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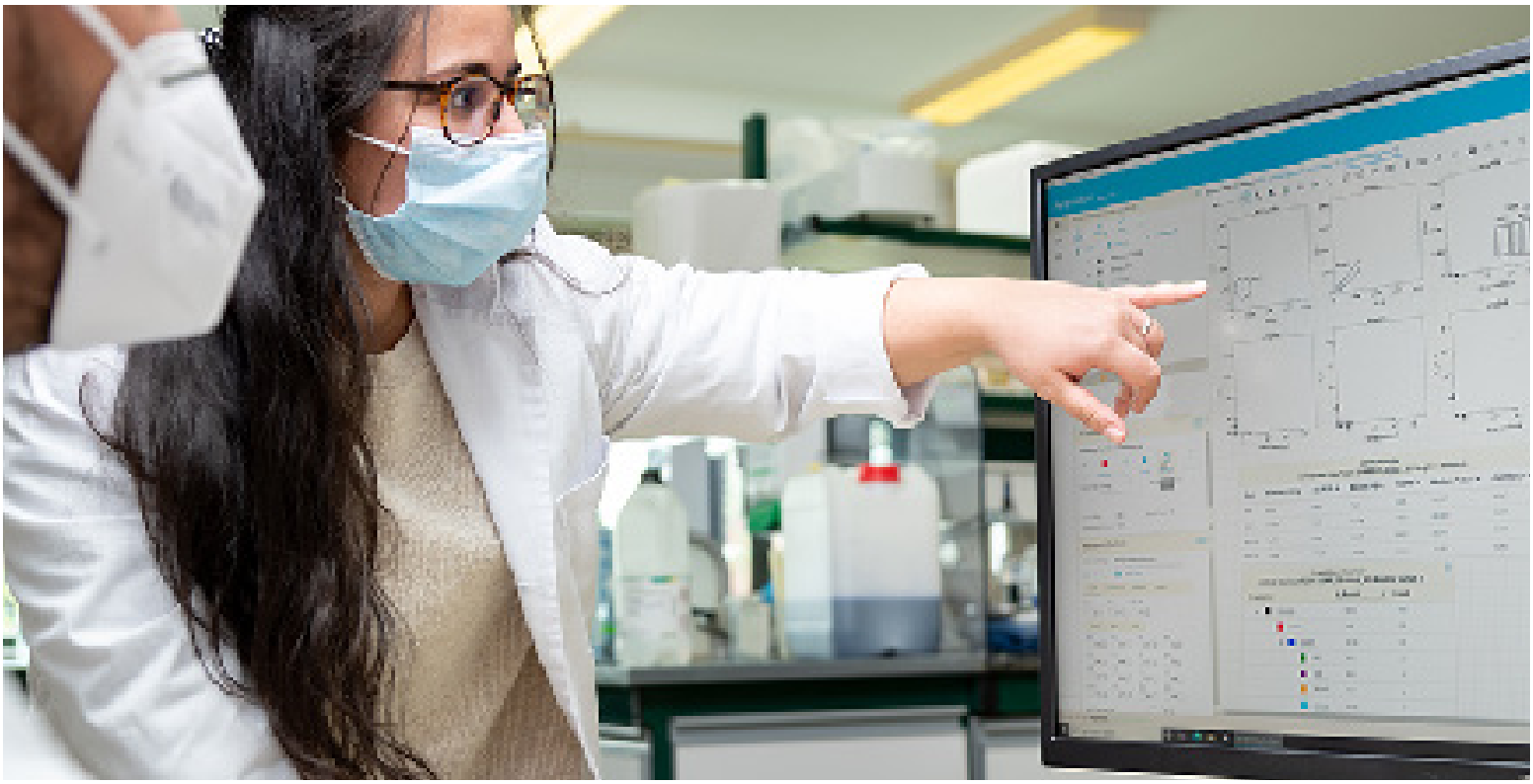
Serology SARS-CoV-2 Products For Research and Diagnostic



www.sars-cov-2-test.immunostep.com

ImmunostepSL
info@immunostep.com
@immunostep
@ImmunostepSL

Innovating to deliver high-quality reliable testing technology: We know how to improve serology performance.

