

COVID-19 Serology Testing - Innovative Antibody Detection & Novel Neutralisation Determination

The novel coronavirus, SARS-CoV-2 and the COVID-19 pandemic, has seen the biopharmaceutical industry leap into action to better understand the disease and develop suitable vaccines and therapies.

With over 1 million deaths reported worldwide, and second waves appearing in Europe, the need for improved testing and continued support of clinical development efforts is no less urgent than when the first COVID-19 related death was reported on the 9th January 2020.

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

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 novelly determines the neutralization potential of the sample by detecting the presence of neutralizing antibodies which prevent the binding of the SARS-CoV-2 spike protein to the ACE2 target receptor.

SYNEXA'S HIGH PERFORMANCE SARS-COV-2 SEROLOGY ASSAY IS PERFECTLY SUITED TO EXPEDITE THERAPY AND VACCINE DEVELOPMENT AS WELL AS LARGE-SCALE SCREENING INITIATIVES.



Innovative Science

The assay provides best-in-class clinical insight, relevant to your therapy or vaccine development programme.

- Novel neutralization assay
- High-throughput capabilities
- No specialised biosafety procedures required
- Multiplex format provides all results in a single run
- 99.1% sensitivity and 100% specificity for IgG at 4 - 8 weeks

We remain committed to supporting our global biopharma partners in the immediate and long-term efforts required to eradicate COVID-19.

Our expertise in immunology biomarker and translational research makes us well-suited to provide support to groups at the centre of SARS-CoV-2 therapeutic and vaccine development programs. Our approach is simple - to work as a fully integrated partner providing consultative and collaborative support every step of the way.

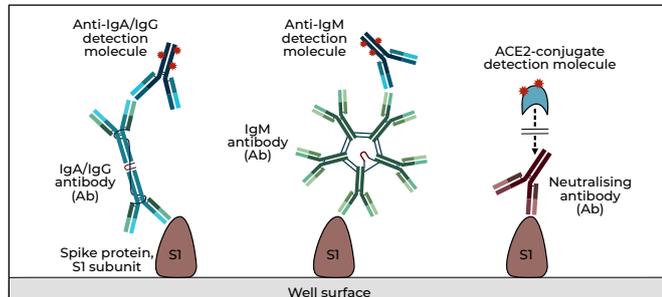
The assay's multiplexed format makes it suitable for high-throughput clinical research and large scale screening applications.

The assay has been validated according to the necessary guidelines and provides novel therapeutic insights not available in competing assays.

Assay Design & Performance:

The novel serology assay has been designed using a versatile, high-throughput sandwich-ELISA format, compatible with a wide range of matrices.

Run as a multiplexed platform, the detection of IgG, IgM and IgA as well as the neutralization potential of each sample to the ACE2-targeting Spike protein, is obtained in a single run.



Assay performance has been shown to be well within the acceptance criteria stipulated by FDA and EMA guidelines, an important consideration for vaccine and therapeutic development trials.

	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'S SEROLOGY ASSAY DOES NOT REQUIRE SPECIALISED BIOSAFETY PROCEDURES, THUS IMPROVING THE TURN-AROUND-TIME AND LOWERING THE COST FOR EACH TEST.

Applications:

Synexa's serology assay panel provides an array of applications including:

- Measurement of humoral responses
- Determining seroconversion
- Identification of convalescent individuals at risk of re-infection.

The assay panel provides qualitative detection of anti-SARS-CoV-2 antibodies against a batch specific assay cut point derived from naïve subject samples.

By determining the different antibody measurements specific to SARS-CoV-2, one is able to predict the outcome of a vaccine candidate, further demonstrating the value of this assay.



Quality Expertise

We adhere to the strictest of quality standards, guided by the relevant regulatory bodies, ensuring that the science we provide is sound, reliable and valuable in every study.

- All activities conducted according to **GCP/GCLP** guidelines and in compliance with **ISO/IEC15189:2012**.
- All methods are **validated** according to **FDA/EMA guidelines**.
- **Global footprint** with 3 specialised laboratories.
- **70+** Masters and PhD-level scientists.
- **10 000** bioanalytical samples processed annually.
- **30 client-tailored bioanalytical methods** validated annually.

World Leaders in Biomarker & Bioanalysis Research Services

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

For nearly 20 years we have supported our Biopharma partners across the globe to achieve their clinical milestones. As a deeply scientifically driven CRO we deliver bespoke bioanalytical solutions to meet our client's specific challenges.

Our global purpose-built laboratories have been designed and fitted to meet the fast changing and ever evolving complexity of drug development pipelines.

Guided by a combined scientific experience of over 800 years, our team of world-class scientists pride themselves on going the extra mile to deliver high levels of customer service and quality science that meets your expectations.

Clinical Research Services

Synexa specializes in providing bespoke end-to-end biomarker and bioanalytical solutions, developed and validated to meet your specific challenges.

- Large and novel molecule bioanalysis
- Biomarker analysis
- Immunogenicity & Pharmacokinetics
- Cell-based assays
- Pharmacogenetics
- ProtoTrials®
- Regulatory approval
- *De novo* method development and validation

Technology Platforms

Our bespoke bioassay solutions are paired with proven advanced technology platforms, capable of assessing biomarkers across the biological spectrum.

DNA

- TargetedPGx
- Microarray
- Electrophoresis

Protein

- ELISA
- MSD-ECL
- ELISpot
- Protein arrays
- Nephelometry

RNA

- NanoString®
- RT-qPCR
- PCR expression array

Cell

- Flow Cytometry
- Cell culture assays

Tissue

- NanoString®
- Organotypic culture

Quality Science Delivered On Time and within Budget

Contact our specialist team to discuss how we can support you to achieve your clinical milestones.



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