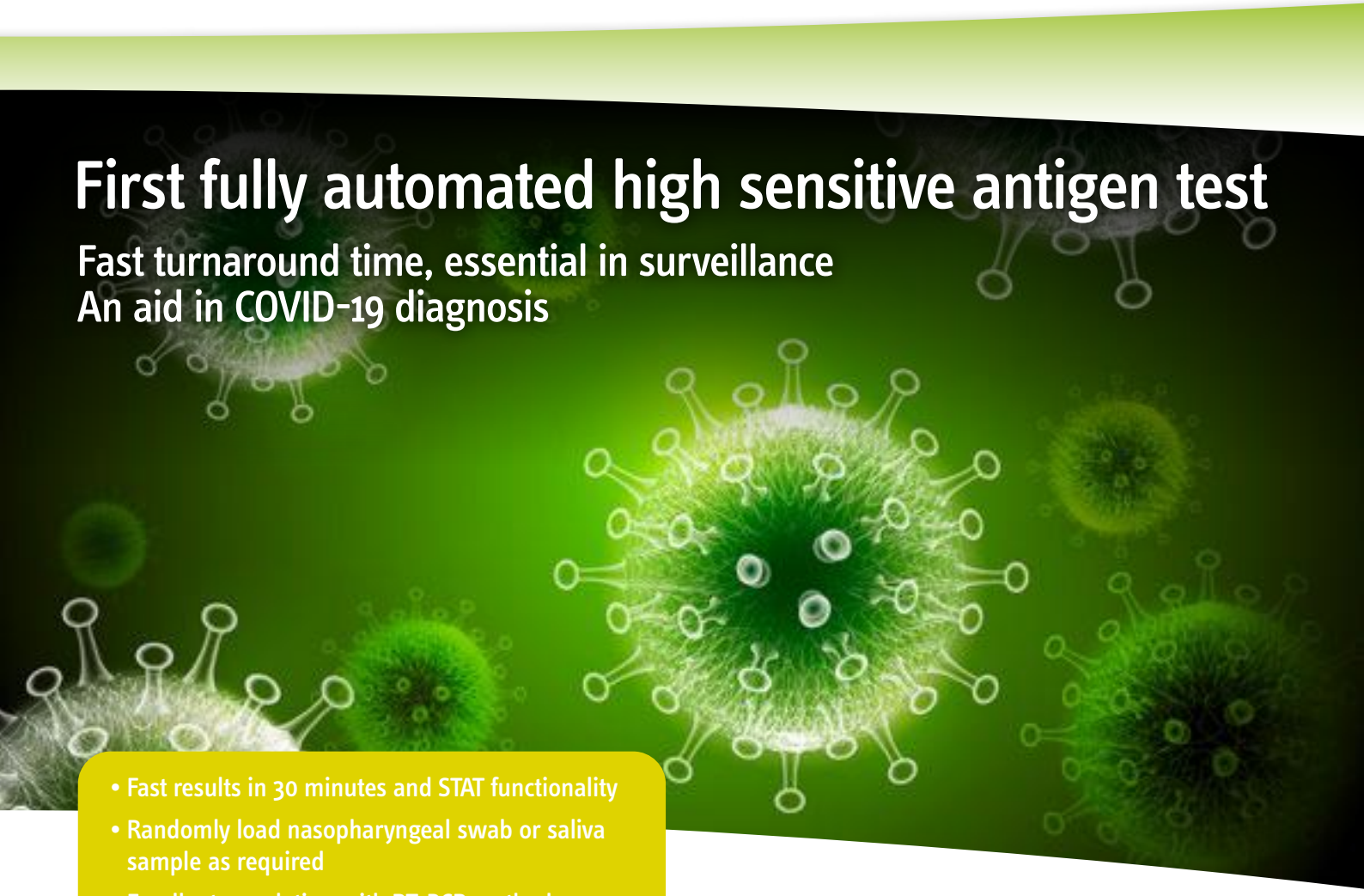
Lumipulse® G SARS-CoV-2 Ag

Detection and quantification



First fully automated high sensitive antigen test

Fast turnaround time, essential in surveillance
An aid in COVID-19 diagnosis

- Fast results in 30 minutes and STAT functionality
- Randomly load nasopharyngeal swab or saliva sample as required
- Excellent correlation with RT-PCR method
- High association with infectiousness[8,10]

