BioHit SARS-CoV-2 Immuno Assay Portfolio

BioHit Health Care is a company which has manufactured Point-Of-Care immuno assays over the last 30 years

Our SARS-CoV-2 Tests have been amongst the first to be CE-IVD marked and released by the FDA-EUA

We have been committed to introduce the best and most novel tests to support the medical community with reliable assays to combat the long fight against the COVID-19 pandemic

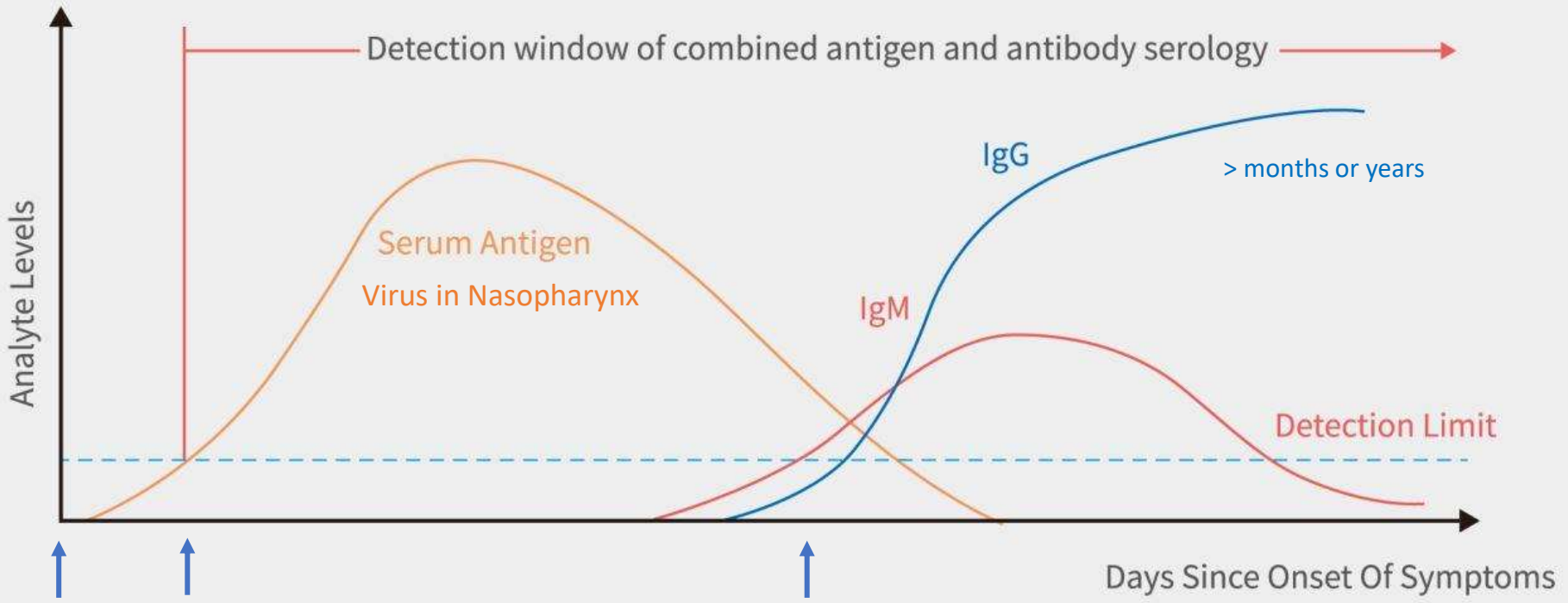
In rapid succession we have introduced assays which have made a real difference in the hands of professionals:

1) Anti-SARS-CoV-2 IgM/IgG Rapid Assay (immuno-gold method)
2) SARS-CoV-2 Antigen Quantitative Antigen Assay Kit (ELISA method)
3) SARS-CoV-2 Antigen Rapid Test (immuno-fluorescence method) – serum/plasma
   NEW - included BioHit Nasopharyngeal Extration Kit

soon to come

4) SARS-CoV-2 Antigen Rapid Tests (immuno-fluorescence based) – capillary blood

SARS-CoV-2 Infection and Immune response

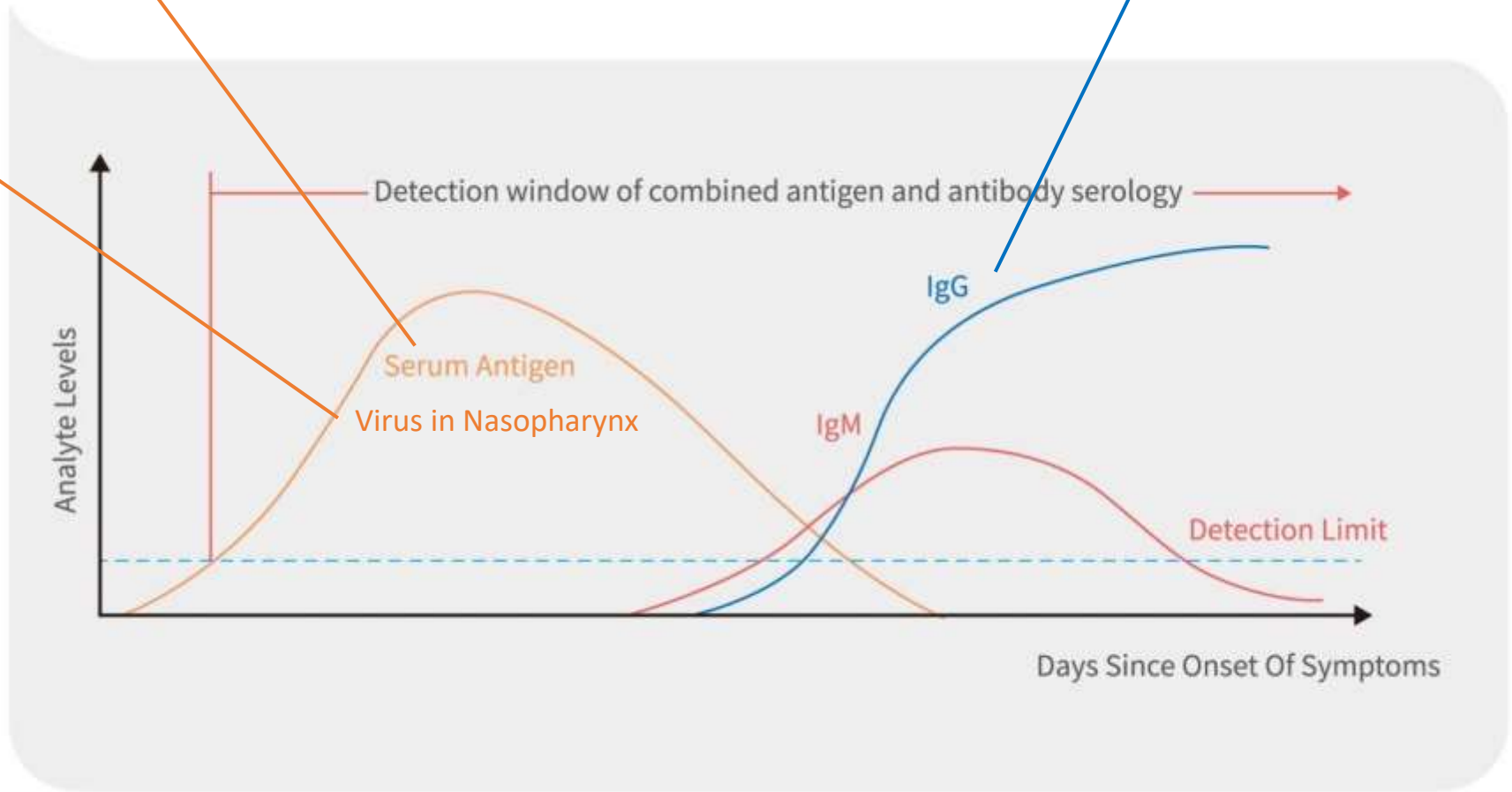


Applicable Tests in COVID Testing

BioHit SARS -CoV-2 Antigen Tests

BioHit SARS -CoV-2 IgM/IgG Rapid Test

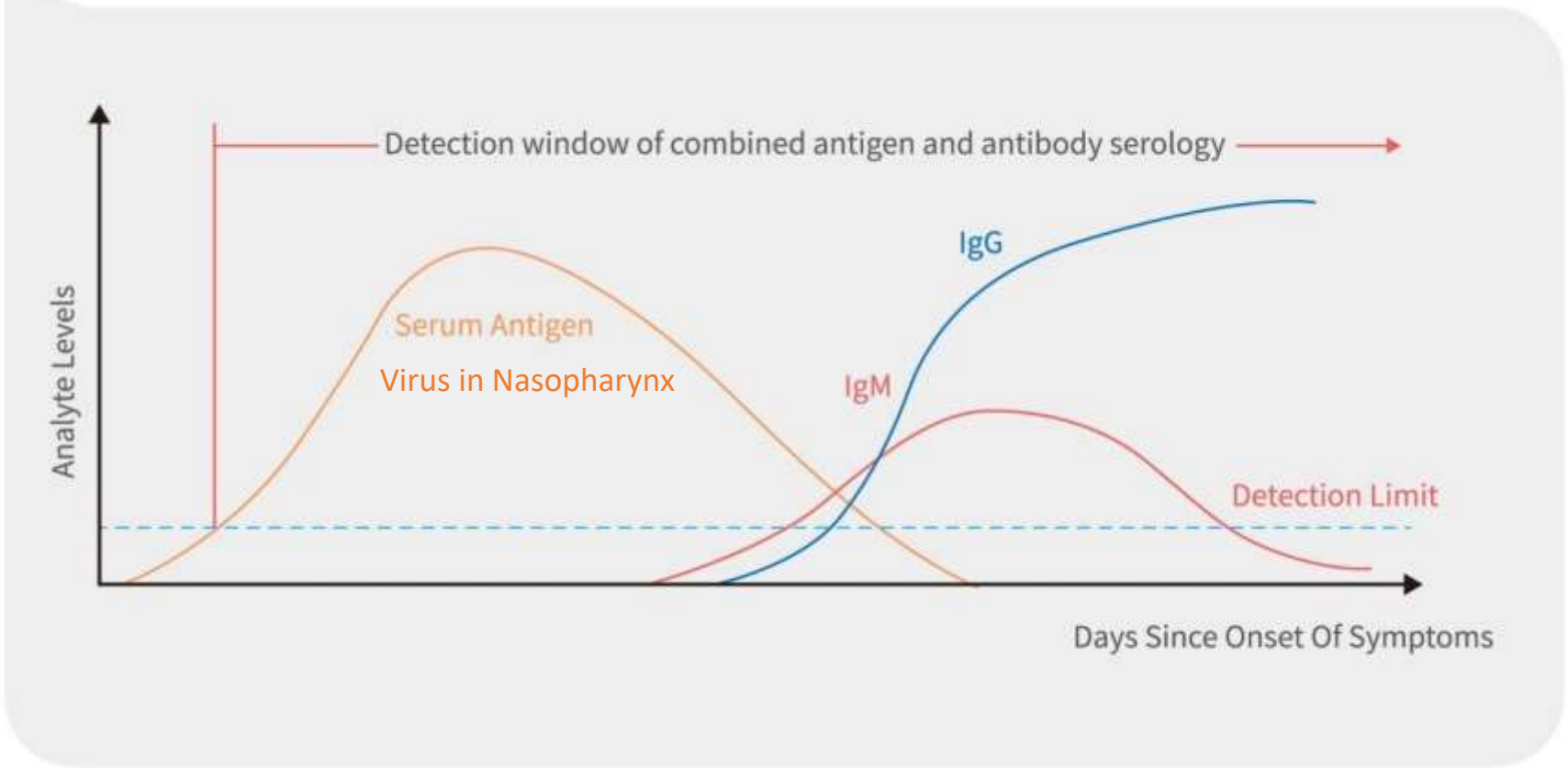
RT-PCR from NP swabs



The Right Test for the Right Question: BioHit Has the Answer

Is it COVID-19?: First Coice: RT-PCR (rapid or lab based)
Second Choice: BioHit Rapid Antigen test

