BioHit Anti-SARS-CoV-2 IgM/IgG Rapid Test (immunogold method)

SARS CoV-2 and COVID-19

In December of 2019, a cluster of severe pneumonia cases related to exposure to live animal market emerged in Wuhan City, PRC
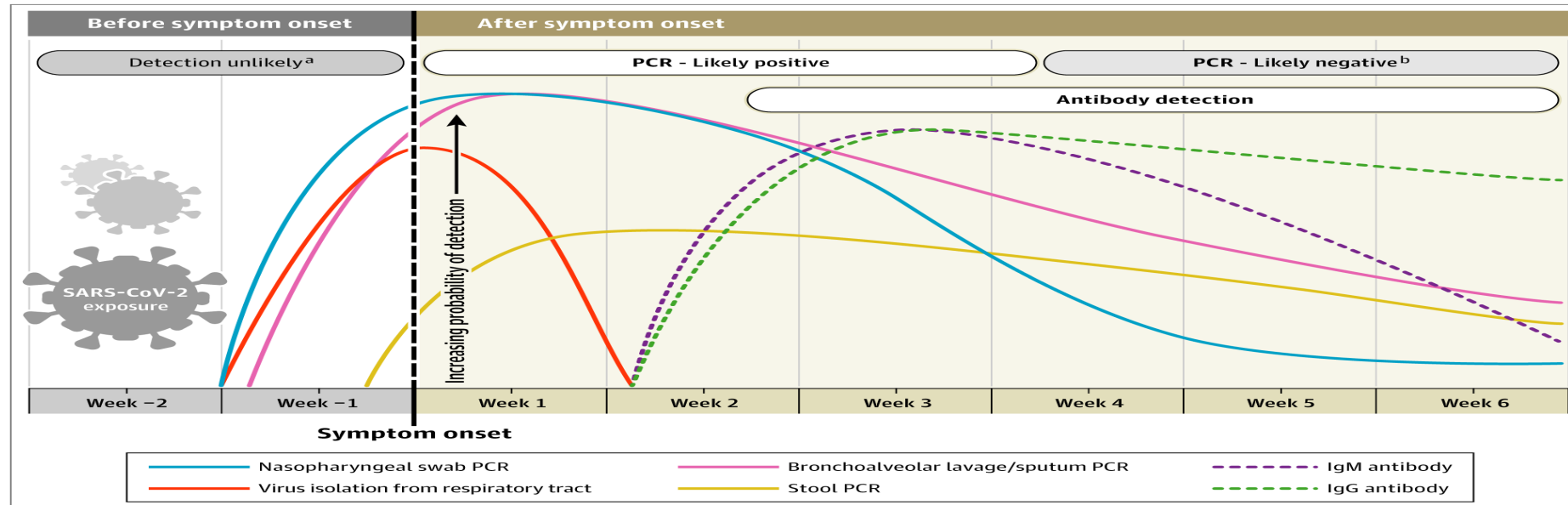
Viral genome sequencing identified novel coronavirus as causative agent (originally named 2019-nCoV)

On February 11, 2020 rhe WHO announced the official name of the novel coronavirus to be SARS-CoV-2 and the official name of the respiratory diosease caused by the virus, COVID-19.

Source: Xu Y. et al., Unveiling the origin and transmission of 2019-nCoV. Trends in Micribiol. (2020); 28 (4):239

