

# GENSPEED

BIOTECH



Rapid detection of specific  
antibodies on site in laboratory quality

[www.genspeed-biotech.com](http://www.genspeed-biotech.com)

# Covid-19 IgG xPOC test system

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The GENSPEED® Covid-19 IgG xPOC is an in vitro diagnostic test for the detection of SARS-CoV-2 specific immunoglobulin G from human capillary blood, serum or plasma. For antibodies directed against the viral spike or the receptor binding domain of the spike protein a quantitative result in BAU/mL is given and for antibodies directed against the nucleocapsid protein a qualitative result is given. The test can be performed in laboratory quality with 20 µL of blood from the fingertip in only 20 minutes.

This is made possible by the patented GENSPEED® micro-ELISA technology. The combined use of microfluidics and state-of-the-art optical readout technology reduces the test time of a standard laboratory ELISA from 2 - 4 h to only 20 minutes with comparable quality. The GENSPEED® system is compact, fully automated and can be used practically anywhere.

GENSPEED® provides an easily accessible test system which can be applied area-wide and can even help in taking preventive actions. This was also shown in a recent study at the JKU Linz<sup>1</sup>: by statistical evaluation of anonymised data of GENSPEED® Covid-19 IgG xPOC measurements in the Upper Austrian population the population's current immune situation was assessed. When regions with low immune status are identified early, suitable protective measures for containment could be launched in time.

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The GENSPEED® R2 Analyzer comes with a tablet (incl. keyboard), is powered via USB and the pre-installed software accounts for the intuitive operation.

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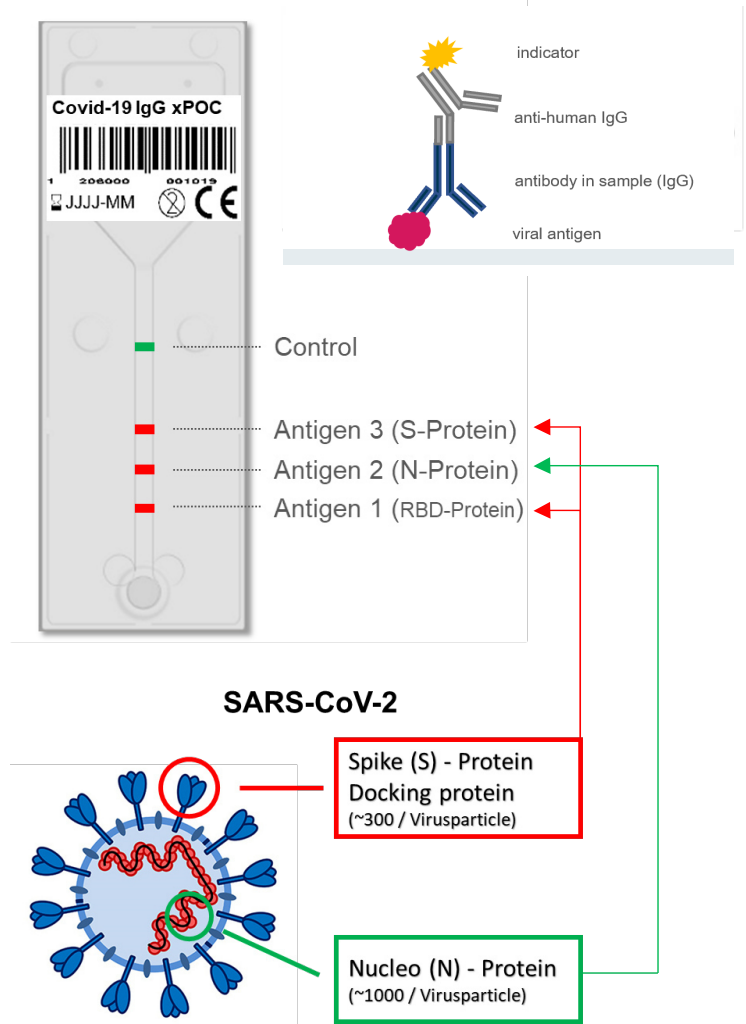


<sup>1</sup> Doppler *et al.*, Low-entry-barrier point-of-care testing of anti-SARS-CoV-2 IgG in the population of Upper Austria from December 2020 until April 2021 – a feasible surveillance strategy for post-pandemic monitoring? Anal Bioanal Chem. 2022 Feb 28. doi: 10.1007/s00216-022-03966-z

# Covid-19 IgG xPOC test chip

The biochemical testing principle of the GENSPEED® Covid-19 IgG xPOC is similar to that of a miniaturised laboratory ELISA (see top right). Immobilised viral antigens act as capture molecules. If antibodies (in this case immunoglobulin G, IgG) are present in the sample, they bind to the antigens and are subsequently labelled by a secondary detector antibody that allows optical detection.