Was I exposed to SARS-CoV-2?: BioHit IgM/IgG Rapid Test



The BioHit Anti-SARS-CoV-2 IgM/IgG Antibody Test Kit (immunogold)

- **Laboratory quality results**
- **Rapid access to results: 15 minutes**
- **Easy to use, 10 ul capillary blood**
- **Inexpensive**
- **CE-IVD marked, FDA EUA registered for professional use, since June 2020**
- **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
  - Departement of Health, USA

The BioHit SARS-CoV-2 ANTIGEN Rapid Test Kit (immuno fluorescent)


EC Declaration of Conformity

Manufacturer: BIOHIT HealthCare (Hefei) Co., Ltd.

Address:

European Representative:

Address:

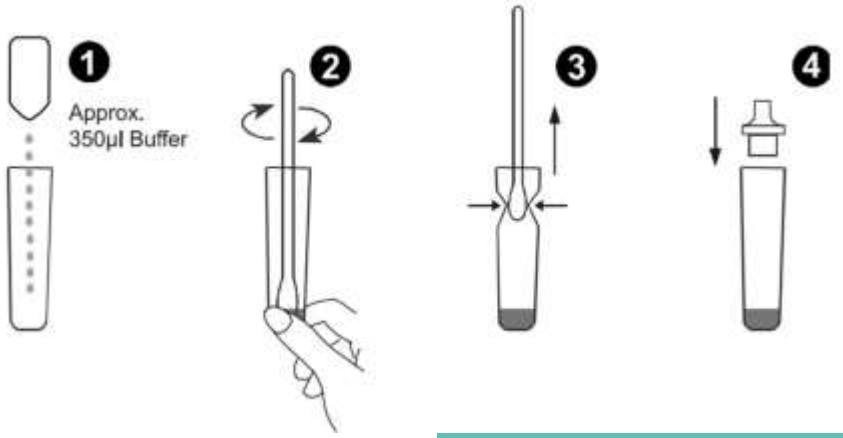
Product:

Classification:

CE

- No pre-analytical errors
- Rapid access to results: 15 minutes
- Use 80 ul of plasma or serum
- Sensitivity of 3 pg/ml viral antigen
- CE-IVD marked
- Manufactured by a reputable Finnish company in China
- Quick shipping 48 hours from order
- Quality confirmed by an independent study:
  - CoreMedica of Geneva

The BioHit SARS-CoV-2 ANTIGEN Rapid Test Kit (immuno fluorescent) plus BioHit Nasopharyngeal Extration Kit



- Rapid access to results: 15 minutes
- Use 80 ul of Nasopharyngeal extract using a separately provided extraction kit
- Sensitivity of 7 pg/ml viral antigen in NP extract
- CE-IVD marked
- Manufactured by a reputable Finnish company in China
- Quick shipping 48 hours from order
- Quality confirmed by an independent studies:
  - University of Paris, INSERM, Paris, France

The BioHit SARS-CoV-2 ANTIGEN Rapid Test Kit (immuno fluorescent) included BioHit Nasopharyngeal Extration Kit

