fzmb GmbH,
Forschungszentrum für Medizintechnik und Biotechnologie
Geranienweg 7 | 99947 Bad Langensalza | Germany
www.fzmb.de

Technical Validation Report COVID-19 Antigen Lateral Flow Assay

Date: 2021-03-16

Assay Name: COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay)
Assay LOT: 0672015
Manufacturer: Lansion Biotechnology Co., Ltd.
Distributor: Lifetest.ch by CTSC AG

Summary

The test COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay) has passed the validation criteria as described by the Swiss Society of Microbiology ("Recommendation of the Swiss Society of Microbiology for usage of SARS-CoV-2 specific antigen tests", Updated version 4.0, 2020-12-06). At CT values of 23, 26, and 29 the Lansion Biotechnology COVID-19 Antigen Test Kit showed a technical sensitivity of 100%, 97.44% and 94.59% compared to a reference standard Roche SARS-CoV-2 Rapid Antigen Test (REF: 9901-NCOV-01G, LOT: QCO390065I) showing a technical sensitivity of 100%, 87.18% and 72.97%, respectively. The technical specificity was 100%.

Technical Sensitivity and Specificity

Technical sensitivities at CT values of 23, 26, and 29, as well as the overall specificity are shown in Table 1. Figure 1 shows the percentage sensitivity in relation to CT values over the range of 155 PCR positive clinical samples.

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

CT value	Number samples	Sensitivity		Specificity	
		Roche	Lansion	Roche	Lansion
22-24	32	100%	100%	100%	100%
25-27	39	87.18%	97.44%		
28-30	37	72.97%	94.59%		

fzmb GmbH,
Forschungszentrum für Medizintechnik und Biotechnologie
Geranienweg 7 | 99947 Bad Langensalza | Germany
www.fzmb.de

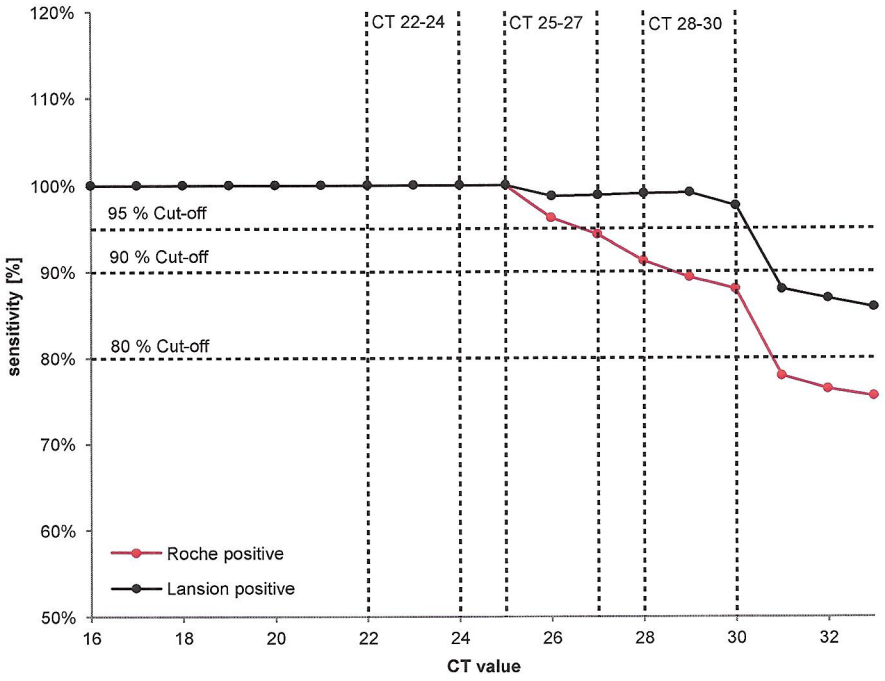

Figure 1: Sensitivity in relation to CT values over the range of 155 PCR positive clinical samples.

Limit of Detection

The serial dilution of high PCR positive clinical sample indicates that the Lansion Biotechnology COVID-19 Antigen Test Kit reached the minimal positivity of CT 23.

Table 2: 2-fold serial dilution of high PCR positive clinical sample. + = clear positive reaction, (+) = faint positive band, - = negative result. Green shade indicates the range within the test has to be positive.

Dilution	CT value	Roche	Lansion
1	20	+	+
1:2	21	+	+
1:4	22	+	+
1:8	24	+	+
1:16	25	+	+
1:32	26	+	+
1:64	27	(+)	(+)
1:128	29	(+)	(+)
1:256	30	-	-
1:512	31	-	-

fzmb GmbH,
Forschungszentrum für Medizintechnik und Biotechnologie
Geranienweg 7 | 99947 Bad Langensalza | Germany
www.fzmb.de

Methods

The technical performance was validated in (i) 155 PCR positive and 200 PCR negative clinical samples and (ii) in a serial dilution in order to determine and compare the diagnostic limit of detection. The validation was done using nasopharyngeal left-over material from the PCR assay. 50 µl of the left-over material was mixed with 50 µl of the sample buffer of the respective assay and then the entire volume was applied to the lateral flow assay. The test procedure and incubation time were done according to the manufacturer indication. The reference test (Roche SARS-CoV-2 Rapid Antigen Test; REF: 9901-NCOV-01G; LOT: QCO390065I) was read out with the ESEQuant LR3 from DIALUNOX GmbH after 15 minutes. The Lansion Biotechnology COVID-19 Antigen Test was read out automatically with the LS-2100 Dry Fluorescence Immunoassay Analyzer from Lansion Biotechnology Co., Ltd. To determine the cut-off, the mean of all PCR negative clinical samples + three standard deviations of the mean was calculated. In addition, the Lansion Biotechnology COVID-19 Antigen Test was tested for specificity on 50 samples including the following viruses: HCoV-OC43 (n=4), HCoV-HKU1 (n=4), HCoV-NL63 (n=5), HCoV-229E (n=4), MERS-CoV (n=3), Adenovirus Type 2 Hexon (n=3), Parainfluenza Virus Type 1-3 (n=4 each), Influenza A and B (n=6 each), Respiratory Syncytial Virus (n=3).

PCR-system: RealStar® SARS-CoV-2 RT-PCR Kit 1.0; Altona Diagnostics (measuring system: LightCycler 480, Roche); E-Gene was considered for CT values.

Minimal acceptance criteria to successfully pass the validation:

i. Sensitivity at CT values of 23, at least 95%
ii. Sensitivity at CT values of 26, at least 90%
iii. Sensitivity at CT values of 29, at least 80%
iv. Specificity, at least 99%
v. Serial dilution has to detect up to CT 23

This validation report was released by

fzmb GmbH
Forschungszentrum für Medizintechnik
und Biotechnologie
Geranienweg 7
D-99947 Bad Langensalza
Tel. 03603 / 83 30, Fax 83 9

Dr. Peter Miethe
CEO
fzmb GmbH, Forschungszentrum für
Medizintechnik und Biotechnologie
Geranienweg 7
99947 Bad Langensalza
E-Mail: PMiethe@fzmb.de