



Best-in-class clinical insight, while  
maintaining patient comfort

# SARS-CoV-2 serology testing

## Post-approval efficacy surveillance

*The Synexa assay kit is supplied for research purposes only. Not for therapeutic or diagnostic use.*

*hemaPEN® is supplied for therapeutic or IVD use in Australia, New Zealand, UK, EU and USA only; ARTG number: 280007; CE mark, general IVD; US FDA number: D410490. Outside of the territories listed above, the hemaPEN is supplied for research purposes only and not for therapeutic or diagnostic use.*

In response to the COVID-19 pandemic, the biopharmaceutical industry has leaped into action to better understand the disease, and develop suitable vaccines and therapies.

Trajan Scientific and Medical and Synexa Life Sciences have validated an innovative, market-leading SARS-CoV-2 serology assay, available for high-throughput clinical research applications, using advanced precision microsampling technology to expedite therapy and vaccine development as well as large-scale screening and sero-surveillance initiatives.

Best-in-class clinical insight, while maintaining patient comfort



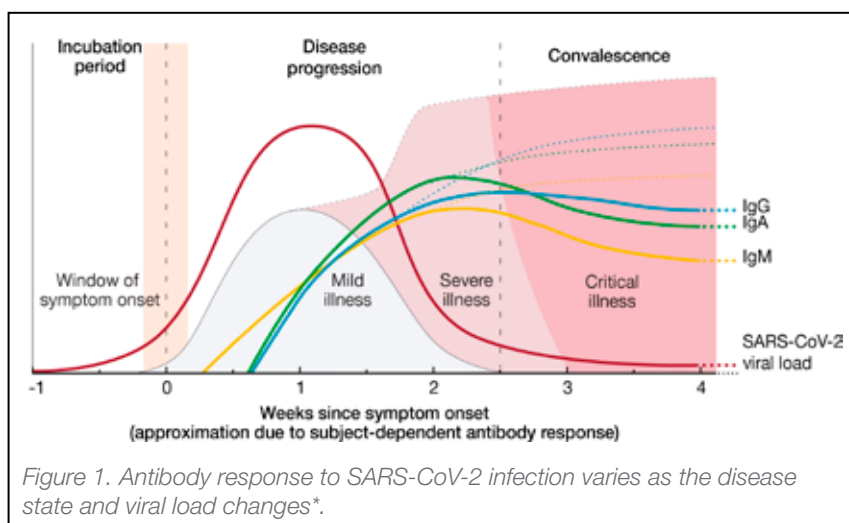
## SARS-CoV-2 immune response

### Understanding the profile of viraemia and antibody responses in SARS-CoV-2 infected COVID-19 patients

Since the beginning of the COVID-19 pandemic, several international groups have characterized the profile of viraemia and antibody responses to SARS-CoV-2 infection (Figure 1\*).

Different illness states have been identified with varying degrees of viral load and antibody response.

Antibody profiling of COVID-19 patients has indicated initial seroconversion of IgM as little as 3 days post-illness onset (PIO), peaking at 14-21 days PIO. IgG and IgA, the predominant antibody in mucosal tissue, is similarly detectable after 4 days PIO, peaking at 14-17 days PIO.



It is as yet unclear how long the antibody response to SARS-CoV-2 lasts, however current literature indicates a rapid decline in IgG and IgM after 28 days post-recovery, with IgA titres being sustained for significantly longer.

\*Adapted from: Azkur, AK., et al. 2020 (<https://doi.org/10.1111/all.14364>) and Cevik, M., et al. (<https://doi.org/10.1136/bmj.m3862>).

# COVID-19 vaccination programs

## Importance of monitoring humoral immunity in vaccinated individuals

- Clinical investigations and trials have been conducted by biopharmaceutical companies in order to produce safe vaccines against the spread of COVID-19. Through unprecedented collaboration and regulatory fast-tracking, trial timelines have been dramatically reduced to control the spread of the virus.
- Due to the rapid pace of development, further post-approval vaccine efficacy surveillance programs remain paramount to better understand the use, safety and efficacy of each vaccine, particularly in various population groups and geographical settings.

## Synexa Life Sciences | SARS-CoV-2 serology

### Assay design and performance

The ELISA-based SARS-CoV-2 serology assay has been developed for the detection of several antibody isotypes, including IgG, IgM and IgA - the predominant antibody present in mucosal tissue, with an exceptionally high sensitivity and specificity.