Highest analytical sensitivity because of immuno-fluorescence

- **Rapid access to results: 15 minutes**
- **Use 80 ul of Nasopharyngeal extract**
- **Sensitivity of 3 pg/ml viral antigen serum**
  7 pg/ml varial antigen in NP extract
- **CE-IVD marked**
- **Manufactured by a reputable Finnish company in China**
- **Quick shipping 48 hours from order**
- **Highest sensitivity of any NP Antigen Rapid Test:**
  Limit of Detection: 7 pg/ml N-Antigen
  40 TCID50/ml

  Abbott reports: 157 TCID50/ml
  Innova reports: 340 TCID50/ml

The BioHit SARS-CoV-2 Antigen Quantitative ELISA Assay Kit

- Central laboratory test
- 90 samples per kit, includes calibration and control
- 50 ul serum or plasma
- LOD below 3 pg/ml
- Inexpensive
- CE-IVD marked since April 2020
- Manufactured by a reputable Finnish company in China
- Quick shipping 48 hours from order
- Uses standard ELISA lab equipment

Everybody Uses RT-PCR Swab Tests, Why Shift to Antigen Tests from Serum?

Clinicians have found that the weakness of the RT-PCR tests is the preanalytic step – the collecting of samples. Viral RNA was not found in more than half of patients although they hat proven SARS-CoV-2 infection!!

Swabs from the nose or the throat are very unreliable. The published false positive rates are shocking. No matter whose test the clinician uses, the taking of sample will be the biggest single source of error:

Interpreting Diagnostic Tests for SARS-CoV-2

Nandini Sethuraman, MD[1]; Sundararaj Stanleyraj Jeremiah, MD[2]; Akihide Ryo, MD, PhD[2]

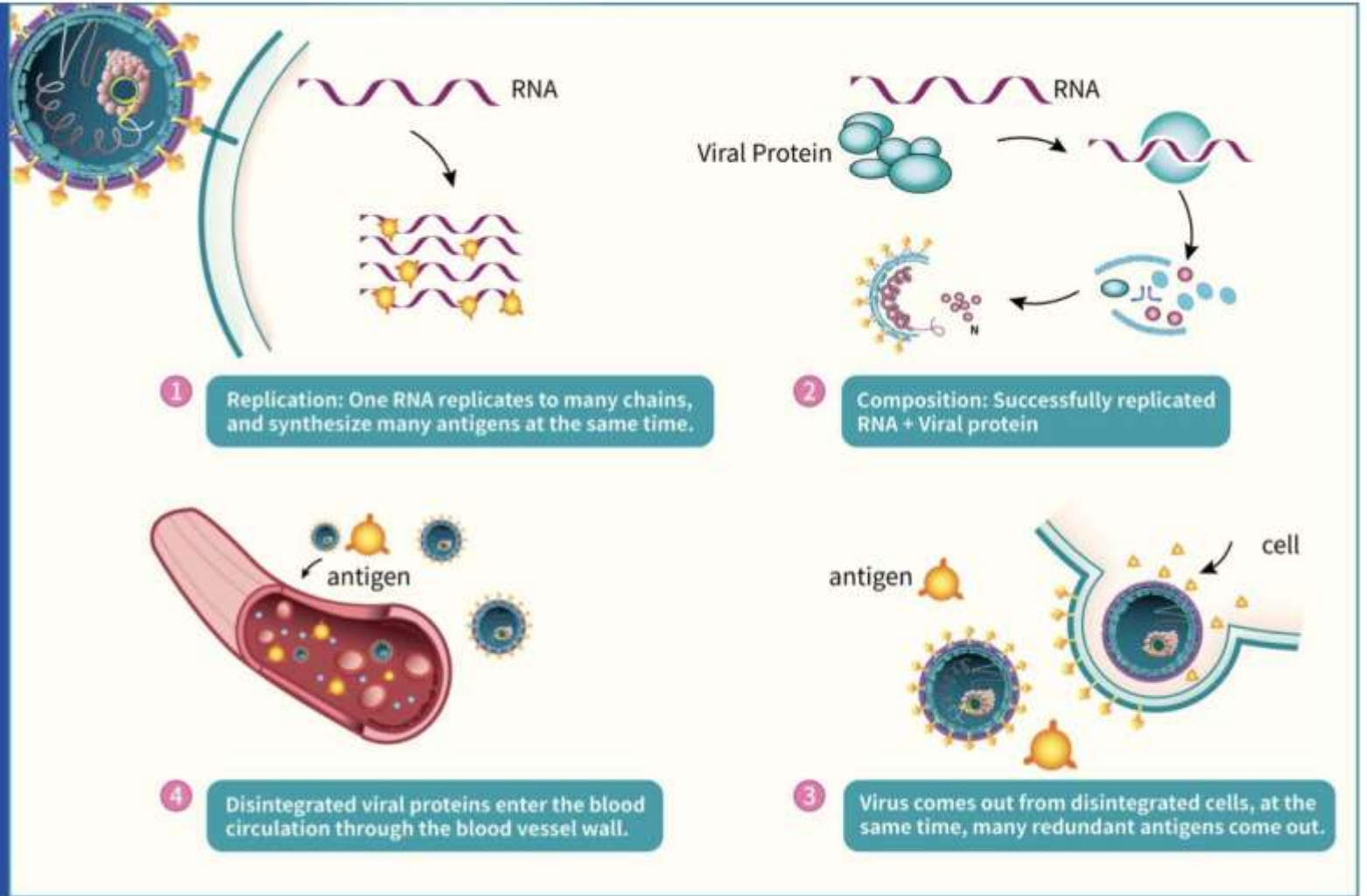
» Author Affiliations | Article Information

