338**
Number also negative by the rapid test: **337**
False-positives: **1**

Sensitivity: 89,0% (95% C.I: 83,69 – 93,06)
Specificity: 99,70% (95% C.I: 98,36 – 99,99)
Positive Predictive Value*: 99,42% (95% C.I: 96,00 – 99,92)
Negative Predictive Value*: 94,13% (95% C.I: 91,47 – 96,00)
* calculated based on the actual RT-PCR prevalence of the study population during the validation of this RDT of 36%

[1]https://www.bag.admin.ch/bag/en/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/besonders-gefaehrdete-menschen.html

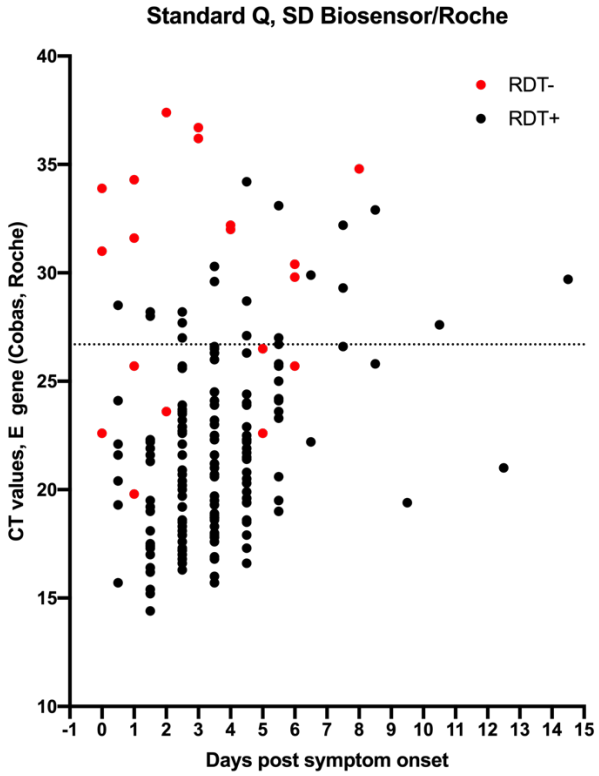

Figure 3. Ct values and RDT results by time of symptom onset for 183 symptomatic, RT-PCR positive individuals tested with the Standard Q COVID-19 Rapid Antigen Test (SD Biosensor, Roche) for whom date of symptom onset was known. Black dots – Antigen RDT positive, red dots – Antigen RDT negative. Dotted line: CT value of 26,7 which corresponds to a viral load of $1x10^6$ SARS-CoV-2 RNA copies/mL (considered threshold for presence of culturable virus)

Out of the 183 PCR-positive individuals for whom days post symptom onset was known, 141 (77,0%) had symptoms for 0-4 days (less than 96h) and did not have any comorbidities as defined by the current criteria of the FOPH[1]. In this subgroup, sensitivity of the rapid antigen test was 90,85% (C.I 95% 84,85 – 95,03) and negative predictive value was 96,29% (95% C.I 93,92 – 97,75).

