

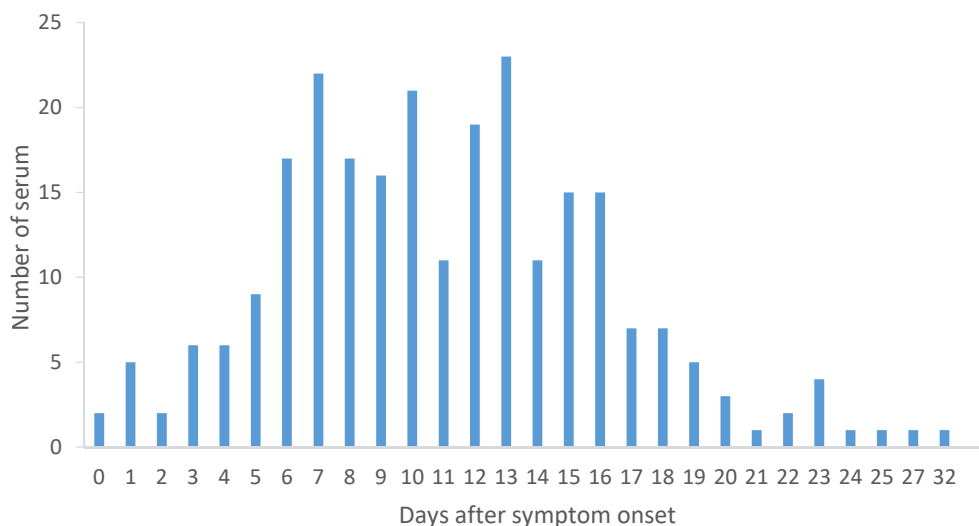
Evaluation of clinical performance and use of  
NG-Test IgG-IgM COVID-19 All-in-one assay diagnostic tests  
for the detection of SARS-CoV-2.

Service de Bactériologie-hygiène, Hôpital Bicêtre, Inserm U 1184 ; LabEx LERMIT, Université Paris-Saclay Le Kremlin-Bicêtre, France ;

Service de Virologie, Hôpital Paul-Brousse, Inserm U 1193 ; Université Paris-Saclay Villejuif, APHP Paris-Saclay, France.

## 1. Selection of samples:

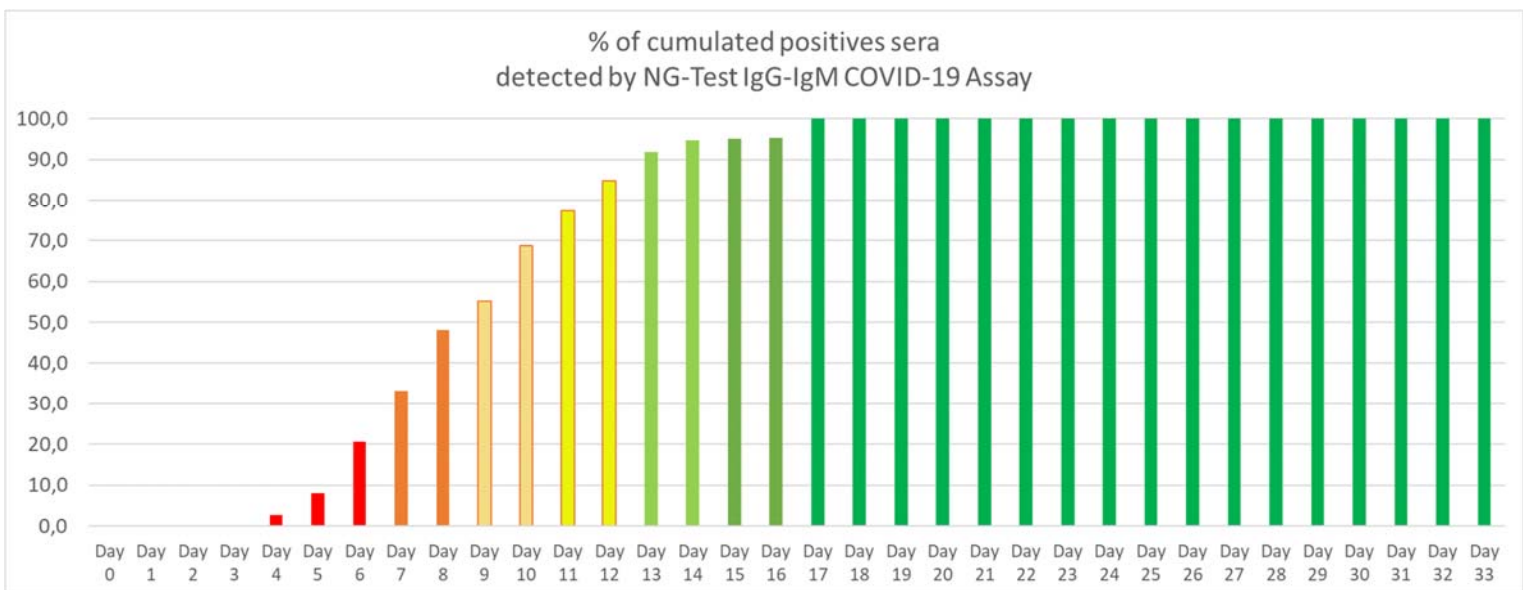
- **250 positive sera** from 158 RT-PCR confirmed patients; Randomisation by group of delay after symptoms onset: 0-5 days, 6-10 days, 11-15days, 16-21days, >21 days.
- **106 negative sera** from pre-COVID period (before dec 2019), including challenging sera (with some positives for common coronaviruses, non-SARS-CoV-2)



Graph 1: Sample selection, number of serum according to days after symptom onset.

