Dr. Selina Schwegler, Federal Office of Public Health

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Technical validation report Rapid COVID-19 Antigen test

Assay name: Antigen Rapid Diagnostic Test (LS1100)
Assay Lot number: 672009/ 672011

Company: Lansion Biotechnology Co.
Distributor: Lifetest.ch, E Beqiri

Summary

The **Antigen Rapid Diagnostic Test (LS1100) pass** the validation criteria as described by the Swiss Society of Microbiology. At viral load (VL) of 1e+5, 1e+6 and 1e+7, the **Antigen Rapid Diagnostic Test (LS1100)** assay showed a technical sensitivity of **85%, 95.47%** and **99.5%** compared to a reference standard (Standard Q Roche) showing a technical sensitivity of **75%, 94.4%** and **100%**, respectively. The technical specificity was **98.8%**.

Interpretation of technical sensitivity and specificity

Technical sensitivities at VL of 1e+5, 1e+6 and 1e+7, as well as the overall specificity is shown in **Table 1**. **Figure 1** shows the percentage sensitivity in relation to viral loads over a range of 100 PCR-positive clinical samples. In order to detect 80%, 90% and 95% of PCR positive samples, the **Antigen Rapid Diagnostic Test (LS1100)** test requires a minimum VL of about 5E+05, 2E+06 and 2.3E+08, respectively.

	Sensitivity			Specificity
	VL 1e+5 (Ct28-30)	VL 1e+6 (Ct25-27)	VL 1e+7 (Ct21-23)	
Standard Q Roche	75% (74.3-80.4%)	94.4% (85.1-94.2%)	100% (96.9-100%)	100%
Rapid Ag LANSIONBIO	85% (74.3-78.9%)	95.47% (81.6-89.2%)	99.5% (92-93.9%)	98.8%

Table 1. Technical sensitivity and specificity, expressed in percentage. For sensitivities at VL 1e+5, 1e+6 and 1e+7 a threshold of 95%, 90% and 80% has to be reached. Overall specificity needed to be at least 99%.

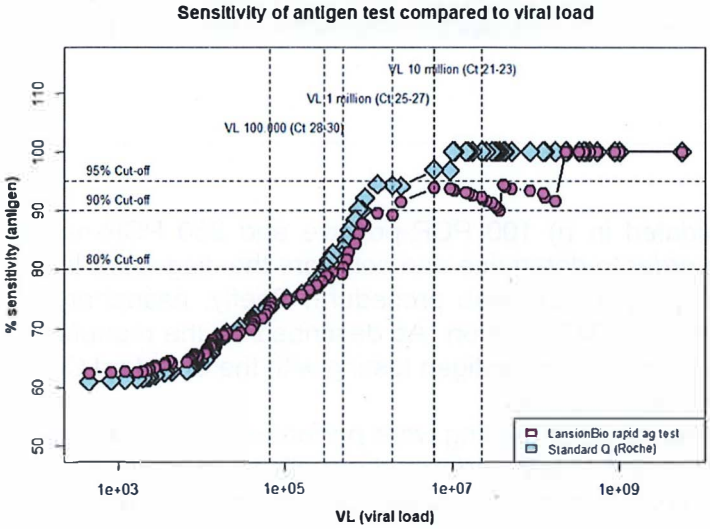

Figure 1. Sensitivity of antigen compared to Viral loads of samples.

The median VL in antigen positive samples were **2.4e+07** for the **Covid-19 Antigen Rapid Test Cassette** and 3.5e+07 for the reference standard (Standard Q Roche) (Figure 2).