JAMA. 2020;323(22):2249-2251. doi:10.1001/jama.2020.8259

In a study of 205 patients with confirmed COVID-19 infection, RT-PCR positivity was highest in bronchoalveolar lavage specimens (93%), followed by sputum (72%), nasal swab (63%), and pharyngeal swab (32%).[5] False-negative results mainly occurred due to inappropriate timing of sample collection in relation to illness onset and deficiency in sampling technique, especially of nasopharyngeal swabs.

Antigen of the SARS-CoV-2 virus is found in the blood during the early phase of infection
If there were no viral particles and debris the body would not make an immune response

When SARS-CoV-2 invades the lung cells, it will express a large amount of self protein to reassemble the virus particles, causing cell damage and forming inflammation. The virus protein expressed in excess and the virus protein released from the disintegration of virus particles killed by the body in the lesions will enter the blood circulation through the vessel wall with increased permeability due to inflammation in the lesions.

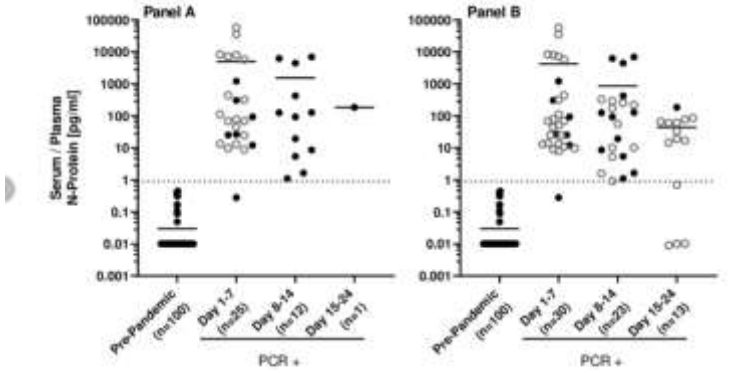


Two Studies in September Have Shown that Viral Antigen Is Detected in Blood at The Same Time as RT-PCR

SARS-Coronavirus-2 nucleocapsid protein measured in blood using a Simoa ultra-sensitive immunoassay differentiates COVID-19 infection with high clinical sensitivity.