Immune response to SARS-CoV-2, causative agent of COVID-19

Anti-SARS-CoV-2 IgG & IgM antibodies are detectable from 1-2 weeks after onset of symptoms
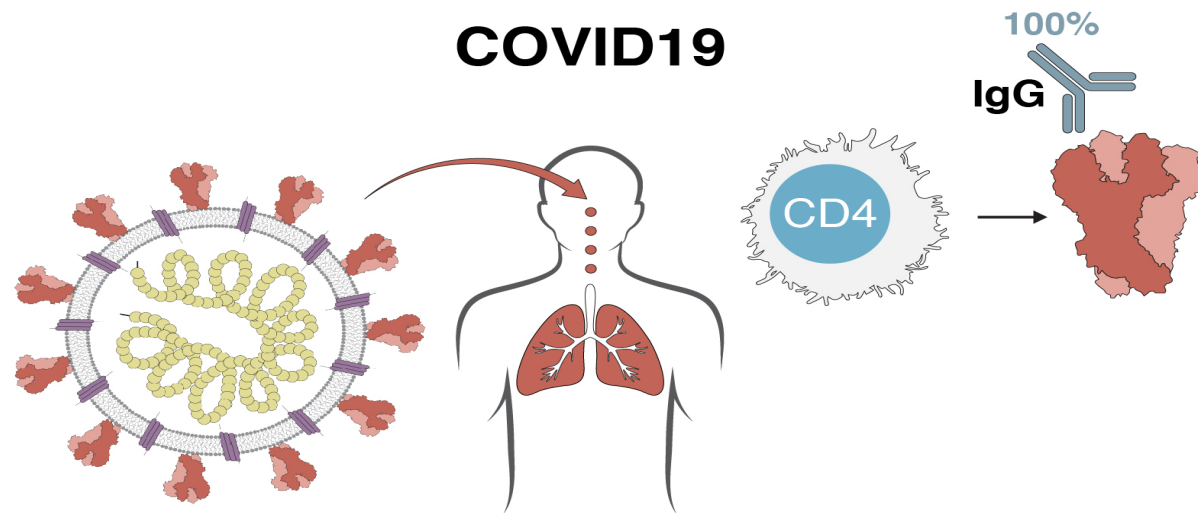

Nandini Sethuraman, MDn et al, Interpreting Diagnostic Tests for SARS-CoV-2.
JAMA. 2020 May 6. doi: 10.1001/jama.2020.8259. Online ahead of print.

https://jamanetwork.com/journals/jama/fullarticle/2765837

- **IgM only = Indicates acute/early response to infection, patient most likely infectious**
- **IgM & IgG = Indicates ongoing response, patient could still be infectious**
- **IgG only = Indicates past Infection, patient no longer infectious**

Immune Response to SARS-CoV-2

- **100%** of all **recovered** COVID-19 patients had detectable IgG

- **IgG targets the structural proteins of the virus, which are detected in this assay**

COVID19

100%

IgG

CD4

Alba Grifoni et al, Targets of T cell responses to SARS-CoV-2 coronavirus in humans with COVID-19 disease and unexposed individuals.
Published:May 14, 2020•DOI:https://doi.org/10.1016/j.cell.2020.05.015