## 2. SENSITIVITY

250 positive sera from 158 RT-PCR confirmed patients



Days after onset of symptoms	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30	Day 31	Day 32	Day 33
n	47	47	44	42	38	37	34	33	27	29	32	31	33	37	38	41	43	41	44	44	45	45	45	45	45	45	45	45	45	45	45	45	45	45
% of cumulated positives	0,0	0,0	0,0	0,0	2,6	8,1	20,6	33,3	48,1	55,2	68,8	77,4	84,8	91,9	94,7	95,1	95,3	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	

Table 1: Percentage of cumulated positive sera with the NG-Test IgG-IgM COVID-19 assay according to days after onset of symptoms

**Sensitivity: 95.1 % after 15 days (CI95% 95.6- 100.0)**

### 3. SPECIFICITY

106 negative sera from pre-COVID period (before dec 2019), including challenging sera (with some positives for common coronaviruses, non-SARS-CoV-2)

Tested Sera (characteristic)	Obtained Results with NG-Test IgG-IgM COVID-19 « All-in-one » assay	
	Negative	Positive
Rheumatoid Factor	3	0
Hyperglobulinemia IgG	6	0
Hyperglobulinemia IgM	3	0
Syphilis	57	0
Healthy donors	22	0
Other coronaviruses*	15	0

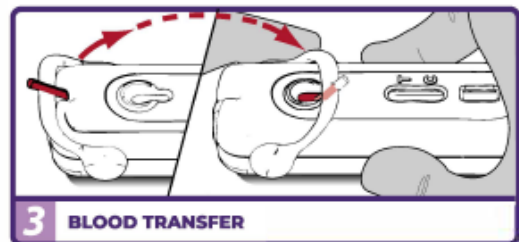
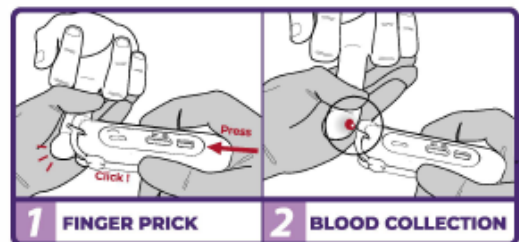
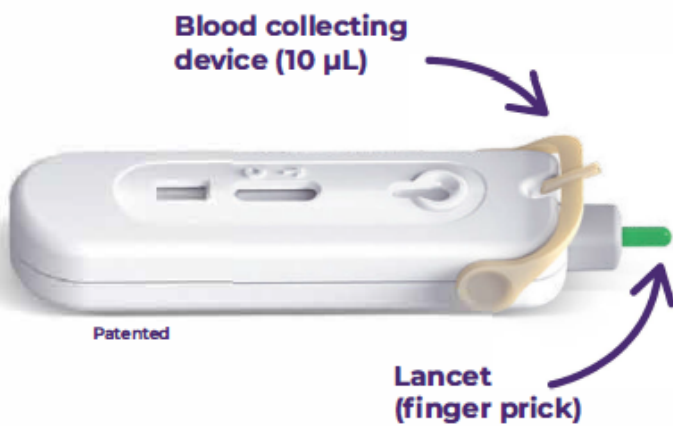
Table 2: Challenging sera tested and results obtained with the NG Biotech assay

\*(Other coronaviruses tested: E229:3; NL63:4; OC43: 3; HKU1:7)

**Specificity: 100.00 % (CI95% 95.6 - 100.0)**

# NG•TEST®/IgG-IgM COVID-19

All-in-One



**INTERPRETATION OF THE RESULTS**

<b>NEGATIVE</b>		<b>POSITIVE</b>			
<b>INVALID</b>					



WAIT FOR TO GET RESULT



PRODUCT	SPECIMEN	FORMAT	PACKS	STORAGE & CONSERVATION	REF.
NG•TEST®/IgG-IgM COVID-19 <i>All-in-One</i>	Whole blood, plasma, serum	«ALL-IN-ONE» System	5 Tests	4-30°C 24 months	NGB-COV-W23-102
NG•TEST®/IgG-IgM COVID-19 <i>Cassette</i>	Whole blood, plasma, serum	KIT CASSETTE	20 Tests	4-30°C 24 months	NGB-COV-W23-004