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SZABO SCANDIC

we know how
immunostep

Improving serology testing performance

Innovating to deliver high-quality reliable testing technology.

At IMMUNOSTEP we develop innovative products in order to help improving diagnostic and clinical research performance.

We will continue to work every day to deliver high-quality technology in order to fight against the global health emergency by assuring reliable results.

RELIABILITY

Detecting SARS-CoV-2 immune response with an accuracy close to 100%.

INNOVATION

High sensitivity and specificity targeting highly antigenic structural and non-structural proteins.

EFFICIENCY

Very early antibody detection from the onset of the symptoms identifying IgG, IgA and IgM

Our Commitment: Reliability and Innovation.

In response to the Covid-19 pandemic, CSIC research groups have worked in collaboration with Immunostep to develop serological tests capable of detecting specific SARS-CoV-2 antibodies and monitoring immune response.

*Patented Protein for immunological analysis. Under CSIC Patent licence. Assay for detection of Cysteine-like Protease (Mpro) of SARS-CoV-2" | EP 203824958.

CSIC
Consejo Superior de Investigaciones Científicas

SARS-CoV-2 ELISA Mpro* Kit

Indirect Enzyme Immunoassay for the detection of IgG Immunoglobulins against Mpro/3CLpro specific SARS-CoV-2 Protein.

CE IVD

Multiaplex IgG+IgA+IgM Assay

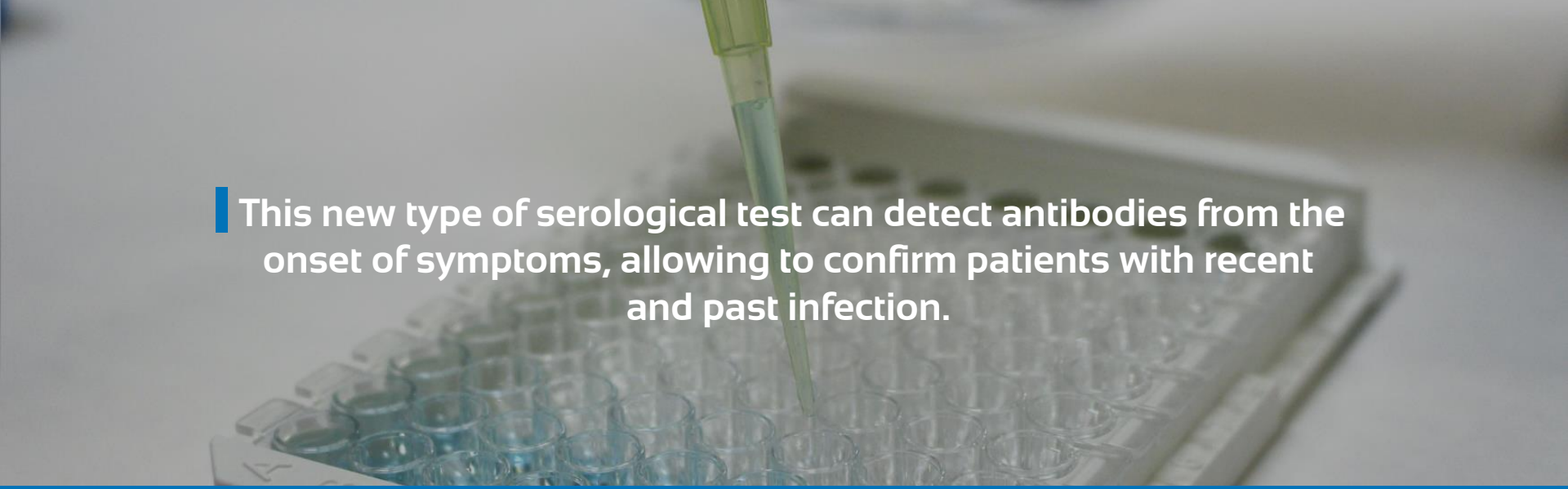
Indirect Enzyme Immunoassay for the detection of IgG Immunoglobulins against Mpro/3CLpro specific SARS-CoV-2 Protein.

SARS-CoV-2 ELISA RBD Kit

Indirect Enzyme Immunoassay for the detection of IgG Immunoglobulins against RBD SARS-CoV-2 Protein.

SARS-CoV-2 ELISA Spike Kit

Indirect Enzyme Immunoassay for the detection of IgG Immunoglobulins against Mpro/3CLpro specific SARS-CoV-2 Protein.



This new type of serological test can detect antibodies from the onset of symptoms, allowing to confirm patients with recent and past infection.

SARS-CoV-2 ELISA Mpro* Kit

Indirect Enzyme Immunoassay for detection of specific antibodies against Mpro/3CLpro protein of the SARS-CoV-2 virus (Covid-19)..

AIDS IN DIAGNOSIS & PATIENT SURVEILLANCE AFTER INFECTION

VALIDATED BY THE IMMUNOSLOGY SERVICES OF IMPORTANT HOSPITALS AND LABORATORIES

DESIGNED TO BE USED IN HUMAN SERUM AND PLASMA SAMPLES

Highly sensitive and specific test | Under CSIC patent license.

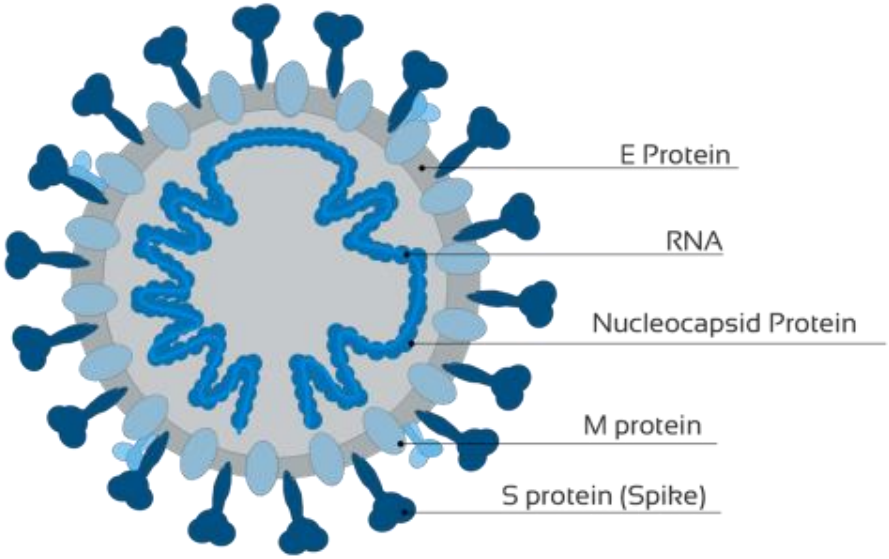
In an attempt to increase the diagnostic possibilities of COVID-19 patients, this assay was developed for the detection of specific antibodies against one of the 16 non-structural proteins, the main viral protease (Mpro or 3CLpro), which plays a critical role in viral replication.