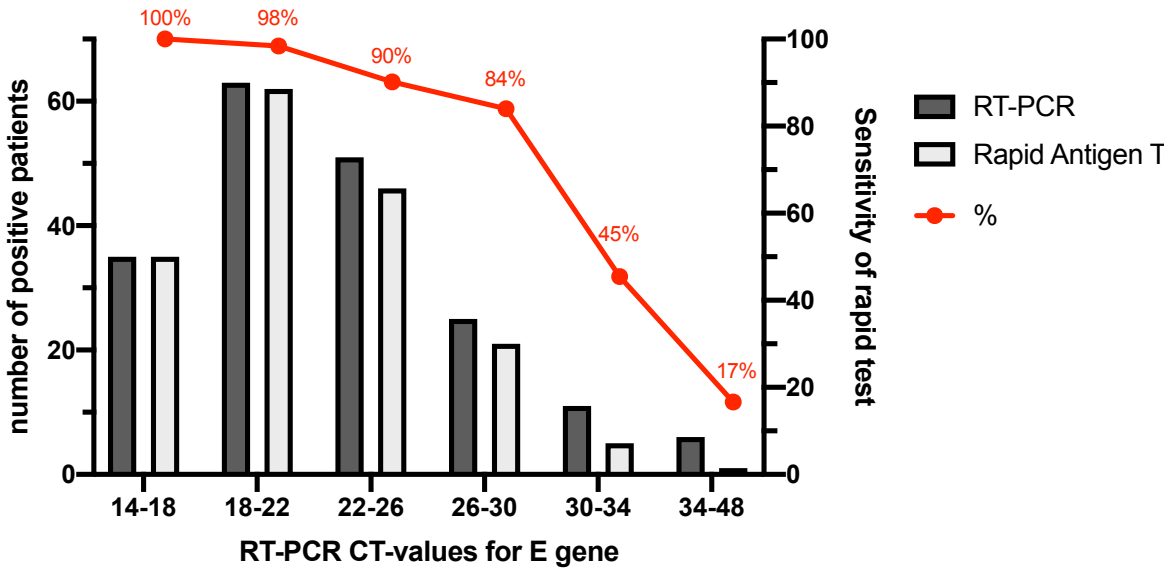

Figure 4. Sensitivity of the Standard Q (SD Biosensor/Roche) RDT depending on CT-values of RT-PCR. The dark grey bars represent the number of patients positive by RT-PCR. The light grey bars represent the number of patients positive with the rapid test. The red line represents the sensitivity (%) of the rapid test.

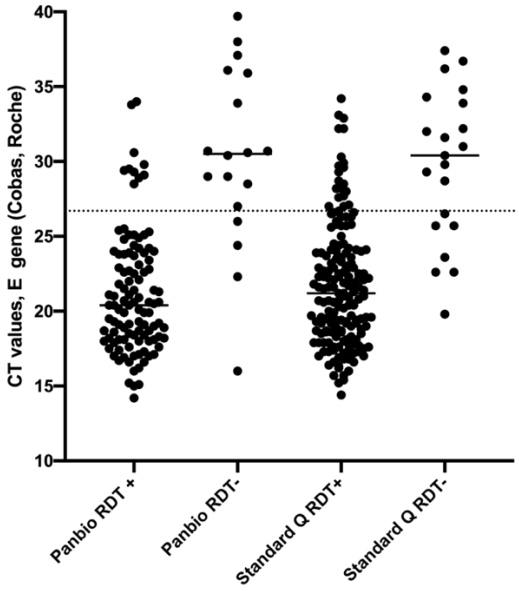

Figure 5. Ct values and RDT results for all RT-PCR positive individuals. Dotted line: CT value of 26,7 which corresponds to a viral load of $1x10^6$ SARS-CoV-2 RNA copies/mL (considered threshold for presence of culturable virus)

Interpretation

Our results show that both validated SARS-CoV-2 antigen RDTs, Panbio™ Covid-19 Ag Rapid Test (Abbott) and the Standard Q (SD Biosensor/Roche), fulfil the criteria as defined by WHO with ≥ 80% sensitivity and ≥97% specificity[2], which is in line with independent validations from other studies.[3,4] Of note, although RDT test results show highest concordance in samples with low CT values (indicating a high viral load), a small proportion of samples with low CT values/high viral load were missed (false-negative) by RDT.

This report should be considered as pre-final analysis and will be completed as a full paper rapidly.

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[2]COVID-19 Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0, 29 September 2020, https://www.who.int/publications/m/item/covid-19-target-product-profiles-for-priority-diagnostics-to-support-response-to-the-covid-19-pandemic-v.0.1

[3]Krüger L.J. et al. Evaluation of the accuracy, ease of use and limit of detection of novel, rapid, antigen-detecting point-of-care diagnostics for SARS-CoV-2. medRxiv 2020.10.01.20203836; doi: https://doi.org/10.1101/2020.10.01.20203836

[4]van Beek J et al., From more testing to smart testing: data-guided SARS-CoV-2 testing choices. medRxiv 2020.10.13.20211524; doi: https://doi.org/10.1101/2020.10.13.20211524