While laboratory ELISA methods or conventional strip tests can only use single viral proteins (antigens) as capture molecules for the target antibodies, the GENSPEED® technology enables the detection of antibodies against the three most important SARS-CoV-2 antigens in a single measurement (see layout of the test chip on the right).



# Covid-19 IgG xPOC

## Features and advantages

- Measurement uses one drop of blood (20 µl) from the fingertip
- Results within 20 minutes
- Highly sensitive
  - comparable with laboratory ELISA Test <sup>2</sup>
- Highly specific
  - antibodies directed to three different antigens of SARS-CoV-2 <sup>2</sup>
- Information on antibody titre
  - information on current concentration of neutralizing antibodies\*
  - information on previous infection by detecting nucleocapsid-specific antibodies
  - quantitative measurement enables individual follow-up and monitoring of immune status

### Laboratory Results

Antibody type	Result	Concentration (BAU/mL)
COVID-19 Anti-Spike/RBD IgG	DETECTED	603 BAU/mL
COVID-19 Anti-Nucleo IgG	NOT DETECTED	-

<sup>2</sup> C. Wechselberger *et al.*, Performance evaluation of serological assays to determine the immunoglobulin status in SARS-CoV-2 infected patients, Journal of Clinical Virology 131, 2020

\* Studies establish a correlation between high titre of neutralizing antibodies and high vaccine efficacy and reduced risk of symptomatic infection respectively (see literature Wajnberg *et al.*, Feng *et al.*, Earle *et al.*, Khoury *et al.*)

# Covid-19 IgG xPOC

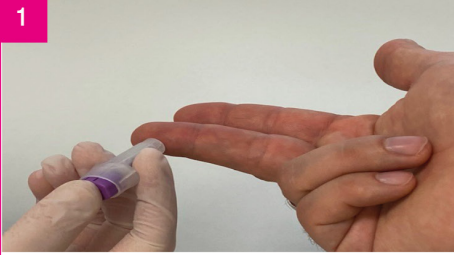

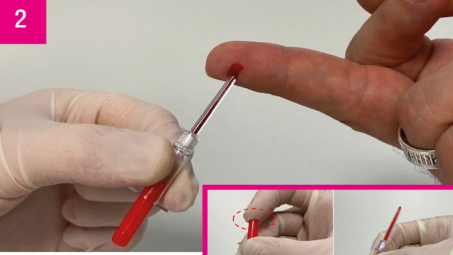
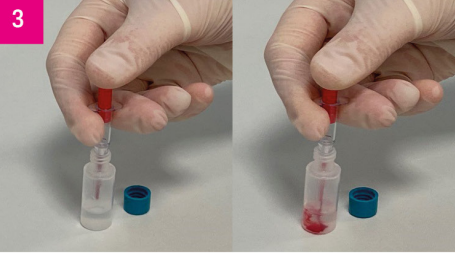


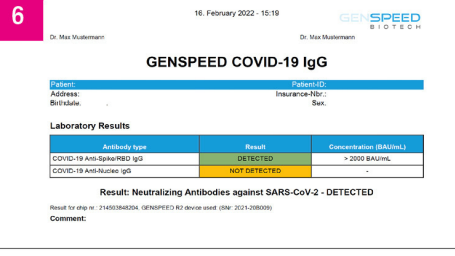
## Comparison of methods

Test typ Criterion	lateral flow test	Lab-ELISA	GENSPEED Micro-ELISA
Sensitivity	++ (due to technology)	+++ (gold standard)	+++ (comparable to lab)
Specificity	+ (often N-protein only)	++ (either N- or S-protein)	+++ (N-, S- and RBD simultaneously)
Handling	+++ (approx. 1 min.)	- (depending on automation)	+++ (approx. 1 min.)
Usability at the point of need	+++ (mobile)	- (large devices)	+++ (mobile)
Time to result	+++ (15 - 20 min.)	- (2 - 4 h)	+++ (20 min.)