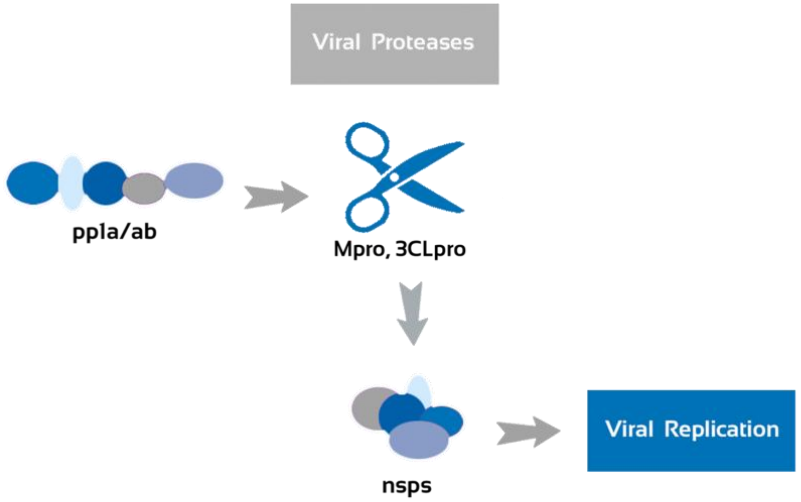
- Exclusive Specific SARS-CoV-2 antigen (Mpro).
- Highly sensitive and specific detection of covid-19 antibodies.
- Reliable SARS-Cov-2 infection determination.
- Aids in diagnosis & patient surveillance.
- Serum and plasma samples.

Exclusive Protein: Mpro/3CLpro

Non-structural Antigen	Highly immunogenic
Released by infected cells	Crucial target in viral replication

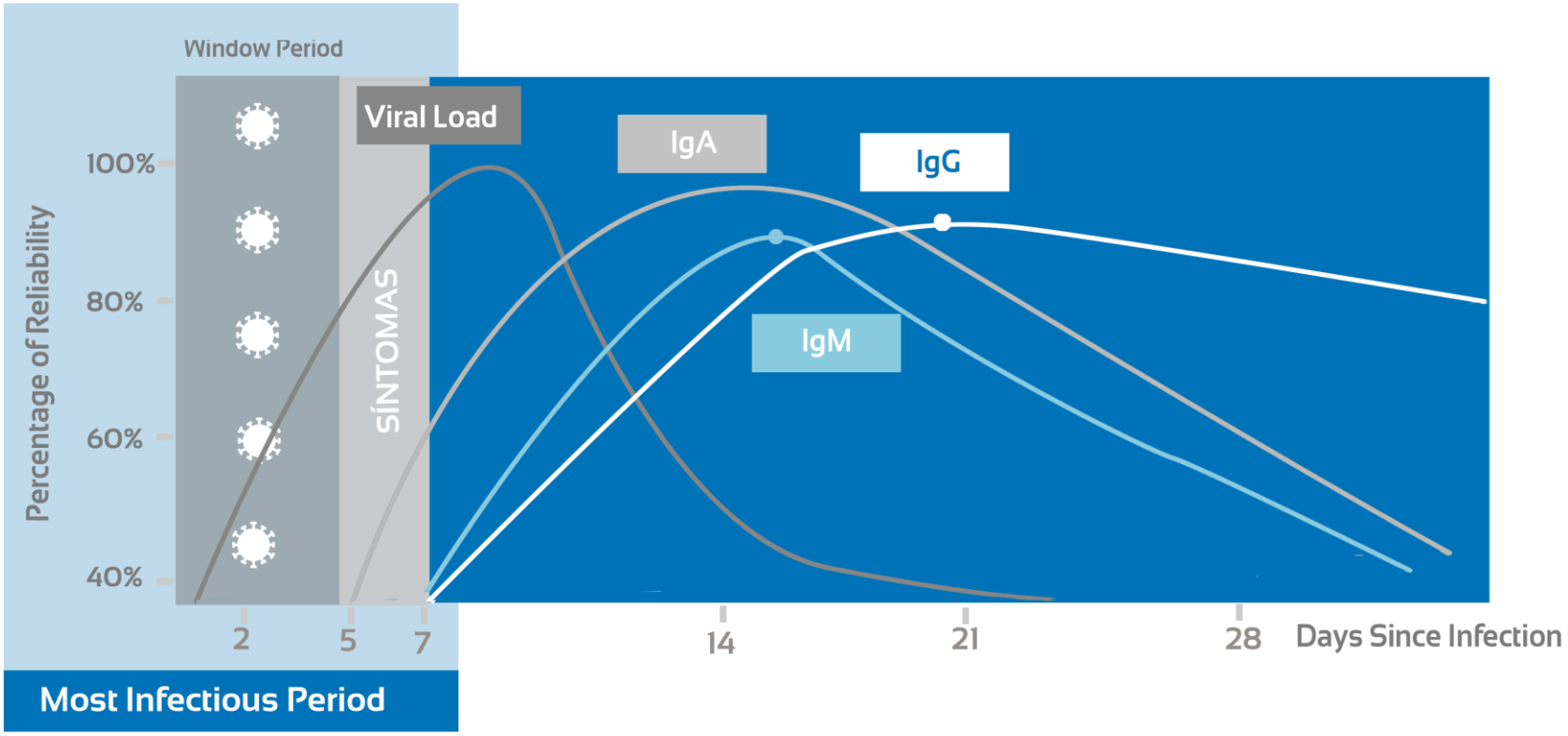
The Mpro protease plays a vital role in processing the polyproteins that are translated from the viral RNA. Although this protein is not exposed in the viral particle, Mpro is elicited after viral infection. Like other b-coronaviruses, SARS-CoV-2 is a positive-sense RNA virus that expresses multiple proteins as a single polypeptide chain, and Mpro cleaves the polyprotein to release mature proteins for the virus. Inhibitors that can block viral replication are promising potential drug candidates that could be used to treat patients suffering from the COVID-19 coronavirus infection.





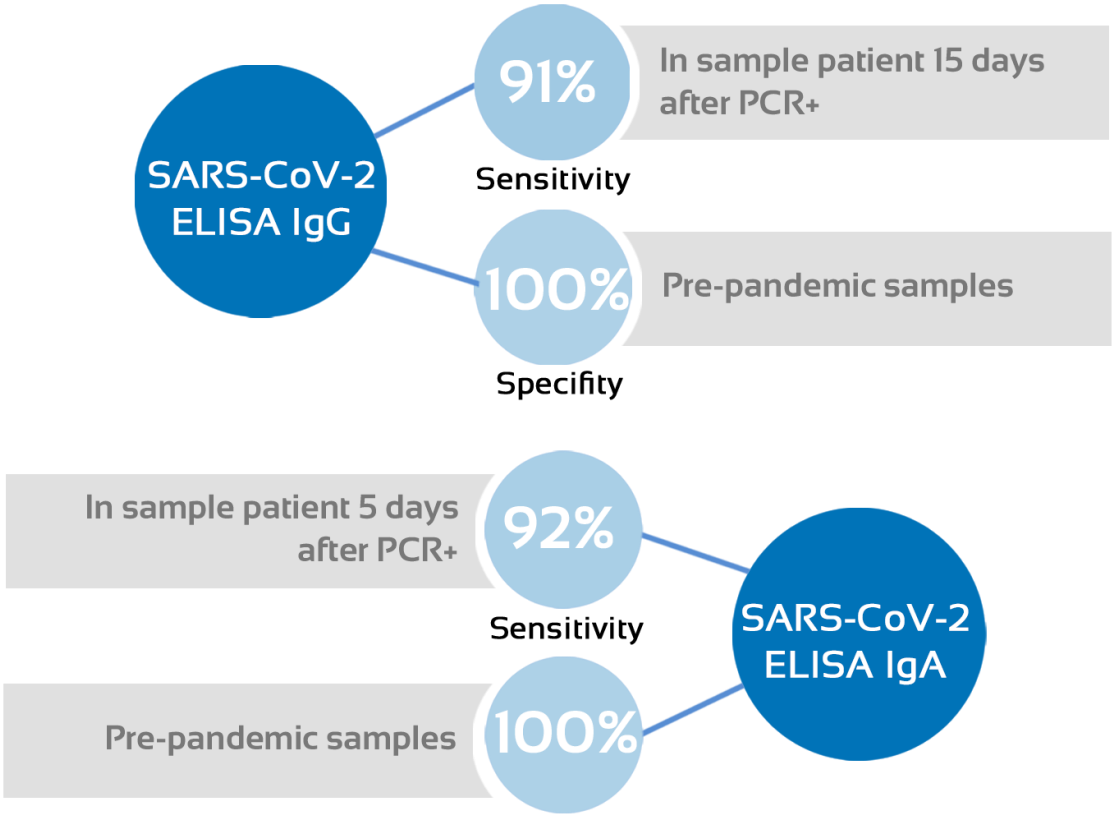
Very early antibody detection from the onset of symptoms

