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Technical validation report Rapid COVID-19 Antigen test

Assay name: MP COVID-19 Antigen Rapid Test
Assay Lot number: 20112502
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Summary
The **MP COVID-19 Antigen Rapid Test** has **passed** the validation criteria as described by the Swiss Society of Microbiology. At Ct-values of 23, 26 and 29, the **MP COVID-19 Antigen Rapid Test** assay showed a technical sensitivity of **100%, 100%** and **81%** compared to a reference standard showing a technical sensitivity of **100%, 100%** and **81%**, respectively. The technical specificity was **100%**.

Interpretation of technical sensitivity and specificity
Technical sensitivities at Ct 23, 26 and 29, as well as the overall specificity is shown in **Table 1**. **Figure 1** shows the percentage of antigen positivity in relation to Ct values over a range of 100 PCR-positive clinical samples. In order to detect 90% and 80% of PCR positive samples, the **MP COVID-19 Antigen Rapid Test** required a minimum Ct 27.03 and 30.54, respectively, in contrast the reference standard requires a minimum Ct of 28.20 and 30.54.

	Sensitivity			**Specificity**
	Ct 23	**Ct 26**	**Ct 29**	
Reference	100%	100%	81%	100%
Wondfo	100%	100%	81%	100%

Table 1. Technical sensitivity and specificity, expressed in percentage. For sensitivities at Ct 23, 26 and 29 a threshold of 95%, 90% and 80% has to be reached. Overall specificity needed to be at least 99%

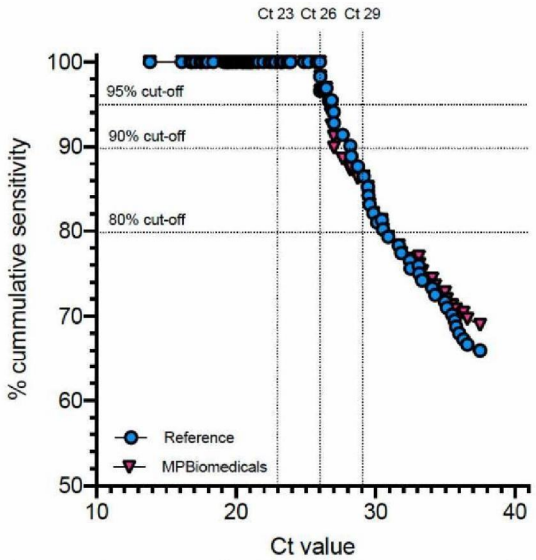

Figure 1. Percentage of antigen positivity compared to Ct values of samples.

The median Ct values in antigen positive samples were 21.06 for the **MP COVID-19 Antigen Rapid Test** assay and 21.01 for the reference standard (**Figure 2**).

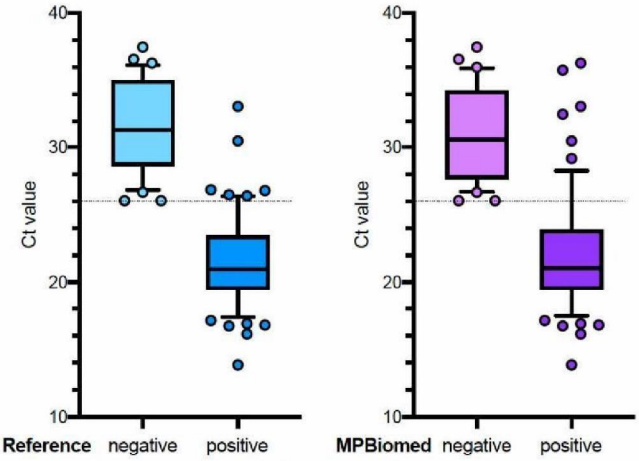

Figure 2. Ct values of SARS-CoV-2 specific rapid antigen positive and negative tested samples from routine diagnostics. Boxes show median and interquartile range, whiskers show 10-90th percentile.

Samples tested from serial dilution

The serial dilution from positive samples indicates that the **MP COVID-19 Antigen Rapid Test** assay had a 1-titer higher sensitivity. The minimal positivity of 23.3 and 23.1 has been reached.

	Ct	21.1	21.9	23.3	24.4	25.1	26.1	27.7
Cell culture supernatant	MP	+	+	+	+	-	-	-
	Reference	+	+	+	+	(+)	-	-
	Ct	**21.4**	**22.3**	**23.1**	**24.1**	**25.5**	**26.4**	**27.3**
Clinical sample	MP	+	+	+	+	-	-	-
	Reference	+	+	+	(+)	-	-	-

Table 2. Serial dilution of 2 highly positive sample in a back-to-back comparison. +, clear positive reaction, (+) faint band, and – negative. Green shade indicates the range within a test has to be positive.

Methods

The technical performance was validated in (i) 100 PCR-positive and 200 PCR-negative samples and (ii) in a serial dilution against a reference standard in order to determine and compare the diagnostic limits of detection.

In general samples were used from the routine diagnostic of the validating laboratory. To allow for a cross-laboratory comparison, 5 SARS-CoV-2 PCR-positive samples were used from aliquoted samples of one single laboratory and distributed to all laboratories. In addition, 50 SARS-CoV-2 PCR negative samples with other respiratory viruses were used and tested by all laboratories. These samples included the following viruses: Coronaviruses (229, HKU1, OC43, NL63, n=3 each), Parainfluenza 1-4 (n=3 each), Rhino/Enteroviruses (n=5 each), Influenza A and B (n=6 each), RSV (n=6 each), and human Metapneumovirus (n=3).

Reference standard: Standard Q COVID-19 Rapid Antigen Test from SD Biosensor/Roche
Reference Lot number: QCO3020105
PCR System: Cobas 6800, Roche, E-Gene was considered for Ct-values

Minimal acceptance criteria to successfully pass the validation:

- Cumulative sensitivity at Ct 23 (approx. 10'000'000 c/mL), at least 95%
- Cumulative sensitivity at Ct 26 (approx. 1'000'000 c/mL), at least 90%
- Cumulative sensitivity at Ct 29 (approx. 100'000 c/mL), at least 80%
- Overall specificity, at least 99%
- Serial dilution has to detect up to Ct 23.3 and 23.1, respectively.

This validation report was released for the FOPH
In behalf of the Swiss Society of Microbiology
Members of the core validation team:

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