- + good / suitable
- ++ very good
- +++ best
- bad / not suitable

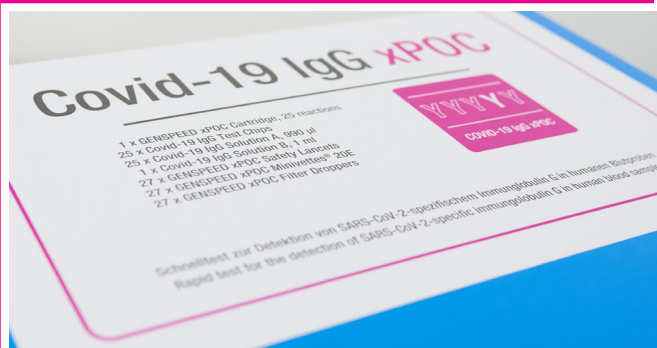
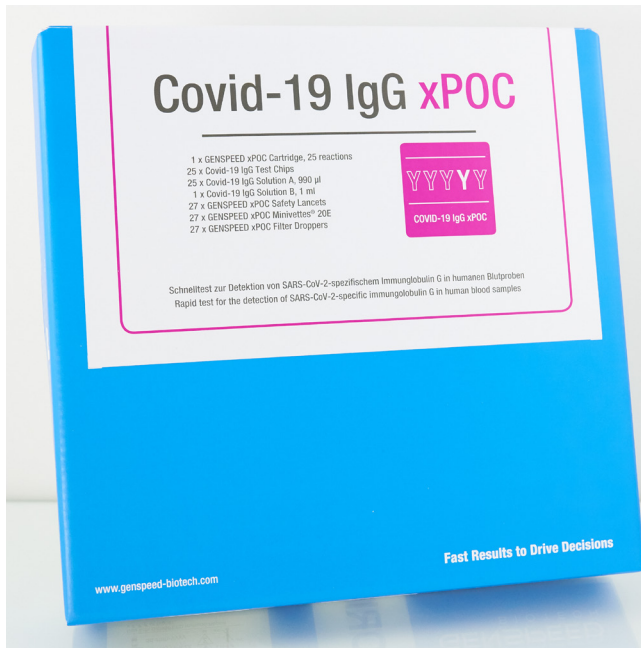
# Covid-19 IgG xPOC procedure

The GENSPEED® Covid-19 IgG xPOC is very easy to perform (see quick guide below). The pre-installed GENSPEED Immuno Report software guides the user step by step through the measurement procedure from sample collection to the result. The test result report is available electronically as a PDF file and can be sent to the patient by e-mail, or simply printed and handed over.

<p><b>1</b></p>  <p><b>Finger prick*</b> Use the included safety lancet [L] to prick the sterilized area of the finger tip. *for processing venous blood see  page 7.</p>	<p><b>2</b></p>  <p><b>Blood collection</b> Fill the Minivette® [M] with capillary blood up to the white stopper.</p>	<p><b>3</b></p>  <p><b>Blood transfer</b> Transfer the <b>entire</b> content of the Minivette® [M] into a tube containing Solution A [A].</p>
<p><b>4</b></p>  <p><b>Mixing and filtration</b> Fix the filter dropper [F] into the tube opening, mix the liquid by hand and apply 1 drop into the test chip [T] inlet. Close the drawer.</p>	<p><b>5</b></p>  <p><b>Incubation and measurement</b> Apply 1 drop of Solution B [B] into the test chip [T] inlet when the drawer re-opens. Close the drawer to start the measurement.</p>	<p><b>6</b></p>  <p><b>Automatic analysis and report</b> The assay is performed automatically by the GENSPEED R2. The results appear in PDF format.</p>

# Covid-19 IgG xPOC test kit

- test in laboratory quality and CE-IVD certified
- all consumables included
- ready-to-use reagents



# Overview of Covid-19 IgG xPOC articles

Art. No.	Description	
IATK204	Covid-19 IgG xPOC	25 analyses
GSHW001	GENSPEED Immuno test system - GENSPEED R2 Analyzer - Tablet incl. GENSPEED Immuno Report Software	1 system

For more information, please visit our website [www.genspeed-biotech.com](http://www.genspeed-biotech.com)

GENSPEED Biotech GmbH  
Gewerbepark 2  
4261 Rainbach · Austria  
E-mail: [office@genspeed-biotech.com](mailto:office@genspeed-biotech.com)  
Tel.: +43 7942 20910

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