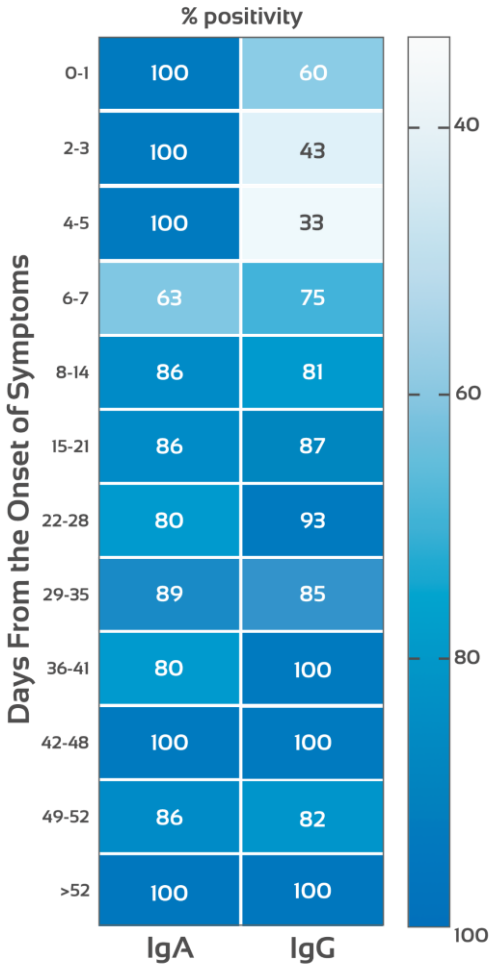
Median seroconversion time is 4 to 6 days for IgA and IgM, while is 5 to 10 days for IgG from onset of symptoms. Data suggest that IgA detection may improve the diagnostic results in the early stages of infection.



Improving Covid-19 Serology performance

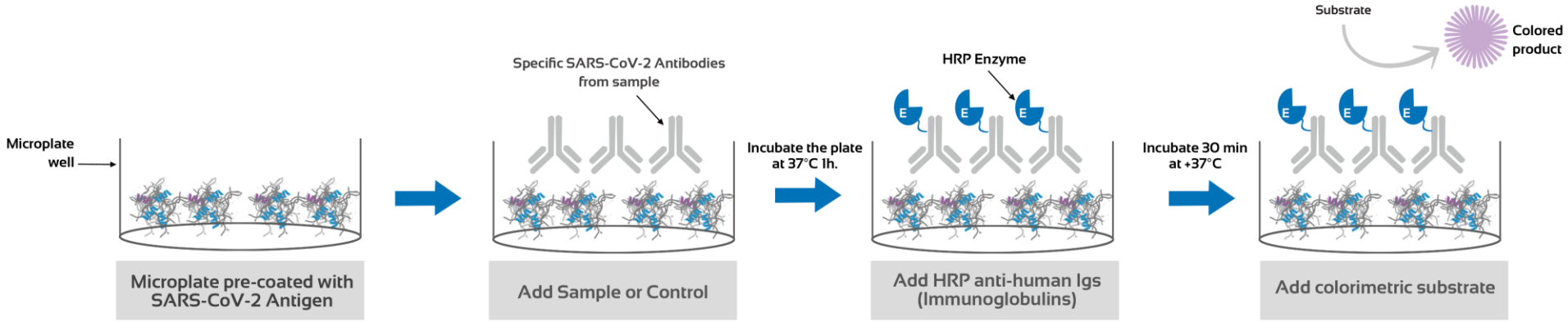
These new ELISA tests provide outstanding values of sensitivity and specificity enabling confirm patients with recent or prior infection and open new immunological questions about the heterogeneity of humoral response against the viral proteins between patients and the potential use of Mpro such as a prognostic indicator.

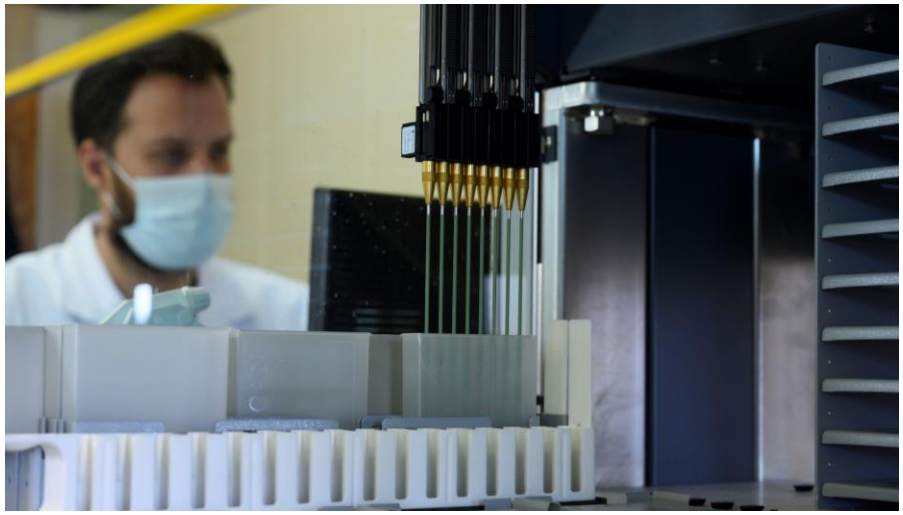




ELISA Method IgG | IgA

96-well plates are coated with the recombinant specific antigen (Mpro / 3CLpro) to bind to the antibodies present in human serum and plasma samples.