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Clinical background

The 2019 novel coronavirus infection disease (COVID-19) is caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1,2] In December 2019, the Health Commission of the City of Wuhan, Hubei Province, China, reported multiple pneumonia patients with unknown cause. On January 7th 2020, the World Health Organization (WHO) announced that the National Health Commission of China identified a new type of coronavirus, SARS-CoV-2.[3]

The WHO declared a COVID-19 pandemic on March 11th 2020 due to the worldwide spread of this novel coronavirus infection.[4]

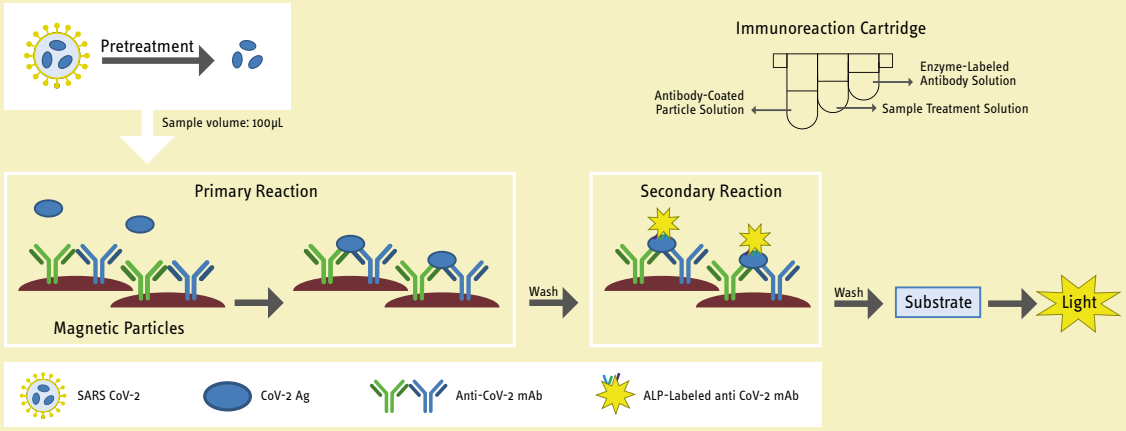
To detect the virus, lower respiratory tract specimen, nasopharyngeal swab fluid and saliva of the patient are shown to be reliable samples for the detection of the SARS-CoV-2 virus.[5,6]

In general, the diagnosis of SARS-CoV-2 infection is made by molecular detection of the SARS-CoV-2 genes. Although nucleic acid-based assays can detect SARS-CoV-2 gene with high sensitivity, it is restricted by the needs of special equipment and turnaround time. SARS-CoV-2 produces multiple viral antigens of which the nucleocapsid protein (N) is the most abundant.[11]

Lumipulse G SARS-CoV-2 Ag is an aid in the diagnosis of COVID-19 by detection and quantification of the SARS-CoV-2 nucleocapsid protein antigen based on the chemiluminescent enzyme immunoassay (CLEIA) principle.[7]

Measurement principle

Lumipulse G SARS-CoV-2 Ag is based on the chemiluminescent enzyme immunoassay (CLEIA) principle.



References

1. Wu F. *et al.* Nature 2020; 579:265-269
2. Coronaviridae Study Group of the International Committee on Taxonomy of Viruses. Nat. Microbiol. 2020; 5:536-544
3. WHO website "Rolling update on coronavirus disease (COVID-19)" (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen)
4. WHO Director-General's opening remarks at the media briefing on COVID-19–11 March 2020 (https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)
5. Di Gennaro F. *et al.* Int J Environ Res Public Health 2020; 17:2690
6. Iwasaki S. *et al.* J Infect. 2020; 81:e145-e147
7. Nishizono I, *et al.* Clin Chem 1991; 37:1639-1644
8. Menchinelli G. *et al.* Clin Chem Lab Med published online ahead of print April 7, 2021 https://doi.org/10.1515/cclm-2021-0182
9. Yokota I. *et al.* http://dx.doi.org/10.2139/ssrn.3719066
10. Hirotsu Y. *et al.* Int J Infect Dis. 2021; 105:7-14
11. Satarker S. *et al.* Arch Med Res. 2020; 51(6):482-491

For use, please read the package insert and instruction manual for each reagent and measurement system.