In addition, the assay determines the neutralization potential of the sample by detecting the presence of neutralizing antibodies (nAb), which prevent the binding of the SARS-CoV-2 spike protein to the ACE2 target receptor (Figure 2).

The assay is designed using a versatile high-throughput sandwich ELISA format which can be multiplexed and run in 96- or 384-well formats. The assay is run on standardized ELISA technology platforms.

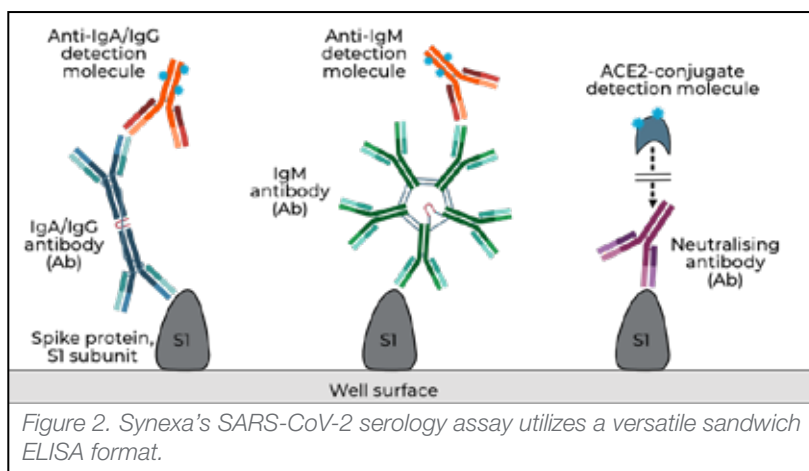


Figure 2. Synexa's SARS-CoV-2 serology assay utilizes a versatile sandwich ELISA format.

Run as a multiplexed platform, the detection of IgG, IgM and IgA as well as the nAb of each sample is obtained in a single run. Synexa's serology assay does not require specialized biosafety procedures, resulting in improved turnaround time and reduced cost for each test.

## Differentiation from other serology assays

Synexa's SARS-CoV-2 serology assays are highly sensitive and specific and differentiate themselves from other serology assays:

- Current SARS-CoV-2 serology assays are qualitative, however can be run in a semi-quantitative manner by using titers which greatly increase costs. Synexa's assay has been developed for semi-quantification without the need for titration, making them far more cost effective.
- The assay can be run on several matrix types including serum, plasma, saliva and dry blood spot technology.
- Synexa's serology assay novelly incorporates the detection of neutralization antibodies to SARS-CoV-2 (in addition to the standardized detection of IgG, IgM and IgA).

Assays have been validated in accordance with FDA and EMA guidelines on ligand binding assays.

	Ab Frequency	Sensitivity*	Specificity
IgG	-	99.10%	100%
IgM	83.49%	-	98.36%
IgA	70.36%	-	94.59%
nAb	77.20%	-	94.90%

\*Detected in convalescent samples (4-8 weeks post diagnosis)



Synexa Life Sciences has validated an innovative, market leading SARS-CoV-2 serology assay, available for high-throughput clinical research applications.

## Monitoring SARS-CoV-2 humoral immunity in a new world of social distancing

- During this pandemic, we have witnessed the emergence of markets that cannot be served by standard phlebotomy. In particular, clinical trials and surveillance programs are significantly hindered as trial sites remain closed or socially distanced.
- Under these conditions, the use of remote specimen sampling has already proven its efficacy and researchers have considerable experience in using at-home blood collection kits for various applications, from monitoring drug therapy of a patient, tracking the spread of infectious diseases such as influenza, to studying environmental exposures. This can be rapidly applied to COVID-19 vaccine trials and post-market surveillance efforts.
- Microsampling maintains centralized testing infrastructure, avoiding multi-laboratory variation, or multi-POCT variation that would hinder the effective interpretation of treatment efficacy.



# hemaPEN<sup>®</sup> | Advanced precision microsampling tool

## Remote patient monitoring

Remote patient monitoring tools hold the potential to better serve patients whilst minimizing their exposure. They enable medical professionals to conduct diagnostic testing whilst remaining socially distanced.

hemaPEN<sup>®</sup> with its pen-shaped easy-to-use design enables self-collection of blood samples in the comfort of a patients' home.