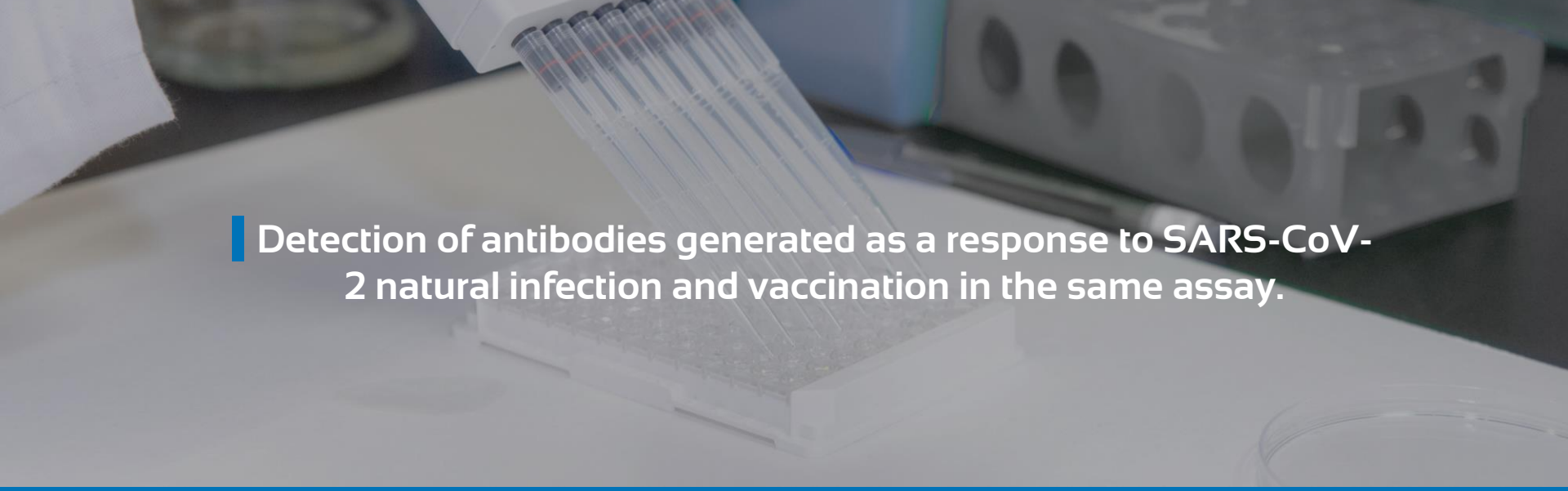
Technical Support and Automation

Furthermore, the process is easily automatable. We are able to provide the necessary materials for this process as well as offer technical support for the installation of the robotic platform if necessary.

Product	Status	Reference
Anti-SARS-CoV-2 Elisa Mpro IgG	CE/IVD	IMS2905
Anti-SARS-CoV-2 Elisa Mpro IgA	CE/IVD	IMS2906

Manufactured in Spain

These tests have been developed, and are currently manufactured in entirely in Spain, which give us the control of the whole process and allows us to guarantee the supply to our distributors and laboratories. Currently, the manufacturing capacity of these kits is 14,000 tests per day and is also easily scalable.



Detection of antibodies generated as a response to SARS-CoV-2 natural infection and vaccination in the same assay.

SARS-CoV-2 ELISA Spike Kit

Indirect Enzyme Immunoassay for detection of specific antibodies against Spike protein of the SARS-CoV-2 virus.

AIDS IN DIAGNOSIS & PATIENT IMMUNE RESPONSE MONITORING

HIGH RELIABILITY IDENTIFYING ANTIBODIES AS A RESULT OF VACCINATION AND NATURAL INFECTION.

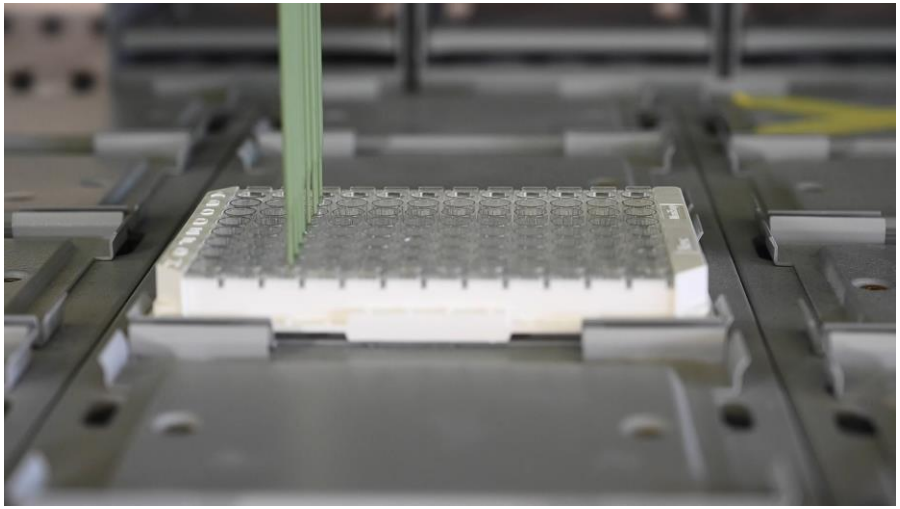
DESIGNED TO BE USED IN HUMAN SERUM AND PLASMA SAMPLES

Detection of SARS-Cov-2 antibodies generated after vaccination

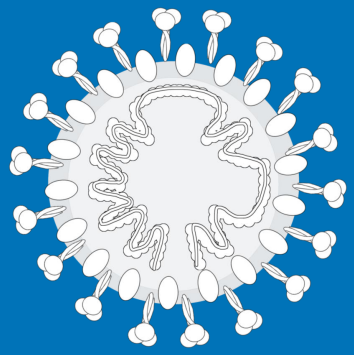
This serological assay can detect and quantify IgG and IgA antibodies generated as a response to SARS-CoV-2 natural infection and vaccination in the same assay. To achieve this goal, 96-well plates are coated with the recombinant specific antigen (Spike Trimer) to bind to the antibodies present in human serum and plasma samples.

Monitoring Immunity after vaccination.

Different serology tests detect antibodies to different parts of the virus, after vaccination the antibodies formed will only be to one part of the virus (the spike protein). To understand if vaccination stimulated an antibody response, **a test specifically designed for the antibodies of interest would need to be used.**



INACTIVATED VIRUS



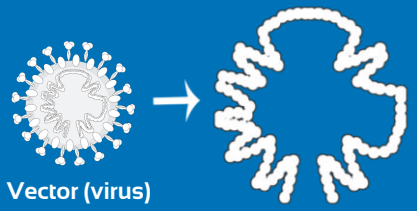
Inactivated
SARS-COV-2 virus vaccines

mRNA

mRNA (genetic material)

S protein of the virus

VIRAL VECTORS



Vector (virus)

DNA (Genetic material)

S protein of the virus

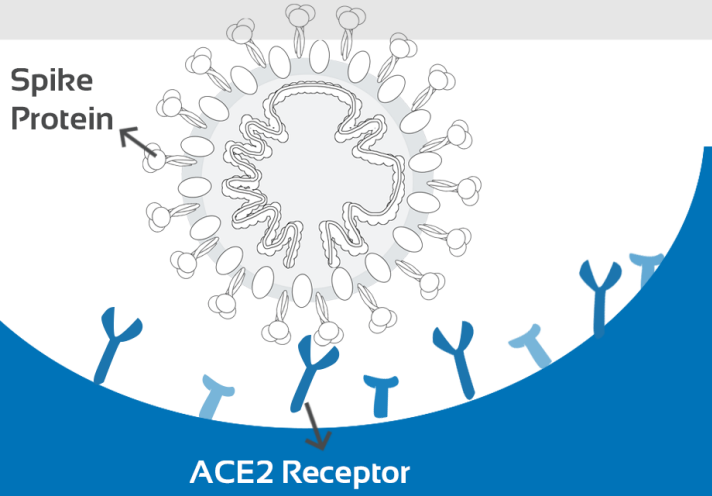
Antibody Testing After the COVID-19 Vaccine.

Identifying antibodies generated as a result of natural infection and vaccination.

Quantitative measurement of SARS-CoV-2 protein S (IU / ml).

High sensitivity and specificity identifying IgG and IgA antibodies.

