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Technical Validation Report COVID-19 Antigen Lateral Flow Assay

Date: 2021-03-18
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 COVID-19 Antigen Test Kit (Dry Fluorescence lmmunoassay) has passed the validation criteria, as described in the final modification of the Ordonnance 3 COVID-19, published on the official page of Federal Office of Public Health (FOPH).
At CT 23, 26, and 29 the Lansion Biotechnology COVID-19 Antigen Test Kit showed a technical sensitivity of 100%, and over all specificity of 100% compared to a reference standard RT_PCR (Seegene _BioRAD), E_gene was considered for CT values.

	Sensitivity			Over all Specificity
CT	23	26	29	
Target	95%	90%	80%	99%
COVID-19 Antigen Lateral Flow Assay	100%	100/%	100%	100%

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%.

Technical Sensitivity and Specificity

A number of CT values ranging 16 to 38 from 106 previous RT_PCR positives samples were used to achieve the validation. 69.98% of the samples have a CT value of ≥28 (viral load > 10e5 copies/ml).
In addition, 1:10 serial dilution of high positive clinical sample confirms the sensitivity of the test.
The overall results indicate very good sensibility (95.2%) and specificity (100%) of the COVID-19 Antigen Test Kit (Dry Fluorescence). The overall sensitivity is calculated on samples which have Ct value from ≥19 to 35.

Technical sensitivities at the different CT values used, as well as the overall sensitivity are

summarized in Table 2.

Ct value	number of samples	sensitivity	
≤19	7	100%	
20-22	19	100%	
23-25	27	96,29	One false negative at CT24
26-28	18	100%	
29-31	15	100%	
32-34	16	81,20%	
35-37	6	50%	
≥38	3	0%	
Total	111		
overall sensitivity		95.2%	

Table 2: Technical sensitivity at the different Ct values and overall specificity, expressed in percentage

CT value	22	25	28	32	35	38	≥40
Dilution	1/10	1/100	1/1000	1/10000	1/100000	1/1000000	
Results	+	+	+	+	-	-	-

Table 3: 1:10 positive sample's serial dilution, the results confirmed the reduced sensitivity in low viral charge (CT≥32)

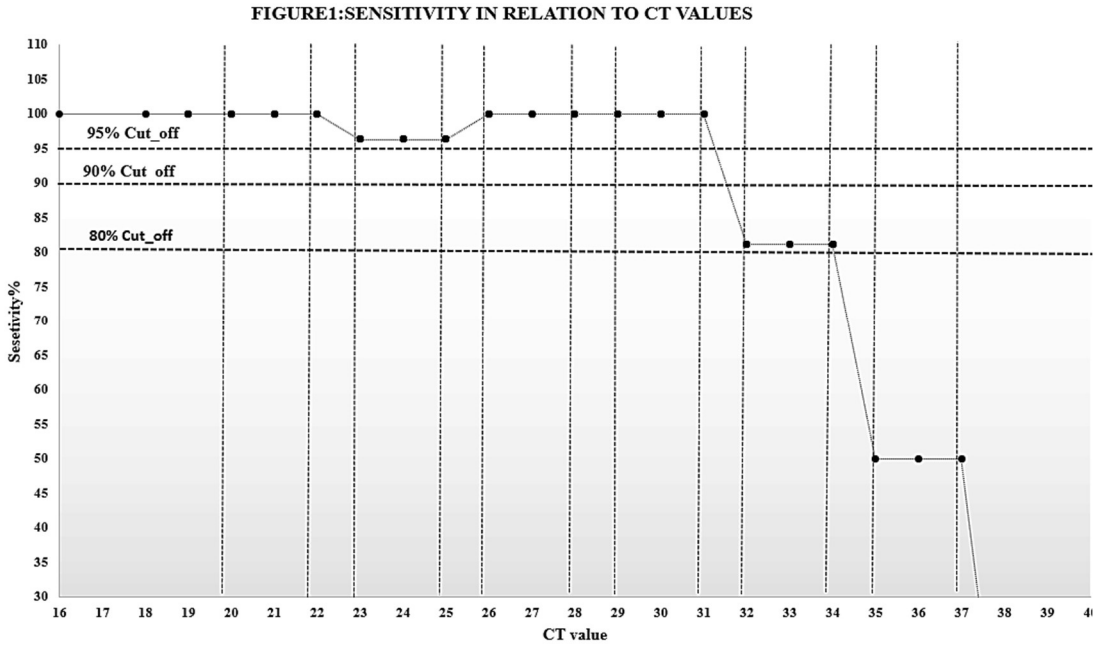

Figure 1Sensitivity in relation to CT values.

Methods:

The technical performance was validated in >100 positives and 300 negative clinical samples, in addition, a serial of 1:10 dilution confirms the sensitivity of the test. The validation was done using a nasopharyngeal left over of patient samples which are used to diagnose SARS_Cov2. 250 ul of left-over material was mixed with 200 ul of the sample extraction buffer included with the test. Then four drops of mixture were applied to lateral flow assay. The test procedure and incubation time were applied according to the manufacturer's indication. The laision Biotechnology COVID_19 Antigen test was read out automatically with LS-2100 Dry Fluorescence Immunoassay Analyzer from lanosion Biotechnology Co,Ltd. To determine the cut off, the mean of all PCR negative clinical samples, +3SD of the mean was calculated.

Reference test used for validation: RT-PCR /Allplex ™ 2019_nCoV Assay, SEEGENE_BIORAD
E_gene was considered for CT values.

Minimal acceptance criteria used in validation:

- Sensitivity at CT 23 (corresponding approx. for 10^7 copies/ml: 95%)
- Sensitivity at CT 26 for (corresponding approx. for 10^6 copies/ml copies/ml: 90%)
- Sensitivity at Ct 29 for (corresponding approx. for 10^5 copies/ml copies/ml: 80%)
- The specificity of the test must reach at least 99%.
- 50 specimens with a viral load of at least 10e5 copies/ml

This validation report is released for the FOPH.
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Neuchatel le 18-3-2021