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Technical validation report Rapid COVID-19 Antigen test

Assay name: NOVA Test SARS-CoV-2 Ag rTK
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Summary

The **NOVA Test** has **passed** the validation criteria as described by the Swiss Society of Microbiology. At Ct-values of 23, 26 and 29, the **NOVA Test** showed a technical sensitivity of **95.4%, 90.1%** and **80.7%** compared to a reference standard showing a technical sensitivity of **95.4%, 96.8%** and **91.5%**, 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 80% and 90% of PCR positive samples, the **NOVA Test** requires a minimum Ct of **29.5** and **26**, respectively, in contrast the reference standard requires a minimum Ct of **30.04** and **36**.

	Sensitivity			Specificity
	Ct 23	**Ct 26**	**Ct 29**	
Reference	95.4	96.8	91.5	**100%**
NOVA Test	95.4	90.1	80.7	

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

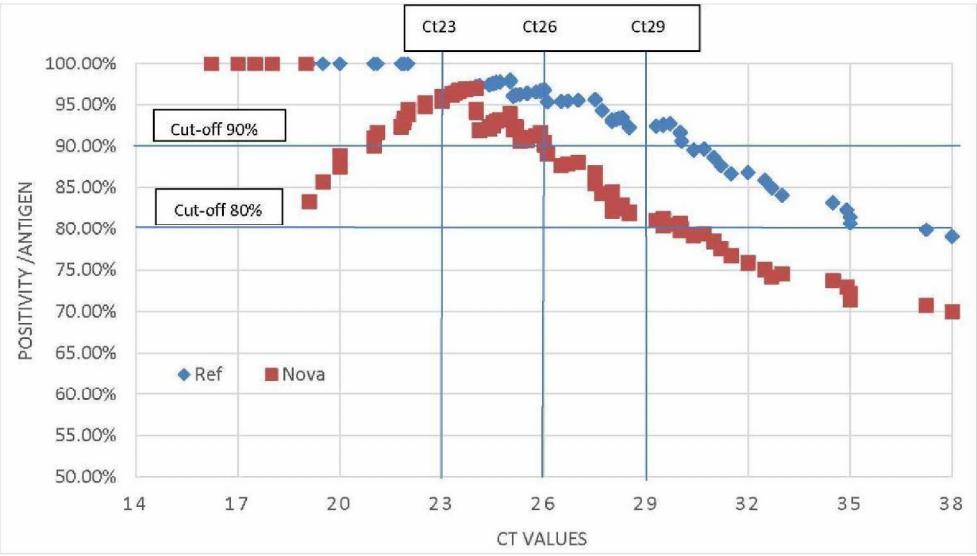

Figure 1. Percentage of antigen positivity compared to Ct values of samples.

The median Ct values in antigen positive samples were **24** for the **NOVA Test** and **24.55** for the reference standard (Figure 2).

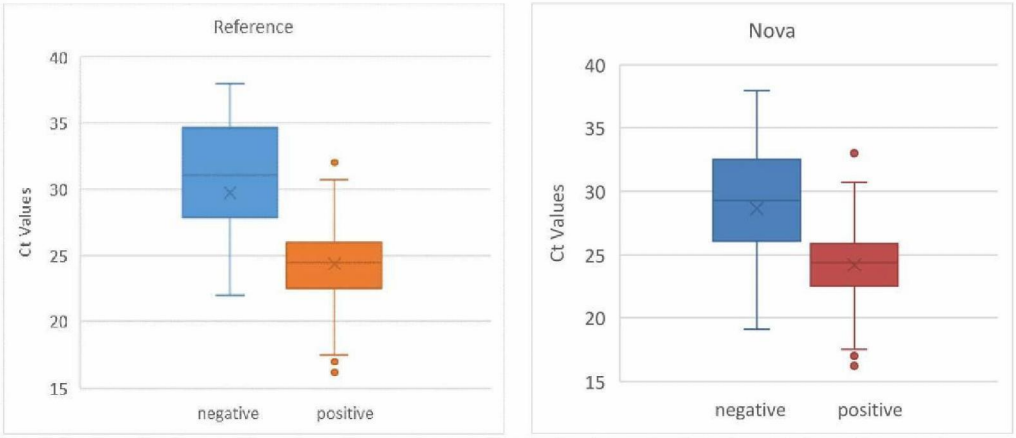

Figure 2. Ct values of antigen positive and negative tested samples from routine diagnostics. Boxes show median and interquartile range;

Samples tested from serial dilution

The serial dilution from positive samples indicates that the **NOVA Test** surpassed the minimal positivity of 23.3 and 23.1 .

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

Table2. 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
PCR System: Seegene Allplex™ 2019-nCoV Assay, E-Gene was considered for Ct-values

Minimal acceptance criteria to successfully pass the validation:

- Sensitivity at Ct 23 (corresponding to approx. 10'000'000 c/mL), at least 95%
- Sensitivity at Ct 26 (corresponding to approx. 1'000'000 c/mL), at least 90%
- Sensitivity at Ct 29 (corresponding to 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 by

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In behalf of the Swiss Society of Microbiology

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