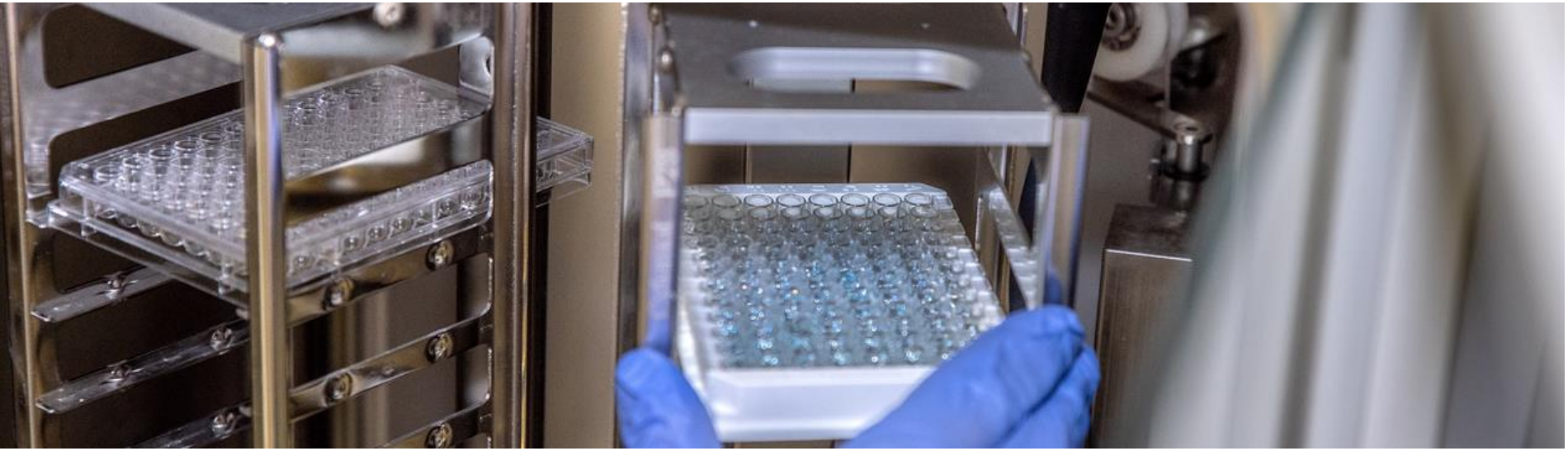
Evaluation of COVID-19 vaccine effectiveness*



* Kit anti-SARS-CoV-2 Mpro: negative control.

Anti-SARS-CoV-2 Elisa Spike IgG | IgA Kits

Product	Status	Reference
Anti-SARS-CoV-2 Elisa Spike IgG	CE/IVD	IMS2907
Anti-SARS-CoV-2 Elisa Spike IgA	CE/IVD	IMS2908



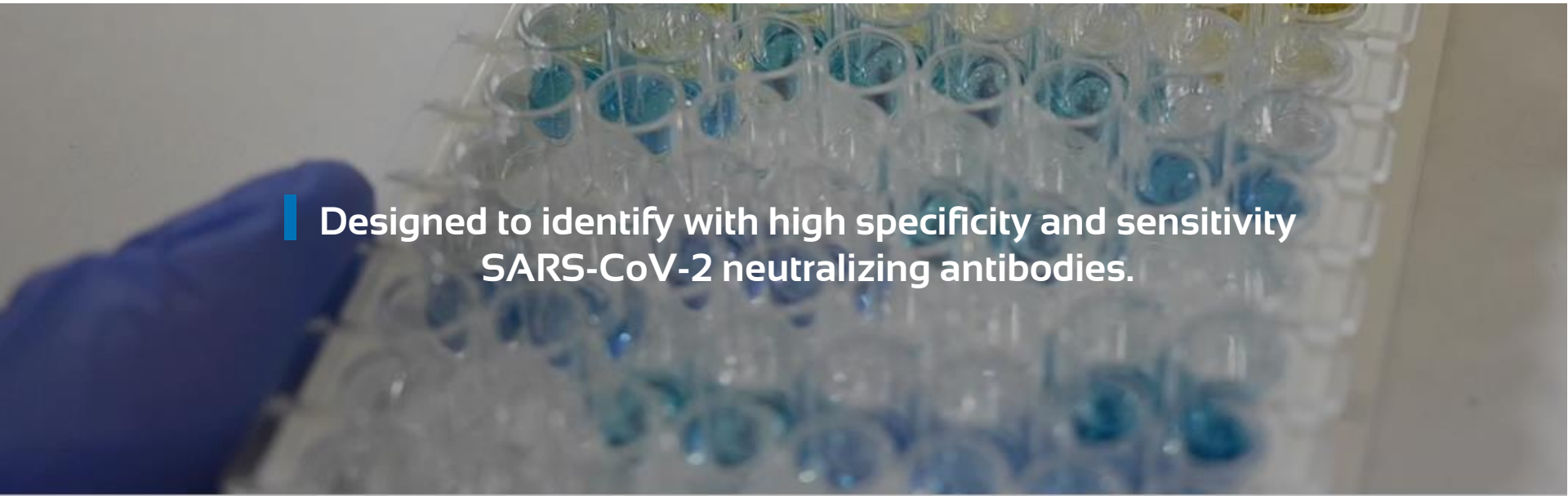
SARS-CoV-2 ELISA RBD Kit

Indirect Enzyme Immunoassay for detection of specific antibodies against RBD protein of the SARS-CoV-2 virus (Covid-19).

AIDS IN DIAGNOSIS & PATIENT IMMUNE RESPONSE MONITORING AFTER VACCINATION

HIGH RELIABILITY IDENTIFYING NEUTRALIZING ANTIBODIES

DESIGNED TO BE USED IN HUMAN SERUM AND PLASMA SAMPLES



Designed to identify with high specificity and sensitivity SARS-CoV-2 neutralizing antibodies.

Neutralizing SARS-CoV-2 antibodies detection.

This serological assay can detect and quantify IgG and IgA neutralizing antibodies generated as a response to SARS-CoV-2 natural infection and vaccination. To achieve this goal, 96-well plates are coated with the recombinant specific antigen (RBD Trimer) to bind to the antibodies present in human serum and plasma samples.

- Identifying COVID-19 neutralazing antibodies
- Highly sensitive and specific detecting IgG and IgA antibodies.
- Quantitative measurement of SARS-CoV-2 protein S (IU / ml).
- Evaluation of COVID-19 vaccine effectiveness*