At IMMUNOSTEP we develop innovative solutions in order to **help improve research and diagnostic performance in key areas of development.** 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.

1. **Reliability:** Detecting SARS-CoV-2 immune response with an accuracy close to 100%.
2. **Innovation:** High sensitivity and specificity targeting highly antigenic structural and non-structural viral proteins.
3. **Efficiency:** Very early antibody detection from the onset of symptoms identifying IgG, IgA and IgM immunoglobulins.

SARS-CoV-2 ELISA Mpro* Kit

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

Main Characteristics of SARS-CoV-2 ELISA Mpro* Kit:

1. Exclusive Specific SARS-CoV-2 antigen (Mpro*).
2. Serum and Plasma Samples
3. Reliable SARS-Cov-2 infection determination.
4. Aids in diagnosis & patient surveillance.
5. Highly sensitive and specific detection of Covid-19 antibodies.

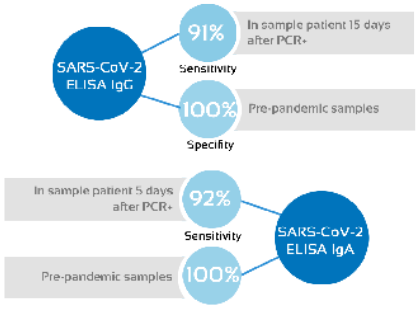


Fig 1: Sensitivity and specificity of SARS-CoV-2 Mpro ELISA Test

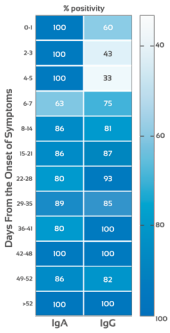


Fig 2. Heatmap of the specificity of SARS-CoV-2 Mpro ELISA Test

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

Targeting a Highly Immunogenic Non-structural Protein: Mpro/3CLpro*

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.

Fig 3: Image of the components of the SARS-CoV-2 ELISA Mpro Kit to detect specific SARS-CoV-2 IgG or IgA antibodies.

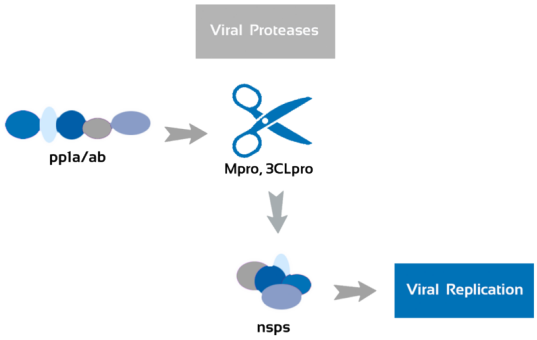


Fig 4: Graphical representation of the key role of Mpro Protein in the viral replication process of SARS-CoV-2.

Name	Unit size	Reference	Content of the Kit	Intended Use
Anti-SARS-Cov-2 ELISA Mpro IgG	96 tests	IMS2905	96-Wells Microplate (12x8), 50ml wash Buffer, 25 ml antibody and sample dilution buffers, 12 ml of TMB, 12ml of Stop solution, 1,5 ml of positive and negative IgG controls, 1,5 ml calibrator, 120 ul of HRP-Conjugated anti-human antibody and 2 units of protective films.	This kit is intended for Human Serum and Plasma Samples (CE-IVD)
Anti-SARS-CoV-2 ELISA Mpro IgA	96 tests	IMS2906	96-Wells Microplate (12x8), 50ml wash Buffer, 25 ml antibody and sample dilution buffers, 12 ml of TMB, 12ml of Stop solution, 1,5 ml of positive and negative IgA controls, 1,5 ml calibrator, 120 ul of HRP-Conjugated anti-human antibody and 2 units of protective films.	This kit is intended for Human Serum and Plasma Samples (CE-IVD)

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

SARS-CoV-2 ELISA Spike Kit

Indirect Enzyme Immunoassay for the detection of specific antibodies against Spike protein of the SARS-CoV-2 virus: This serological assay can detect and quantify IgG 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.