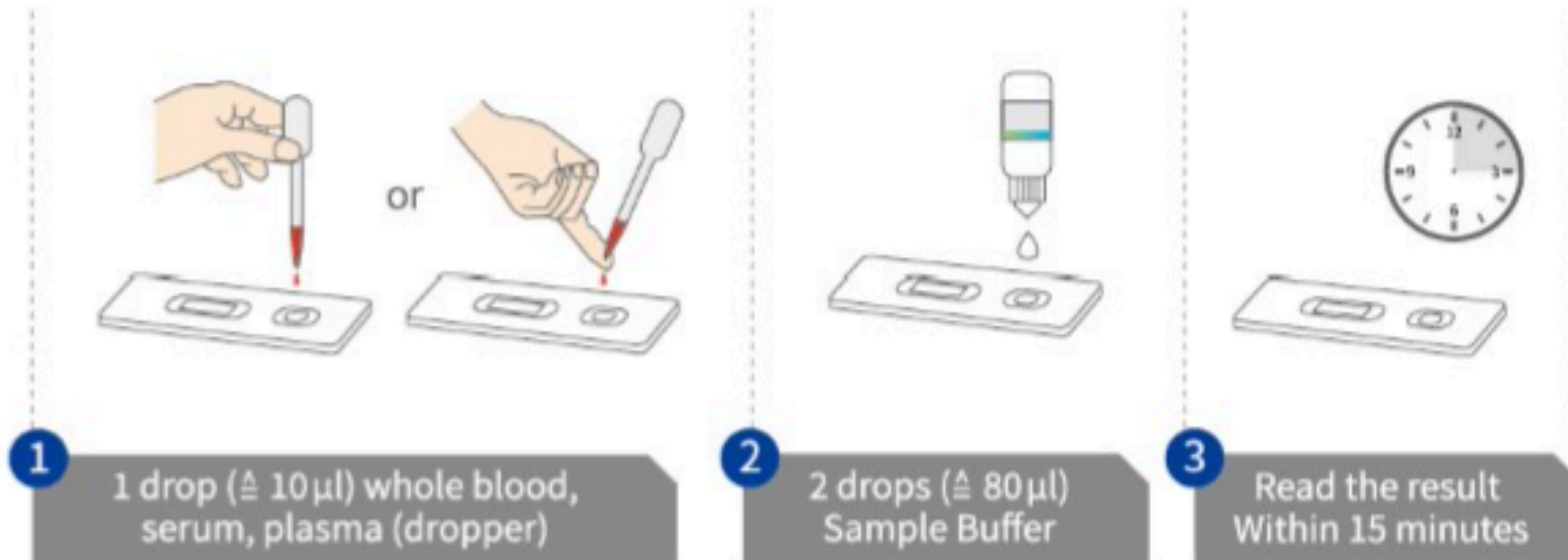https://www.cell.com/cell/pdf/S0092-8674(20)30610-3.pdf

NB: Our assay detects N and S protein: N is the nucleocapsid protein
(in yellow) and the S protein is Membrane 'Spike' protein in red.

The BioHit SARS-CoV-2 IgM/IgG Antibody Test Kit

- **Laboratory quality results**

- **Rapid access to results: 15 minutes**

- **Easy to use, 10 ul capillary blood**

- **Inexpensive**

- **CE marked for professional use**

- **Manufactured by a reputable Finnish company in China**

- **Quick shipping 48 hours from order**

- **Quality confirmed by two independent studies:**
  - Yale University, New Haven CT, USA
  - St.Thomas' Hospital, London, UK

❯ Operation Procedure

1 1 drop (≙ 10 µl) whole blood, serum, plasma (dropper)

2 2 drops (≙ 80 µl) Sample Buffer

3 Read the result Within 15 minutes

Sensitivity Results Yale University/AMU Multicentre Trial using the BioHit Rapid Test

Multicenter trial at Yale School of Public Health USA and Anhui Medical University PRC:
454 SARS-CoV-2 positive patients and 1438 SARS-CoV-2 negative patients

	SARS-CoV-2 Positive Samples			
Clinical site(s):	Hefei CDC, Fuyang CDC, Anhui Province CDC, CHINA		Yale New Haven Hospital, New Haven, CT, USA	
Infection time:	1-14 days	>14 days	1-14 days	>14 days
Sample quantity	294	118	31	9
IgM/IgG positive	134	111	24	9
IgM positive	133	111	24	9
IgG positive	103	109	24	9
None	160	7	7	0
Sensitivity - IgM/IgG [95% CI]	45.6% [39.8-51.46%]	94.1% [88.2-97.6%]	77.4% [58.9-90.4%]	100% [66.4-100%]
Sensitivity - IgM [95% CI]	45.2% [39.5-51.1%]	94.1% [88.2-97.6%]	77.4% [58.9-90.4%]	100% [66.4-100%]
Sensitivity - IgG [95% CI]	35.0% [29.6-40.8%]	92.4% [86.0-96.5%]	77.4% [58.9-90.4%]	100% [66.4-100%]

Source: C.Minteer et al., Multi-site validation of a SARS-CoV-2 IgG/IgM Rapid antibody detection kit, medRxiv, 05.2020