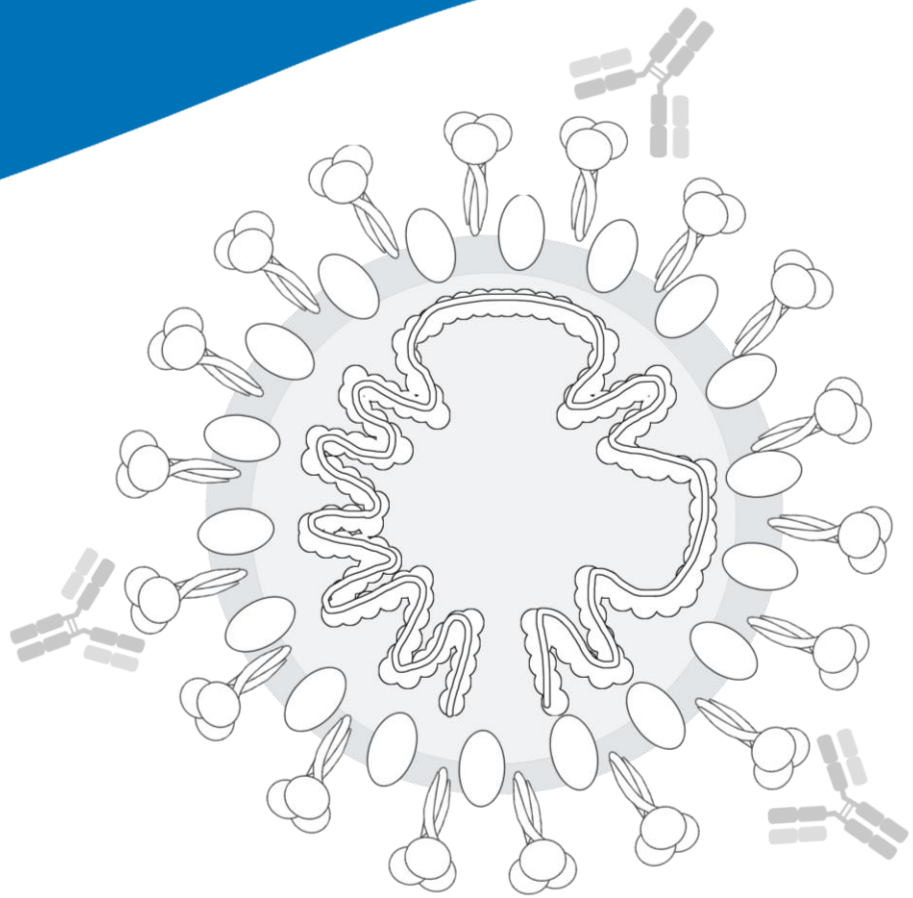
* Kit anti-SARS-CoV-2 Mpro: negative control.

Targeting Neutralizing antibodies.

In order to correctly analyze the immune response to the virus, it is very important to identify the antibodies to which protein we need to target.

IgG antibodies protect our system binding to the surface of the virus. And last studies have demonstrated that IgG antibodies against a particular part of the Spike Protein (RBD) are neutralizing.

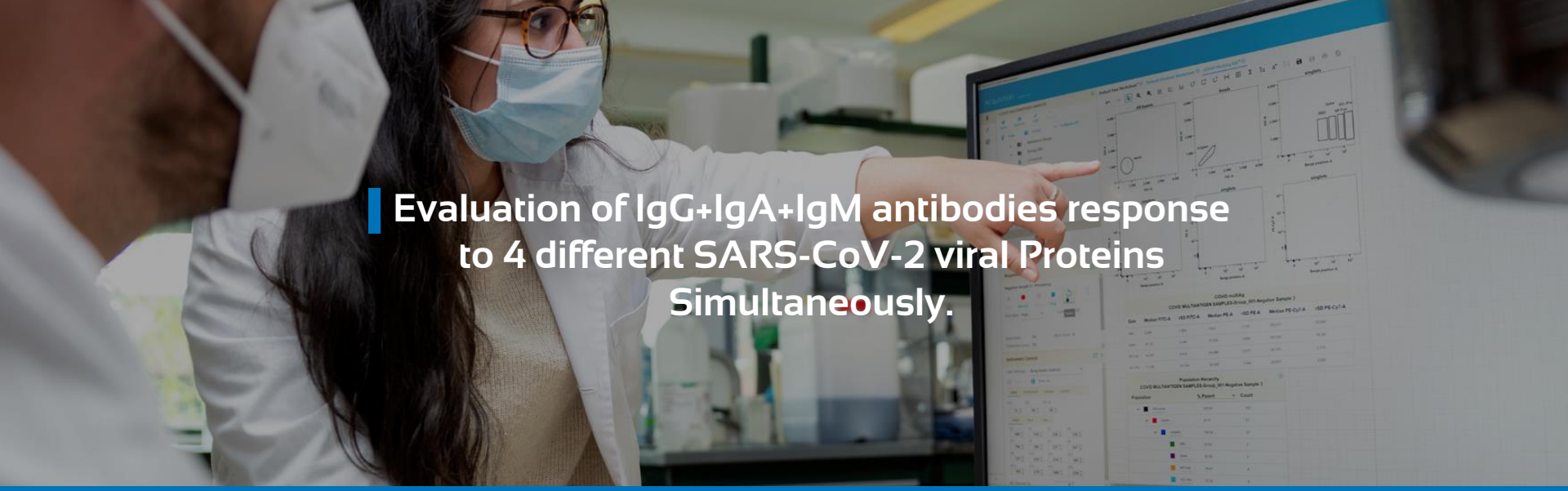
That is the reason why, most of the vaccines that have been developed so far, work expressing the spike protein for our immune system to remember the RBD Domain (RBD), and we will need to target to target the RBD or the full Spike protein to detect antibodies produced after vaccination.



Immunostep´s RBD kit detects circulating neutralizing antibodies against SARS-CoV-2 that block the interaction between the receptor binding domain (RBD) of the viral spike glycoprotein with the ACE2 cell surface receptor.

Anti-SARS-CoV-2 Elisa RBD IgG | IgA Kits

Product	Status	Reference
Anti-SARS-CoV-2 Elisa RBD IgG	CE/IVD	IMS2909
Anti-SARS-CoV-2 Elisa RBD IgA	CE/IVD	IMS2910



Evaluation of IgG+IgA+IgM antibodies response to 4 different SARS-CoV-2 viral Proteins Simultaneously.

SARS-COV-2 Multiplex Serological Assay

Multiantigen IgG+IgA+IgM Assay is a multiplex, microsphere-based, **highly sensitive and specific assay** that measure the presence or absence of antibodies against four different SARS-CoV-2 antigens simultaneously.

RBD

RBD

Detecting SARS-CoV-2 neutralizing antibodies.

S

SPIKE

Identifying immune response after vaccination.

N

NUCLEOCAPSID

Identifying immune response to natural infection.

Mpro

MPRO

Identifying immune response to viral replication.