*"Having a phobia of needles does always make blood donation difficult. In order to donate serum, I have to make sure that I am not looking when the blood is taken. I have no such issue with the hemaPEN device. The non-invasive finger prick and collection generates no anxiety or concern. It is quick and effective."*

hemaPEN user



HEMAPEN<sup>®</sup>

Convenience | Volumetric accuracy  
and precision | Sample integrity

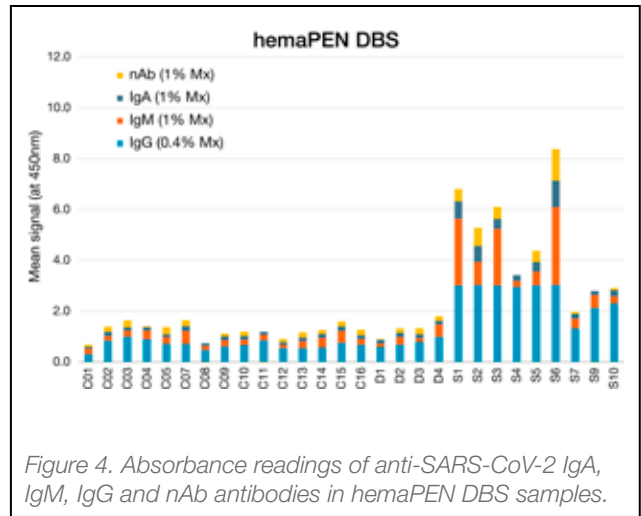
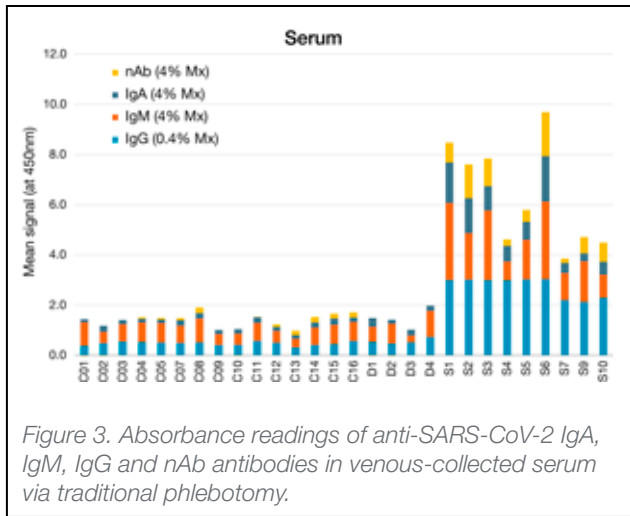
hemaPEN leverages existing DBS evidence for the development of vaccines or serological diagnostics.

hemaPEN is an easy to use, advanced precision microsampling tool that enables the collection of four volumetrically fixed, accurate and precise, samples from a single source. Where there is no option to compromise, the hemaPEN is designed to maintain sample integrity for quantitative analysis and enable information-rich decision making. hemaPEN can be used by anyone in any place, which could revolutionize patient monitoring in the new world of socially distanced living while still maintaining high level patient care.