Dandan Shan, Joseph M Johnson, Syrena C Fernandes, Muriel Mendes, Hannah Suib, Marcella Holdridge, Elaine M Burke, Katie G Beauregard, Ying Zhang, Megan Cleary, Samantha Xu, Xiao Yao, Purvish P Patel, Tatiana Plavina, David H Wilson, Lei Chang, Kim M Kaiser, Jacob Natterman, Susanne V Schmidt, Eicke Latz, Kevin Hrusovsky, Dawn Mattoon, Andrew J Ball

doi: https://doi.org/10.1101/2020.08.14.20175356



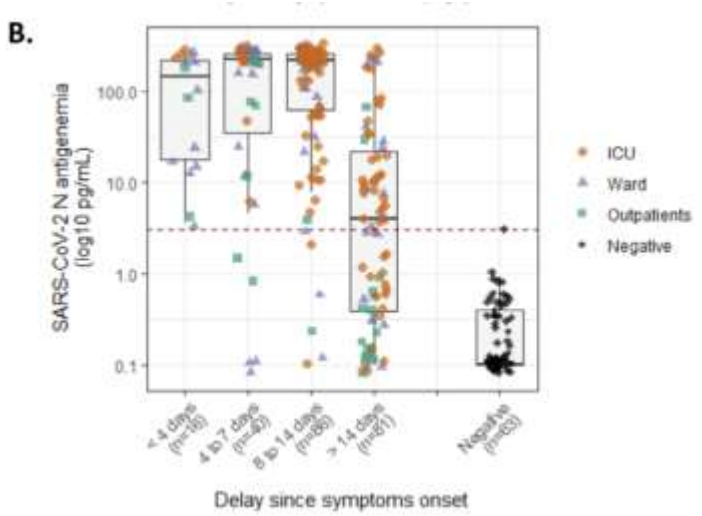
Simoa SARS-CoV-2 N Protein measurements differentiate pre-pandemic from PCR+ donors in serum and plasma. Panel A. Pre-pandemic sera from BioIVT (closed symbols), PCR+ sera from BocaBio (closed symbols) and the plasma samples from U. Bonn (open symbols). PCR+ samples are binned chronologically according to day-fromsymptom or, if asymptomatic, day-from-PCR (BocaBio) and day-from-hospitalization / PCR (U. Bonn). Each point represents a unique donor. Panel B. Measurements from all samples, including multiple longitudinal draws from the U. Bonn patients.

Uses the BioHit SARS-CoV-2 Antigen Test Kit

SARS-CoV-2 N-antigenemia: A new alternative to nucleic acid amplification techniques

Quentin Le Hingrat, Benoit Visseaux, Cedric Laouenan, Sarah Tubiana, Lila Bouadma, Yazdan Yazdanpanah, Xavier Duval, Houria Ichou, Florence Damond, Melanie Bertine, Nabil Benmalek, French COVID cohort management committee, CoV-CONTACT study group, Christophe Choquet, Jean-Francois Timsit, Jade Ghosn, Charlotte Charpentier, Diane Descamps, Nadhira Houhou-Fidouh

doi: https://doi.org/10.1101/2020.09.14.20191759



BioHit SARS-CoV-2 Rapid Antigen Test: The New Alternative to RT-PCR

Detection of antigen at 0 – 7 days post symptoms

Does not miss 50% of patients due to pre-anyalytic errors

Rapid test format:
Vein-to-Brain time, less than 30 minutes

What to focus on?

1) Anti-SARS-CoV-2 IgM/IgG Rapid Assay (immuno-gold method)
   Best in class CE-IVD / FDA EUA / 2 external studies to prove we are the best

2) SARS-CoV-2 Antigen Rapid Test (immuno-fluorescence method) – serum/plasma

3) SARS-CoV-2 Antigen Rapid Test (immuno-fluorescence method) – NP Swab
   Highest sensitivity on the market 3 pg/ml LOD or 20 TCID 50/ml – 10 x more sensitive than the competition

4) SARS-CoV-2 Antigen Rapid Test Finger Blood (immuno-fluorescence based)
   First ever capillary blood based viral antigen test kit. Fast, reliable, mass screening capable