Specificity Results Yale University/AMU Multicentre Trial using the BioHit Rapid Test

Multicenter trial at Yale School of Public Health USA and Anhui Medical University PRC:
454 SARS-CoV-2 positive patients and 1438 SARS-CoV-2 negative patients

	SARS-Cov-2 Negative Samples					
Clinical site(s):	The First Affiliated Hospital of Anhui Medical University, Hefei, CHINA				Hefei CDC, Fuyang CDC, Anhui Province CDC, CHINA	Yale New Haven Hospital, New Haven, CT, USA
Sample type:	Other respiratory samples	Pregnant women	Inpatient's in other departments	Physical examination	Healthy controls	Healthy controls
Sample quantity	281	416	252	112	336	41
IgM positive	6	2	0	0	3	1
IgG positive	0	0	0	0	1	0
None	275	414	252	112	333	40
Specificity - IgM [95% CI]	*97.9%* *[95.4-99.2%]*	*99.5%* *[98.3-99.9%]*	*100%* *[98.6-100%]*	*100%* *[96.8-100%]*	*99.1%* *[97.4-99.8%]*	*97.6%* *[87.1-99.9%]*
Specificity - IgG [95% CI]	*100%* *[98.7-100%]*	*100%* *[99.1-100%]*	*100%* *[98.6-100%]*	*100%* *[96.8-100%]*	*99.7%* *[98.4-99.9%]*	*100%* *[91.4-100%]*

Source: C.Minteer et al., Multi-site validation of a SARS-CoV-2 IgG/IgM Rapid antibody detection kit, medRxiv, 05.2020

Conclusion from the the Clinical Validation

Multi-site Validation of a SARS-CoV-2 IgG/IgM Rapid Antibody Detection Kit

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9. Yale University, Department of Pharmacology, New Haven CT, USA.

Abstract:

Deaths from coronavirus disease (COVID-19) have exceeded 300,000 persons globally, calling for rapid development of mobile diagnostics that can assay widespread prevalence and infection rates. Data provided in this study supports the utility of a newly-designed lateral flow immunoassay (LFA) for detecting SARS-CoV-2 IgM and IgG antibodies. We employed a clinical cohort of 1,892 SARS-CoV-2 patients and controls, including individuals diagnosed by RT-qPCR at Yale New Haven Hospital, The First Affiliated Hospital of Anhui Medical University, the Chinese Center for Disease Control and Prevention of Hefei City (Hefei CDC), Anhui Province (Anhui Province CDC), and Fuyang City (Fuyang CDC). The LFA studied here detects SARS-CoV-2 IgM and IgG antibodies with a specificity of 97.9–100% for IgM, 99.7–100% for IgG, and sensitivities ranging from 94.1–100% for patients >14-days post symptom onset. Sensitivity decreases in patients <14-days post symptom onset, which is likely due to lower IgG/IgM antibody levels in this population. Finally, we developed a visual intensity reporting system that we believe will be suitable for laboratory and point-of-care settings, and will provide granular information about antibody levels. Overall our results support the widespread utility of this and other LFAs in assessing population-level epidemiological statistics.

- **Laboratory quality results, BioHit test as good as laboratory based ELISA**

- **Yale cohort, at 14 days post symptoms**
  Sensitivity IgG: 100%
  Sensitivity IgM: 100%

  Yale cohort, at 14 days post symptoms
  Specificity IgG: 100%
  Specificity IgM: 97,6 %

- **Quote: "Our data support that the BioHit test is an excellent candidate for wide spread implementation"**