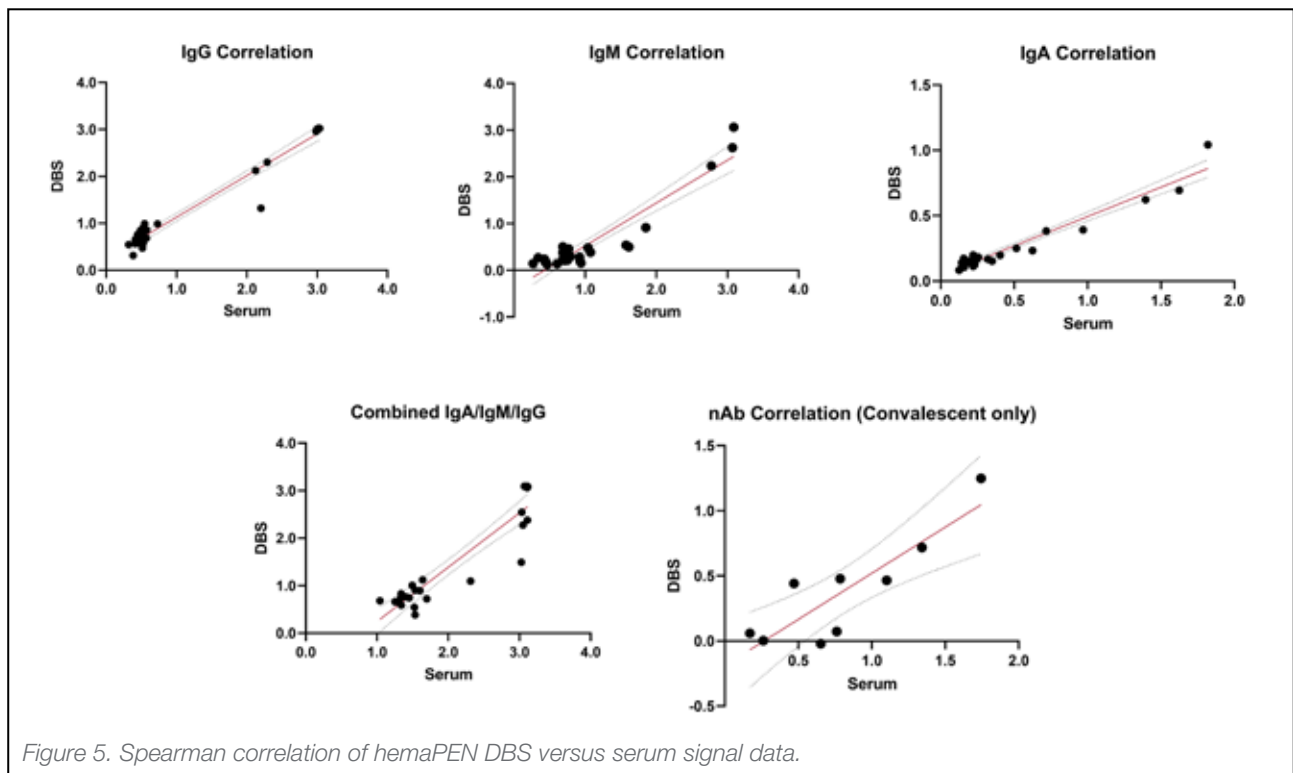
SARS-CoV-2 serology testing

## Comparative serological monitoring between serum and hemaPEN samples

The following figures (Figures 3 and 4) demonstrate relative quantification of anti-SARS-CoV-2 IgA, IgM, IgG and nAb levels compared between serum and hemaPEN samples:



C = Negative controls: SARS-CoV-2 naïve subjects, D = Suspected cases, S = PCR-confirmed SARS-CoV-2 convalescent subjects



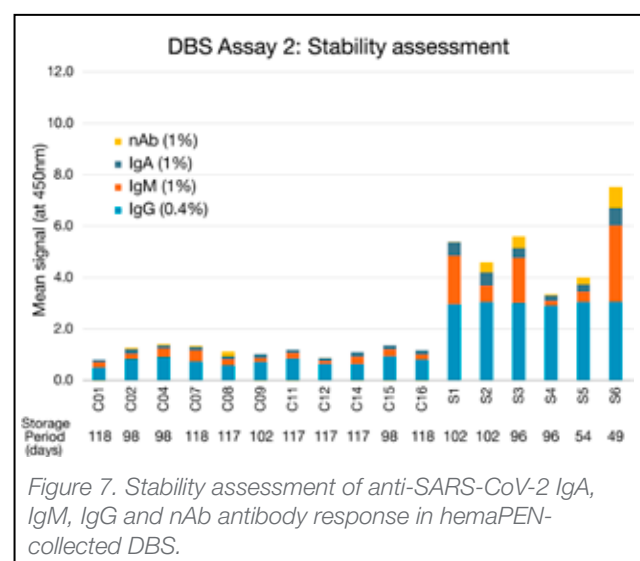
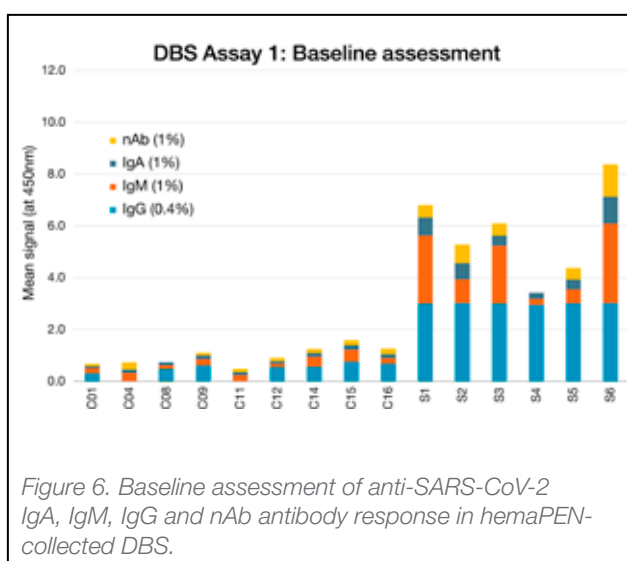
Analyte (serum/DBS)	IgG (0.4% / 0.4%)	IgM (4% / 1%)	IgA (4% / 1%)	nAb_Conv. (4% / 1%)	Combined (4% / 0.4%)
P (two-tailed)	<0.0001	<0.0001	<0.0001	0.0083	<0.0001
P value summary	****	****	****	**	****
Significant? (alpha = 0.05)	Yes	Yes	Yes	Yes	Yes
R squared	0.9561	0.8767	0.939	0.7557	0.8588

