Improved S1 antigen and SARS-CoV-2 antibody detection assay formats

An improved SARS-CoV-2 spike protein subunit (S1) antigen and two exceptional ELISA assay formats for highly specific and sensitive serological detection and measurement of antibodies to SARS-CoV-2.

Proposed Use

A modified version of SARS-CoV-2 S1 protein can be incorporated to any assay format, acting as an improved S1 antigen to significantly enhance the detection of relevant antibodies. The improved S1 antigen can be commercialised for use in existing serological tests, validating vaccine response and as immunogenic composition in the creation of new generation vaccines.

As the demand for antibody-testing rises, the Hybrid DABA (double antigen binding assay) and the extensively validated IgG/IgM capture assays can be commercialised to be used as accurate and robust serological tests for SARS-CoV-2. With potential for use in screening infection rates across populations and validating patient vaccine response.

Problem Addressed

There is a strong need for the best performing and robust diagnostic tests for antibodies to SARS-CoV-2. The failure to detect antibody levels during active infection leading to high levels of false-negatives demonstrates the demand for more accurate detection.

Technology Overview

- The modified version of SARS-CoV-2 S1 protein prevents the binding of the tetrapyrrole compound biliverdin, increasing the interaction between the S1 antigen and relevant antibodies.
- The modified S1 antigen significantly improves the performance of existing serological tests when compared to WT S1 antigen.
- The Hybrid DABA is based on an antigen sandwich and performs exceptionally in testing serum/plasma. This total antibody assay can detect all immunoglobulin types and classes and is suitable for confirming SARS-CoV-2 infection, providing an indirect measure of neutralising antibody levels and detection of vaccine serological response in humans and animals.
- The Hybrid DABA (99.6% sensitivity) performs considerably better when compared to commercially available assays.
- The IgG/IgM capture assay is a dilution independent way of detecting specific SARS-CoV-2 antibodies. This method enables accurate, stable detection and quantification of antibodies in eluates from dried blood spots.

Benefits

- The improved S1 antigen reduces risk of false-negative and significantly enhances sensitivity, particularly for low antibody level samples
- Hybrid DABA demonstrates 100% specificity (n=825) and 99.6% sensitivity on sera (n=276)
- Hybrid DABA exhibits minimal cross-reactivity to circulating irrelevant antibodies
- IgG/IgM capture assay is a non-intrusive self-sampling method
- Robust IgG/IgM capture assay suitable for dried blood spot samples

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Intellectual property information

This technology is protected by UK priority patent applications, number GB2011047.4, number GB2014047.1 and number GB2020199.2

Link to published paper(s)

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31830-4/fulltext

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3739821

https://www.medrxiv.org/content/10.1101/2021.01.21.21249203v1

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