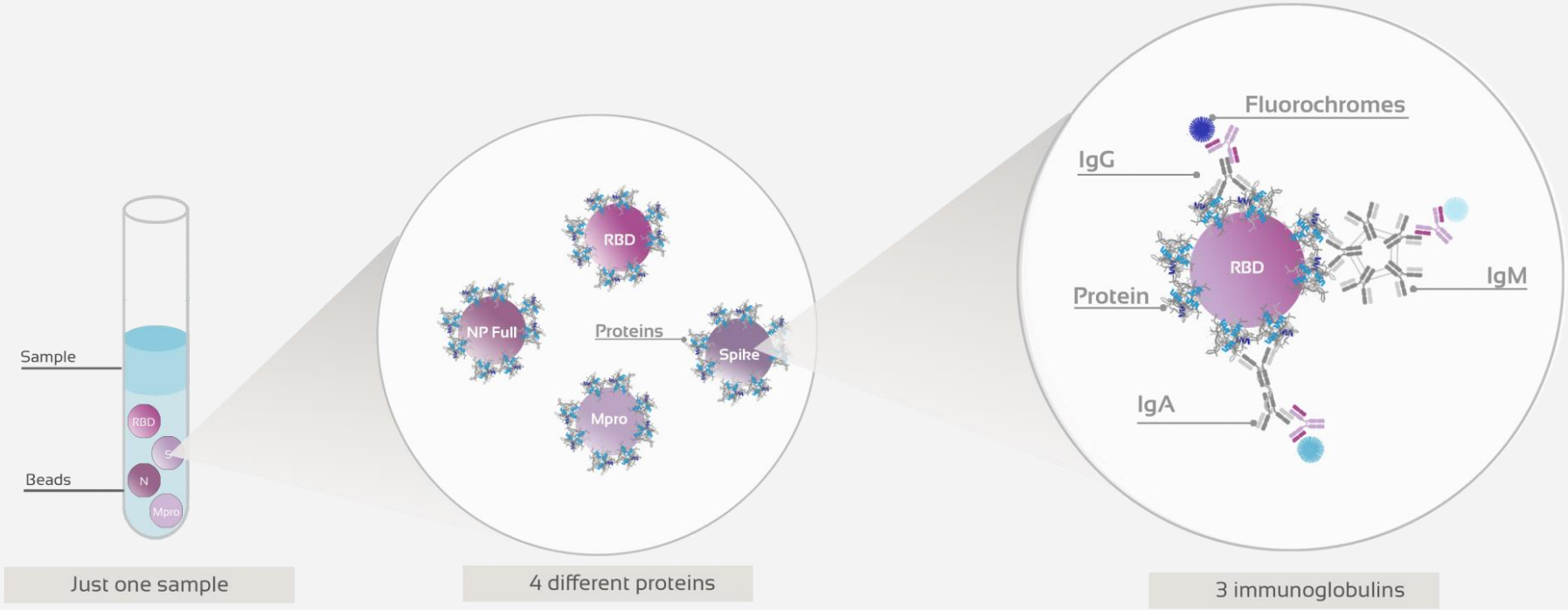
SARS-COV-2 Multiplex Serological Assay

- Exclusive combination of 4 viral antigens analyzed simultaneously
- Wide Linearity Range
- Near to 100% of sensitivity and specificity
- Differentiating natural infection from vaccine response
- Reliable and reproducible results
- More results per sample (>12 plex)

Three Reporter Channels Simultaneously

All the information in just one sample

This bead-based assay by flow cytometry has demonstrated to provide a wide range of information analysing just one sample in a short period: detecting 4 viral proteins and 3 different immunoglobulins, simultaneously.



Differentiating Immune Response by Virus and Vaccination.

Pfizer-BioNTech COVID-19 vaccine (Comirnaty) and COVID-19 positive samples were assayed to evaluate IgG antibody response to RBD, S, N and Mpro viral proteins. MFI levels vary from one sample to another, indicating the existence of different antibody response profiles depending on the viral protein analyzed.

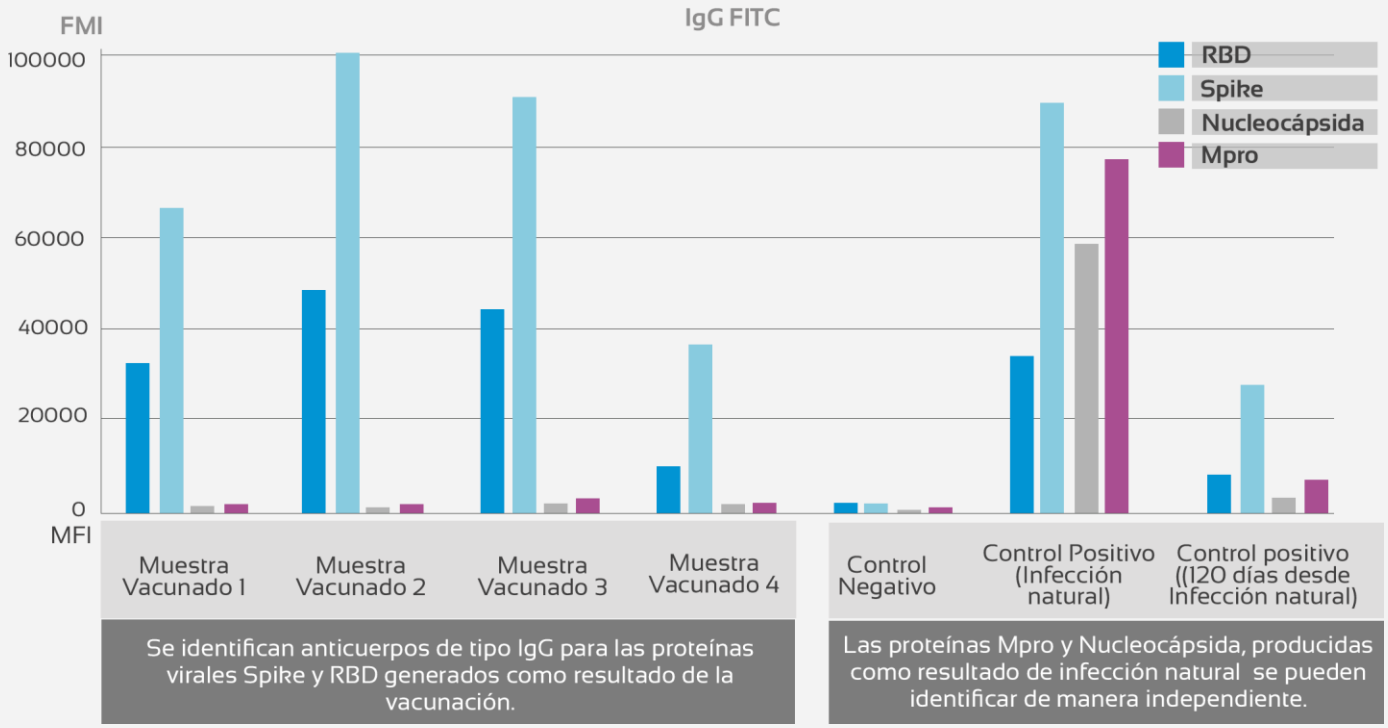
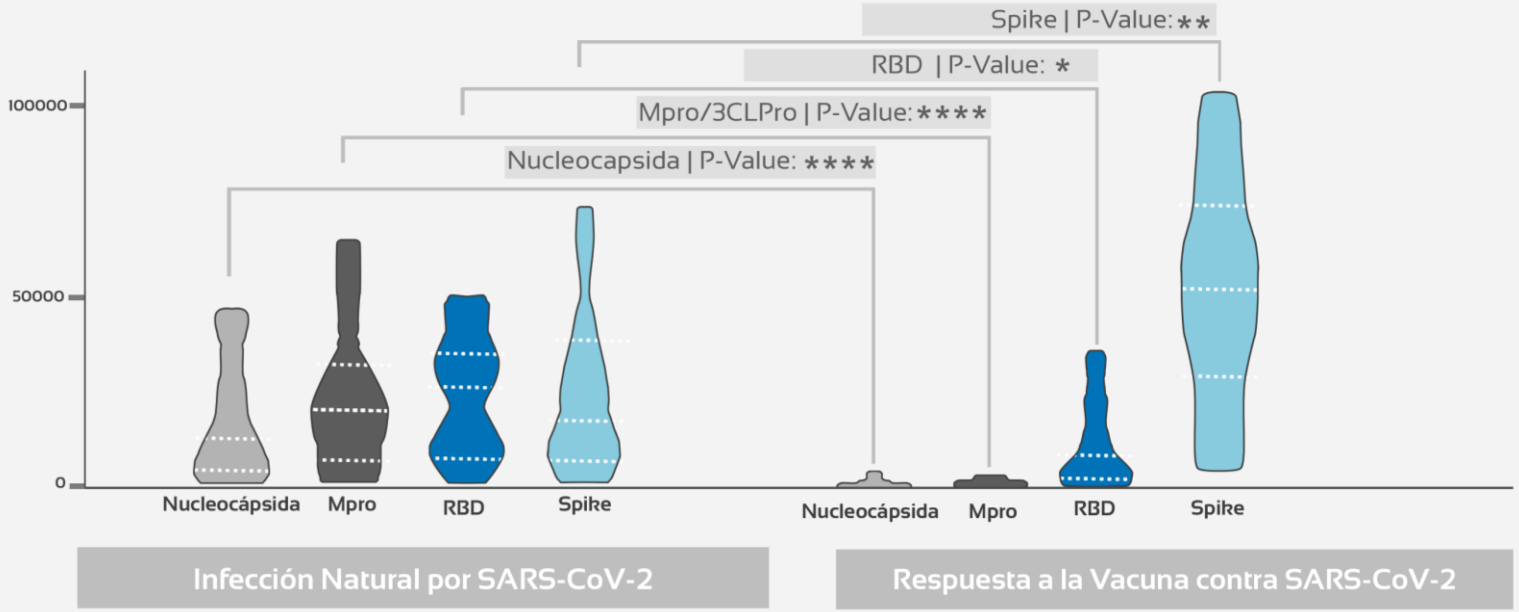


Figure 2: SARS-CoV-2 multiplex assay vaccinated samples data compared with positive and negative samples.
Source: Internal data.