Figure 5 presents the absorbance readings of serological analysis of IgG, IgM, IgA and nAb antibodies in hemaPEN and serum matrices from naïve and/or convalescent samples. Due to the competitive assay format, only convalescent data is presented for the nAb correlation graph. Figure 5 and the associated table represent simple linear regression with line of best fit and 95% confidence intervals for each assay.

## Isotypes stability from hemaPEN samples

Anti-SARS-CoV-2 isotype stability was assessed by comparing performance (i.e. signal readout) of DBS samples before and after extended storage at -20°C.

For each hemaPEN, 2 hemaPEN DBS samples were processed within few a days of collection (Figure 6), and the remaning 2 hemaPEN DBS samples were processed after an extended storage period at -20°C (Figure 7). After extended storage of the hemaPEN DBS samples, comparable results are obtained for each isotype.



## Outcome

- Correlation data described above showed highly comparative performance between traditional phlebotomy-collected serum samples and hemaPEN-collected DBS samples, showing hemaPEN as an excellent alternative matrix to serum.
- hemaPEN DBS sample matrix is stable over at least 118 days and is suitable for batch processing, remote collection and postal delivery to centralized laboratory services.
- hemaPEN presents itself as a unique technology for self-administered blood sample collection using a simple finger-prick that can serve new market needs in a new world of socially distanced patient care.
- hemaPEN technology can be applied to large scale screening and sero-prevalence monitoring post-vaccination in roll-out programs.

# SARS-CoV-2 serology testing

## Post-approval efficacy surveillance

In times of uncertainty, Trajan Scientific and Medical and Synexa Life Sciences have come together to provide a streamlined solution to COVID-19 serology testing and sample collection.

With hemaPEN's innovative easy-to-use design and microsampling technology, large scale screening and serosurveillance studies post-vaccine roll out can be conducted safely and efficiently, while maintaining social distancing protocols and maintaining patient-centricity, comfort and convenience.

Combining this technology with Synexa's innovative, market-leading SARS-CoV-2 serology assay - a versatile technology capable of detecting IgG, IgM, IgA as well as nAb antibody response - has yielded a highly competitive and flexible assay, suitable across a wide range of applications.

Through this collaboration, Trajan and Synexa have developed a powerful platform to assist and support your vaccine program.



For more information and assistance, please contact us at [info@trajanscimed.com](mailto:info@trajanscimed.com)

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### Biomarker and translational research services for COVID-19 vaccines and therapeutics

Synexa is an industry leader in contract bioanalytics and biomarker research services specializing in biopharmaceuticals.

Synexa offers expertise in biomarker selection and panel design for each phase of clinical development. In a time of global crisis, Synexa are playing their part to provide workable solutions contributing to the containment and eradication of the pandemic.

### Synexa Life Sciences

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## Trajan Scientific and Medical

### Science that benefits people

Trajan is actively engaged in developing and delivering solutions that have a positive impact on human wellbeing. Our vision revolves around collaborative partnerships that improve workflows, delivering better results.