Main Characteristics of Anti-SARS-CoV-2 ELISA Spike Kit:

1. Quantitative and qualitative ananlysis of the antibodies generated as a result of natural infection and vaccination.

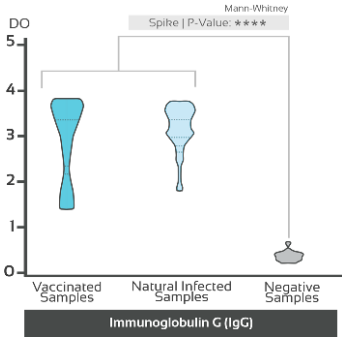


Figure 5: Violin diagram, comparing plasma samples from vaccinated donors and donors who have undergone the infection versus samples from donors neither exposed to the infection, nor vaccinated. Statistical significance was analyzed with a Mann-Whitney test. **** p, 0.0001.

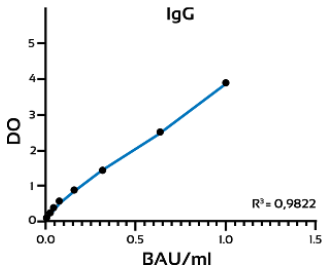


Figure 6: Representative calibration curve of a linear regression model. In some cases, it will be necessary to start by using higher dilutions (1: 2 or 1: 4) of the positive control as the first concentration point for the calibration curve.

2. Quantitative assay calibrated against international standard (WHO). NIBSC Code 20/136.
3. High sensitivity and specificity identifying IgG antibodies.
4. Evaluation of COVID-19 vaccine effectiveness: Kit anti-SARS-CoV-2 Mpro* as negative control.

Name	Unit size	Reference	Content of the Kit	Intended Use
Anti-SARS-Cov-2 ELISA Spike IgG	96 tests	IMS2907	96-Wells Microplate (12x8), 50ml wash Buffer, 25 ml antibody and sample dilution buffers, 12 ml of TMB, 12ml of Stop solution, 1,5 ml of negative IgG control, 1,7 of positive control (standard), 1,5 ml calibrator, 120 ul of HRP-Conjugated anti-human antibody and 2 units of protective films.	This kit is intended for Human and Serum Samples (CE-IVD)

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 and three human immunoglobulins simultaneously.

Fig 7. Image of the components of the SARS-CoV-2 Multiplex Kit to detect specific SARS-CoV-2 IgG+IgA+IgM antibodies.

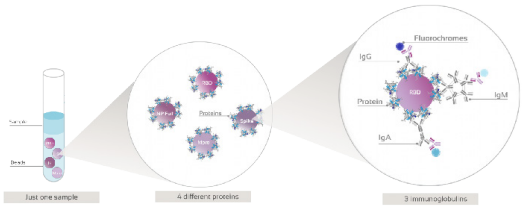


Fig 8: Graphical representation of Anti-SARS-CoV-2 flow cytometry bead-based assay.

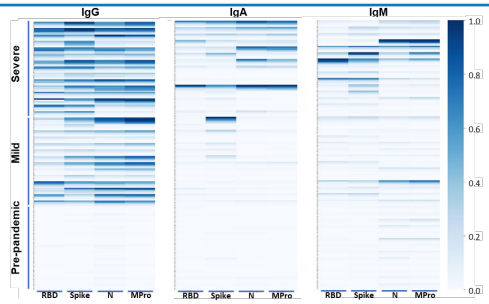


Fig 9. Heatmap of the comparison of 35 symptomatic samples against negative and/or pre-pandemic samples without SARS-CoV-2 related symptoms. Expression of the 4 antigens were tested is quite high compared to samples without symptoms. The intensity of the blue colour represents the amount of antibody detected by this assay.

	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%						

Fig 10. 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.

Main Characteristics of Anti-SARS-CoV-2 Multiplex IgG+IgA+IgM Assay.