Clinical performance data
Excellent correlation with RT-PCR method for both nasopharyngeal and saliva sample

Nasopharyngeal samples[8]

Nasopharyngeal swab samples from individuals with COVID-19 diagnosis (RT-PCR cycle threshold Ct-value ≤ 40) or non-COVID-19 (Ct values >40) were evaluated on the Lumipulse *G* SARS-CoV-2 Ag assay.

To evaluate the correlation of the assay performance according to Ct-range, performance of the Lumipulse *G* SARS-CoV-2 Ag assay was assessed for specified Ct-categories as shown in table below.

		RT-PCR METHOD		
		Ct-value <25	Ct-value <30	Ct-value <35
Lumipulse *G* SARS-CoV-2 Ag	Positive*	87/87	124/127	147/175
	Sensitivity (95% CI)	100.0% (95.8-100.0%)	97.6% (93.3-99.2%)	84.0% (77.8-88.7%)
	Negative	397/400		
	Specificity (95% CI)	99.3% (97.8-99.7%)		

*including results in the grey zone (1.34-10.00 pg/mL)

Comparison of Lumipulse *G* SARS-CoV-2 Ag results versus RT-PCR in different testing groups.[8]

Testing group	Lumipulse *G* SARS-CoV-2 Ag	RT-PCR-Ct-values		
		<25	<30	<35
Diagnostic (symptomatic)	Positive*	35/35	52/53	58/63
	Sensitivity (95% CI)	100.0% (90.1-100.0%	98.1% (90.1-99.7%)	92.1% (82.7-96.6%)
Monitoring (symptomatic)	Positive*	20/20	32/32	46/62
	Sensitivity (95% CI)	100.0% (83.9-100.0%)	100.0% (89.3-100.0%)	74.2% (62.1-83.4%)
Screening (asymptomatic)	Positive*	32/32	40/42	43/50
	Sensitivity (95% CI)	100.0% (89.3-100.0%)	95.2% (84.2-98.7%)	86.0% (73.8-93.0%)

*including results in the grey zone (1.34-10.00 pg/mL)

Saliva samples[9]

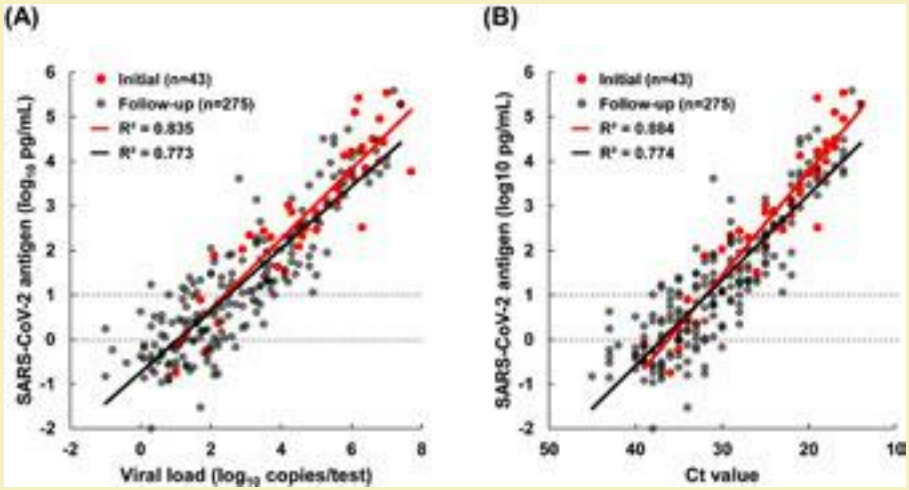
Correlation with RT-PCR method was tested on 2056 specimens from 132 symptomatic and 1924 asymptomatic persons from contact tracing cohort and airport quarantine cohort. A high correlation was observed between the RNA copy number calculated from the Ct (Cycle Threshold) value and the antigen concentration measured with the Lumipulse assay.

