SARS-CoV-2 Multiplex Serological Assay

- Controls provided
- Compatible with Standard cytometers
- No specific software needed

CE IVD

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

RBD | Spike | Nucleocapsid | Mpro*

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

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

IgG+IgA+IgM Multiplex Microsphere-based Assay

All the information, just one sample.

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

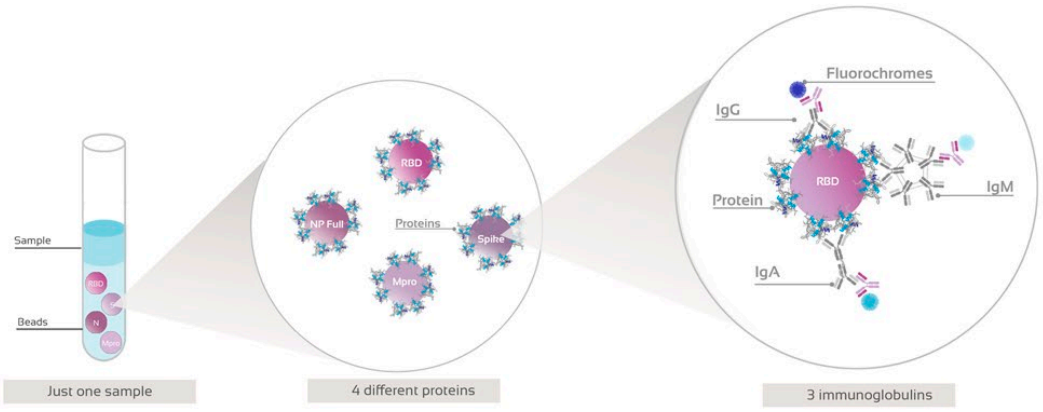
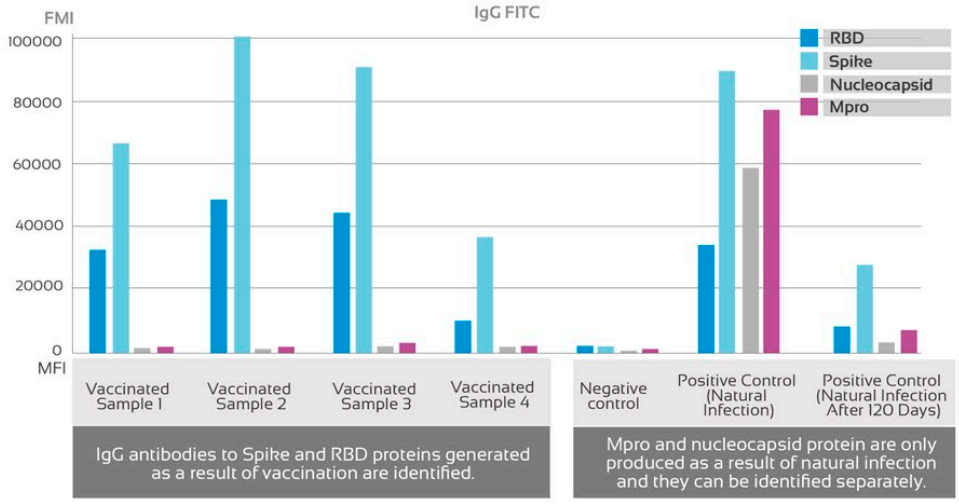


Figure 1: Graphical representation of Anti-SARS-CoV-2 flow cytometry bead-based array procedure. Source: Internal Data.

Differentiating Immune Response by Virus and Vaccination



Facilitating the massive screening of Covid-19 patients to evaluate their immune response.

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 existance of different antibody response profiles depending on the viral protein analized.

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

Providing Outstanding Values of Sensitivity and Specificity

	Days	TP	FN	PPA	95% (C.I)		TN	FP	NPA	95% (C.I)		Total
IgG	<7	30	5	88%	75%	100%	293	5	98%	94%	100%	298
	7-15	47	3	94%	87%	100%						
	>15	25	1	96%	86%	100%						
IgA	<7	33	5	83%	75%	99%	296	12	96%	91%	100%	308
	7-15	46	10	80%	72%	93%						
	>15	28	1	97%	87%	100%						
IgM	<7	29	7	81%	64%	97%	271	21	92%	88%	97%	292
	7-15	47	9	90%	66%	100%						
	>15	20	5	80%	57%	100%						

Table 1. Diagnostic sensitivity and specificity. Plasma specimens collected from patients with confirmated COVID-19 PCR positive results were tested with SARS-CoV-2 Multiplex IgG+IgA+IgM Assay. Negative percent agreement (NPA) was determined by using specimens collected prior to December 2019. TP, true positive; FN, false negative, PPA, positive percent agreement; TN, true negative; FP, false positive.

immunostep
we know how
+34 923 29 48 27
info@immunostep.com
www.sars-cov-2-test.immunostep.com

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).