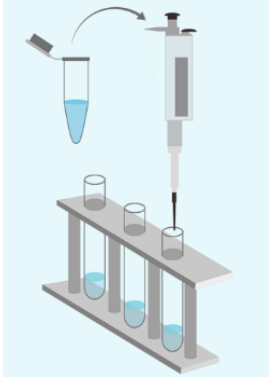
Differentiating Immune Response by Virus and Vaccination.

Not only this assay can identify the moment of the infection the patient is going through but also it is able to monitor the immune response by identifying neutralizing antibodies and differentiating them from other generated antibodies.



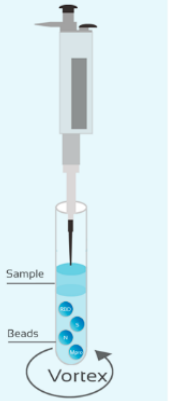
Easy and Efficient Assay to Perform

Step 1



Preparation of sample dilution

Step 2

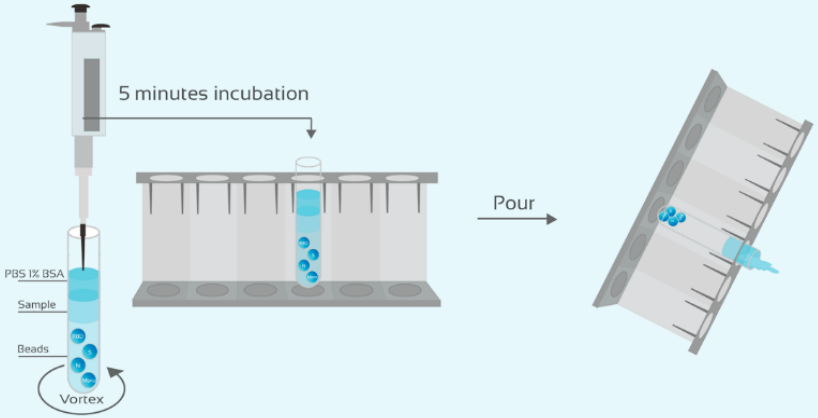


Add Sample and Beads

1 hour RT shaking

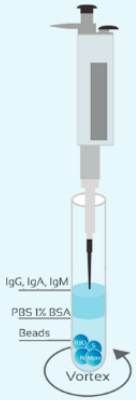
RT= Room Temperature

Step 3



Add Wash Buffer (PBS 1% BSA), incubate in Magnetic rack and pour. Repeat the process (x2).

Step 4



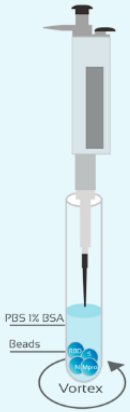
Resuspend and add beads

30 minutes RT Shaking

Room Temperature

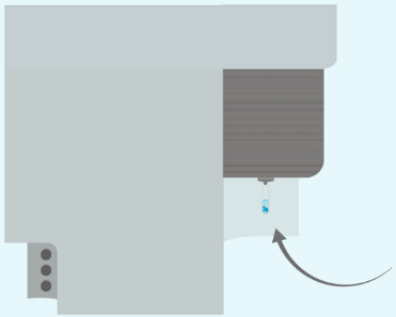
Step 3: Repeat (x2)

Step 5



Resuspend

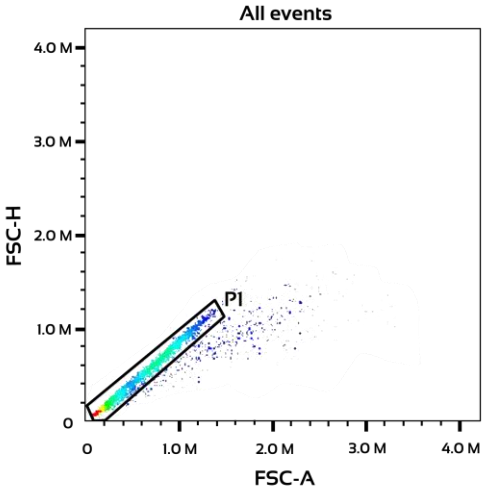
Step 6

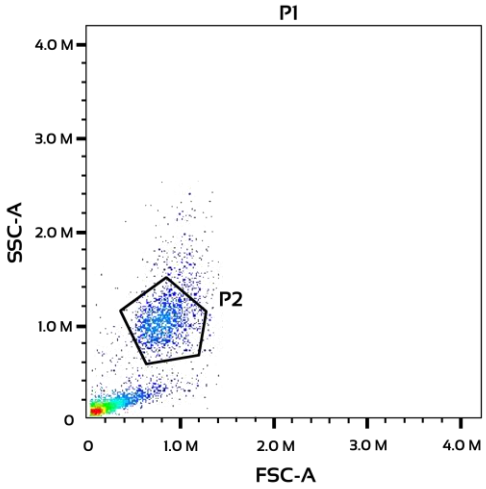


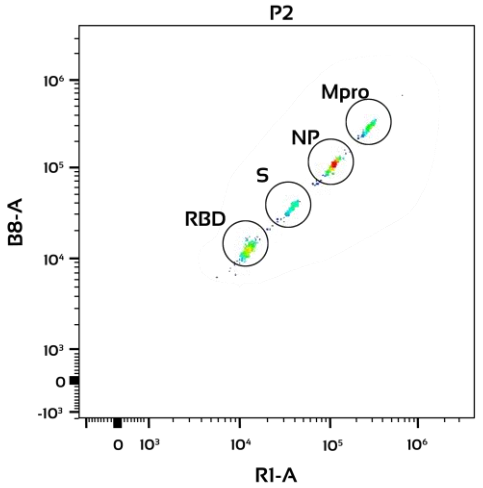
Acquisition on the flow cytometer

Interpretation of Results

This multiplex flow cytometric assay not only provides qualitative and quantitative information on the immune response to the virus, but also answers a large number of questions about how the immune response was activated and when the patient is infected. .







Anti-SARS-CoV-2 Multiplex IgG+IgA+IgM Kit

Product	Status	Reference
Anti-SARS-CoV-2 Multiplex IgG+IgA+IgM	CE/IVD	IMS0509

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GOBIERNO DE ESPAÑA MINISTERIO DE INDUSTRIA, COMERCIO Y TURISMO

Proyecto subvencionado por el Ministerio de Industria, Comercio y Turismo, como parte del programa de ayudas para la fabricación de material sanitario por la crisis de la COVID-19 (2020).