1. Exclusive combination of 4 viral antigens and three human immunoglobulins analized simultaneously.
2. Near to 100% of sensitivity and specificity.
3. Reliable and reproducible results
4. Wide Linearity Range
5. Differentiating natural infection from vaccine response.
6. More results per sample (>12 plex)

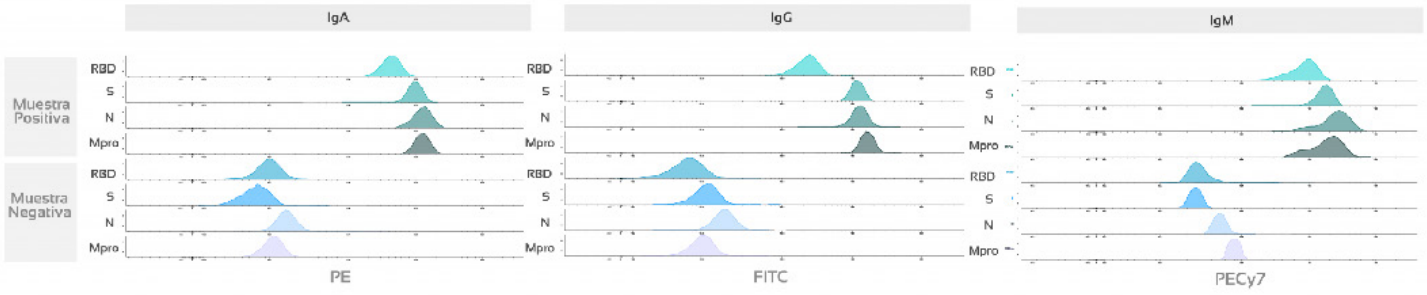


Fig 11: Histogram in cytometry comparing results of analysis of a positive vs. a negative sample for 4 viral proteins. (Mpro: main virus protease or 3c-type protease (Mpro/3CLpro). | NP: nucleocapsid protein (N). | S: stable trimer of the spicule glycoprotein (S). | RBD: receptor-binding domain (RBD) of s-glycoprotein) and 3 immunoglobulins (IgA, IgG, and IgM).

Immunostep provides custom-made reagents for research, academic or industrial purposes. Get further details at: **https://www.immunostep.com**.

Flow cytometry SARS-CoV-2 multiantigen Assay

Flow cytometry is a powerful method used to measure cell numbers, cell viability, programmed cell death (apoptosis), cell division, toxicity, and the differential expression of specific proteins that can help scientists understand the biology of embryonic development, cancer, metabolic and degenerative diseases, drug effects, and even aging. Immunostep, a leading provider of technologies, tools, and services for bioscience research and biopharmaceutical manufacturing, offers of a range of assays, kits and solution for flow cytometry. 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.