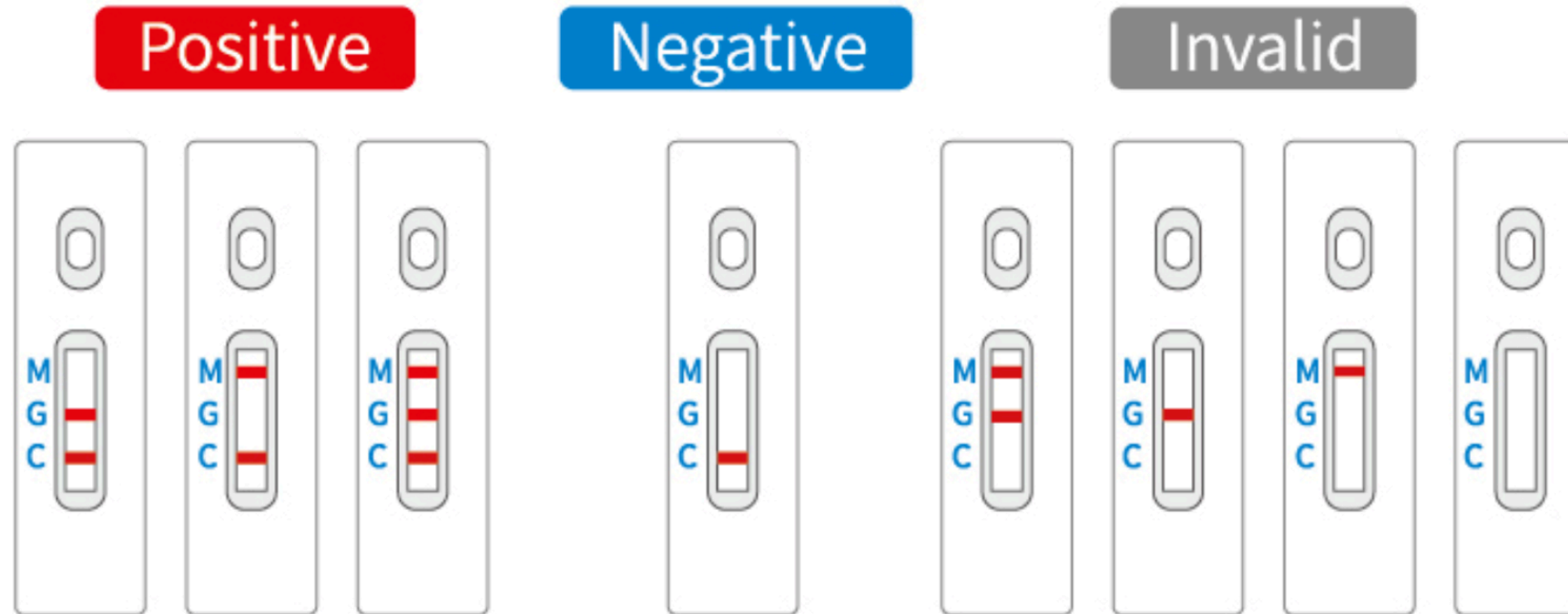# Test Strip Results to Be Expected

Figure 1: SARS-CoV-2 IgM & IgG colloidal gold immunochromatography lateral flow assay

Ordering Information:

To order please enter our website:

dialane.eu

and place purchase order. Or send your purchase order to order@dialane.eu

We can ship between 2 and 5 working days.

Product Information:

Test Box: The test box contains 25 individually wrapped test casettes, 25 canules (droppers), one vial and test instructions. The Test Box DOES NOT contain lancets (finger stick), alcohol wipes or plaster (band-aid). Individual Test Boxes can be ordered but shipping and handling will be charged extra.

Dimensions: 15 x 13.1 x 7,8 cm   Weight: 0,27 kg   Storage: 2 – 30°C

Shipping Unit: The Shipping Unit contains 18 Test Boxes (450 tests in total). This is the smallest shiping unit we sell with no additional shipping charges

Dimensions: 48 x 28,5 x 26,5 cm   Weight: 5,4 kg   Storage: 2 – 30°C

Palette: 8 to 16 Shipping Units fit on Asian Norm Palette:

Price: Selling price will depend on volume