Lumipulse *G* SARS-CoV-2 Ag	RT-PCR Method					
	SYMPTOMATIC			ASYMPTOMATIC		
	Positive	Negative	Total	Positive	Negative	Total
Positive	33	2	35	35	13	48
Negative	8	89	97	13	1863	1876
Total	41	91	132	48	1876	1924
Sensitivity	80.5% (95% CI: 66.0-89.8%)			72.9% (95% CI: 59.0-83.4%)		
Specificity	97.8% (95% CI: 92.3-99.4%)			99.3% (95% CI: 98.8-99.6%)		
Overall concordance rate	98.2% (95% CI:97.6-98.7%) (2020/2056 cases)					

Data based on calculated cut-off value of 0.67 pg/mL.

High correlation between antigen concentration and RNA load with RT-PCR

A high correlation between Ct value and antigen level is demonstrated for initial samples (R^2=0.835) and a lower correlation in follow-up samples (R^2=0.774). Variability increased in follow-up samples which included lower viral load samples collected from hospitalized patients in late phase of infection or recovery.[10]



Assay characteristics

CHARACTERISTICS	SPECIFICATION
Sample volume*	100 µL
Measuring range	0.60 - 5000.00 pg/mL
Analytical sensitivity (LoD)	0.19 pg/mL 0.47 $\log_{10}$ $TCID_{50}$/mL (or 2.95 $TCID_{50}$/mL)[8]
Functional sensitivity (LoQ)	0.60 pg/mL
Cross-reactivity	• No cross-reactivity with inactivated Influenza viruses (Influenza virus H1N1, Influenza virus H3N2, Influenza virus B) • No cross-reactivity with in-house recombinant human coronavirus antigens (MERS-CoV, HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1). • Cross-reactivity observed with in-house recombinant human coronavirus antigen SARS-CoV (not examined with native antigen) • Full list of cross-reactants tested see IFU
Linearity	0.36 – 6056.64 pg/mL
Test result TAT	30 minutes
# of tests	60 tests/hr (on LUMIPULSE G600II) 120 tests/hr (on LUMIPULSE G1200)

*additional dead volume needed depending on sample tube cup used

Multiple sample types can be used

- Nasopharyngeal swab using either a squeeze tube or using regular test tubes.
- Saliva
- Virus preservation solution used for molecular testing

IMPROVE TURNAROUND TIME AND LABORATORY THROUGHPUT FOR COVID-19 TESTING

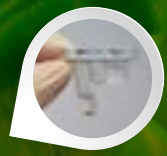
BENEFIT FROM THE EASE OF USE AND THE QUALITY THAT LUMIPULSE *G* HAS TO OFFER

LUMIPULSE® G600II

LUMIPULSE® G1200

01 Single-test cartridges facilitate runs as small as a single specimen

02 Excellent precision leads to more reliable and reproducible results



03 Eliminate the wastage often associated with opened reagent bottles

04 Excellent sensitivity and accuracy

05 Only one calibration per 30 days; no need for full calibration per run

06 Two automated analyzers with easy operator / LIS interface

07 Significantly shorter turnaround time – results within 30 minutes

ORDERING INFORMATION

PRODUCT NAME	# TEST/BOX	CONTENT		REFERENCE CODE
Lumipulse® *G* SARS-CoV-2 Ag Immunoreaction Cartridges	42 tests	Immunoreaction Cartridges	14 tests x 3	260340
Lumipulse® *G* SARS-CoV-2 Ag Calibrators set		Calibrators (Lyophilized)	4 conc x 4	231869
		Reconstituting solution	10 mL x 1	
Lumipulse® SARS-CoV-2 Ag Controls		Controls (Lyophilized)	2 conc x 6	231876
		Reconstituting solution	10 mL x 2	
Lumipulse® *G* SARS-CoV-2 Ag Sample Extraction Solution Set for Nasopharynx swab	20 tests	Sample Extraction Solution	9 mL x 1	231883
		Applicator Tip	10 tips/bag x 2	
		Squeeze tube	10 tubes/bag x 2	

Global Presence
We have a global presence through offices in Europe, United States and Asia and a worldwide commercial distribution network. For further information, please visit:
www.fujirebio.com

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