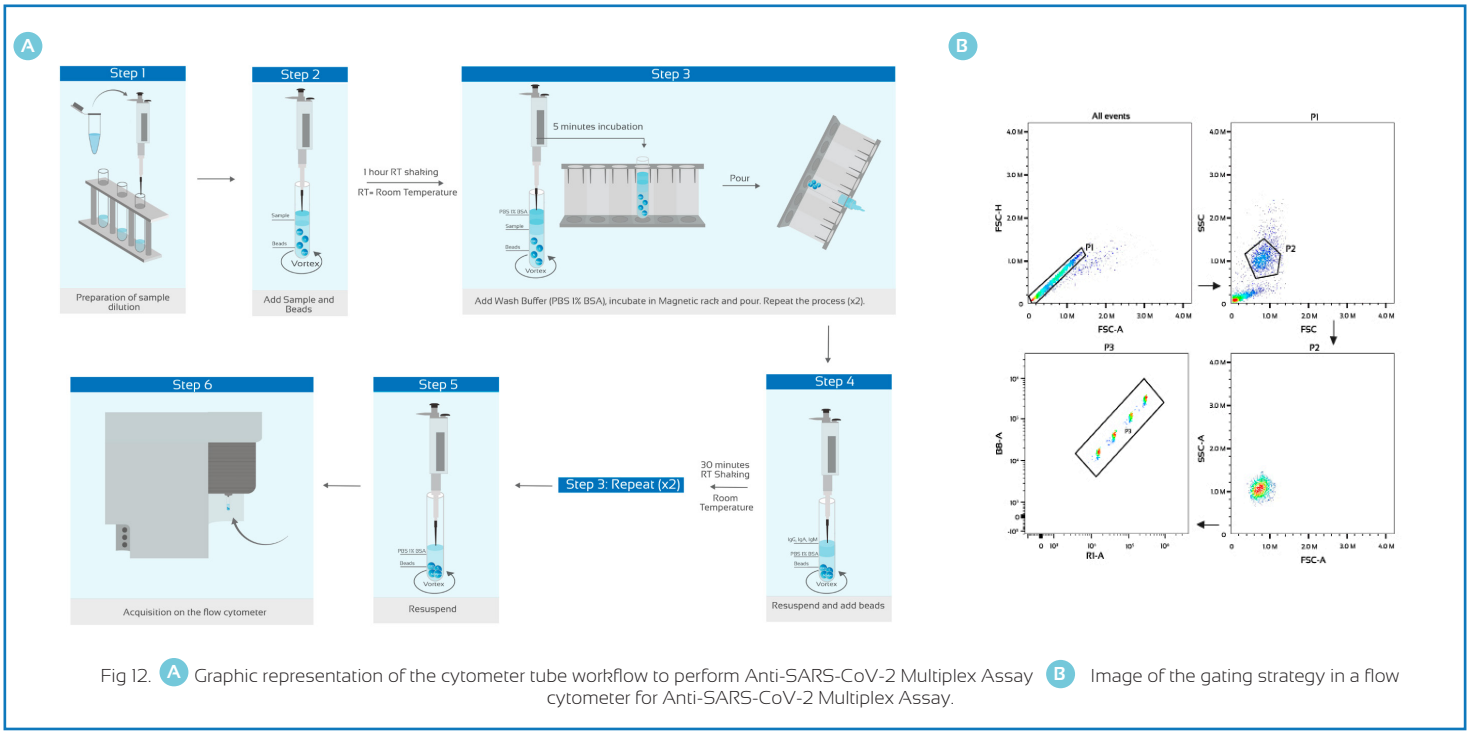


Fig 12. A Graphic representation of the cytometer tube workflow to perform Anti-SARS-CoV-2 Multiplex Assay B Image of the gating strategy in a flow cytometer for Anti-SARS-CoV-2 Multiplex Assay.

Name	Unit size	Reference	Description	Intended Use
Anti-SARS-CoV-2 Multiplex IgG+IgA+IgM Kit	96 tests	IMS0509	4 Magnetic Polystyrene microspheres (RBD, S, N and Mpro) 30ml Wash Buffer (10X) 10 ml Sample Diluent, 160 ul positive and negative controls, 480 ul IgG, IgA and IgM antibodies, 80ul calibrator and 12x8 well black microtiter with tap for protocol in plate.	This kit is intended for Human and Serum Samples (CE-IVD)
RBD coated beads	96 tests	IMS0510	Single Receptor-binding domain of S-glycoprotein (RBD) coated beads.	This reagent is intended for Human and Serum Samples (RUO)
Spike coated beads	96 tests	IMS0511	Single stable trimer of the Spike glycoprotein (S) coated beads	This reagent is intended for Human and Serum Samples (RUO)
Nucleocapsid coated beads	96 tests	IMS0512	Single Nucleocapsid protein (N) coated beads	This reagent is intended for Human and Serum Samples (RUO)
Mpro coated beads	96 tests	IMS0513	Single Main protease or 3C-like protease (Mpro/3CLpro*) coated beads.	This reagent is intended for Human and Serum Samples (RUO)

Immunostep provides custom-made reagents for research, academic or industrial purposes. Get further details at: **https://www.immunostep.com**.

We know how to improve serology testing performance

At IMMUNOSTEP we develop innovative solutions in order to help improve research and diagnostic performance in key areas of development. 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.

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We work to achieve customer satisfaction through quality and differentiation of our products. We are constantly learning and developing as a company and, in the same way, we expect our products and our way of working to be constantly improving for the benefit of all our collaborators.