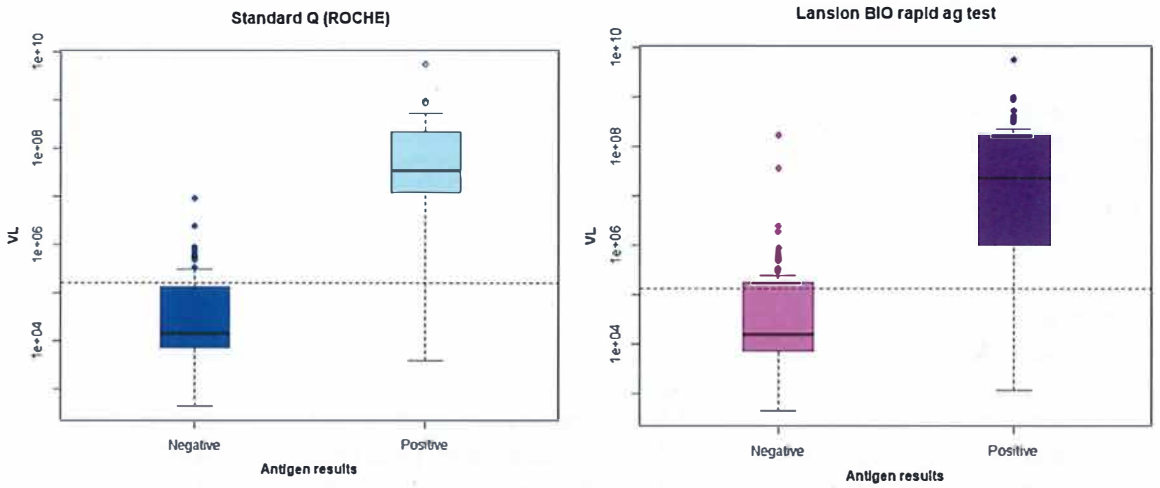

Figure 2. Viral loads of antigen positive and negative tested samples from routine diagnostics. Boxes show median and interquartile range.

Samples tested from serial dilution

The serial dilution from positive samples indicates that the **Antigen Rapid Diagnostic Test (LS1100)** reached the minimal positivity of 6.76E+06.

	VL	2.35E+07	1.26E+07	6.76E+06	3.63E+06	1.94E+06	1.04E+06	5.60E+05
Cell culture super-natant	LANSION Bio rapid Ag test	+	+	+	+	+	-	-
	Ref (Standard Q Roche)	+	+	+	+	I	-	-
	VL	2.35E+07	1.26E+07	6.76E+06	3.63E+06	1.94E+06	1.04E+06	5.60E+05
Clinical sample	LANSION Bio rapid Ag test	+	+	+	+	-	-	-
	Ref (Standard Q Roche)	+	+	+	+	+	-	-

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. I= results impossible to interpret

Methods

The technical performance was validated in (i) 100 PCR-positive and 250 PCR-negative samples and (ii) in a serial dilution in order to determine and compare the diagnostic limits of detection. The validation was done using a wet swab procedure. Briefly, nasopharyngeal swabs were suspended in 3 to 3.5 mcl of UMT solution. As described by the manufacturer (Roche), 350 mcl of the sample were used for rapid antigen testing with the Standard Q, while 300 mcl were used for the LansionBio rapid Ag test.

The rest of the procedure, the incubation and the reading were performed as indicated by the manufacturers, with the reading of Standard Q test performed visually by the technician and the reading of Lansion Bio test performed automatically by the LS1100 analyser, after 15 min of incubation.

In general samples were used from the routine diagnostic of the validating laboratory. To allow for a cross-laboratory comparison, 2 SARS-CoV-2 PCR-positive samples were used from aliquoted samples provided by 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).

PCR System: Cobas 6800 (Roche). E-Gene was considered for Ct-values for all patients.

Minimal acceptance criteria to successfully pass the validation (with a cut-off window including preanalytical & analytical variations):

- Sensitivity at 10'000'000 c/mL (corresponding to approx. Ct 21-23), at least 95%
- Sensitivity at 1'000'000 c/mL (corresponding to approx. Ct 25-27), at least 90%
- Sensitivity at 100'000 c/mL (corresponding to approx. Ct 28-30), at least 80%
- Specificity to reference, at least 99%
- Serial dilution has to detect up to 6.76E+06 (Ct 23).

This validation report was released for the FOPH by

CHUV
Prof. Gilbert Greub, médecin chef
Directeur et Chef de service
Institut de Microbiologie
Rue du Bugnon 48
1011 Lausanne - Suisse

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Prof. Gilbert Greub, MD,PhD,FMH,FAMH
University Hospital of Lausanne
Rue du Bugnon 48
CH-1011 Lausanne

Dr. Giorgia Caruana, MD
University Hospital of Lausanne
Rue du Bugnon 48
CH-1011 Lausanne

In behalf of the Swiss Society of Microbiology
Members of the core validation team:

- Prof. Adrian Egli, Clinical Bacteriology and Mycology, University Hospital Basel
- Dr. Hans Fankhauser, Clinical Microbiology, Cantonal Hospital of Aarau
- Prof. Gilbert Greub, Clinical Microbiology, University Hospital Lausanne
- Prof. Hans H. Hirsch, Clinical Virology, University Hospital Basel
- Reto Lienhard, ADMed Microbiologie, La Chaux-de-Fonds