We seek always to be at the leading-edge of technology in research areas of development, and in order to achieve that goal, we work under an aggressive R&D program headed by a brilliant scientific team. Immunostep has a strong support for a renewal of investment in science and technology in order to support the development of the scientific community and its research efforts on a global scale.

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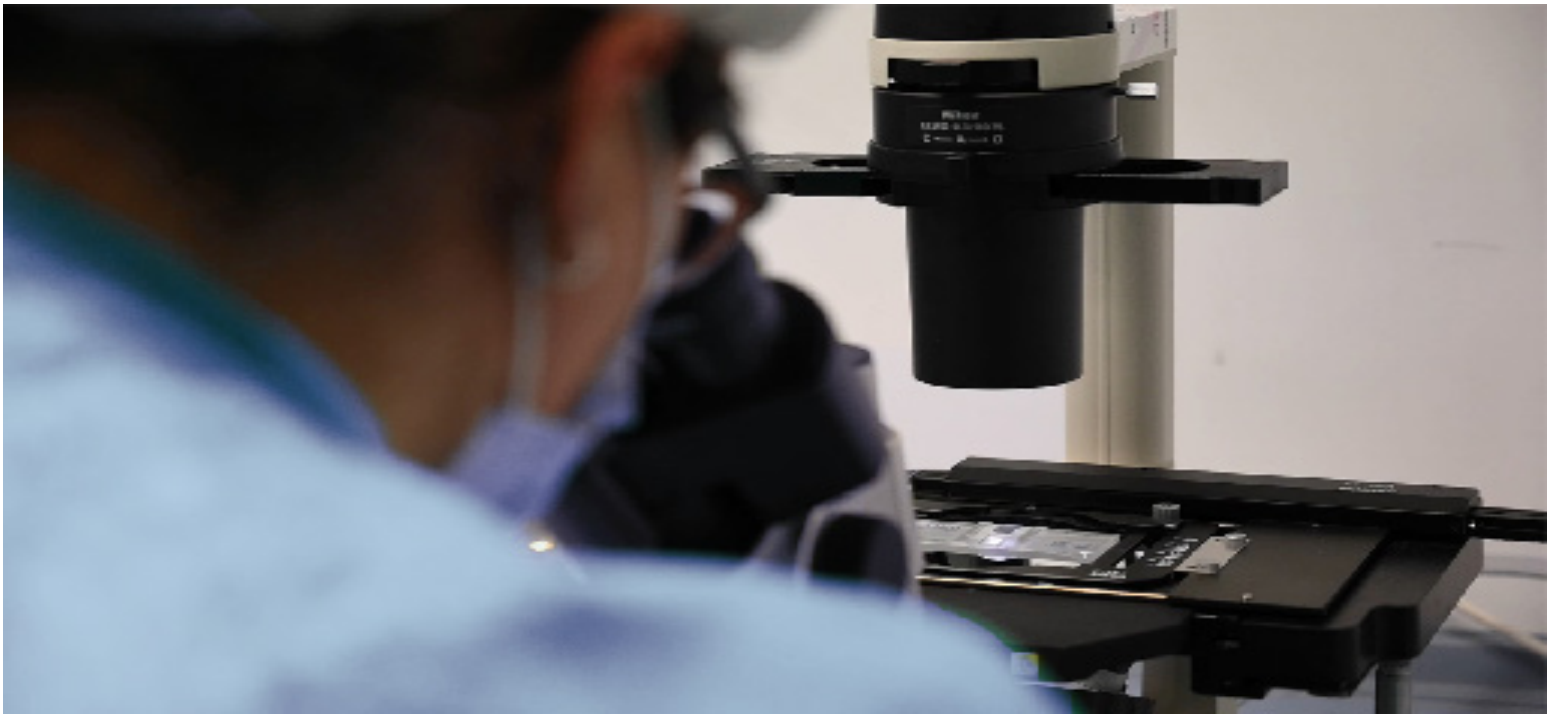

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Centro Investigación del Cáncer (C.I.C) Avda. Universidad de Coimbra, s/n
Campus Miguel de Unamuno 37007 Salamanca

+34 923 294 827 | info@immunostep.com