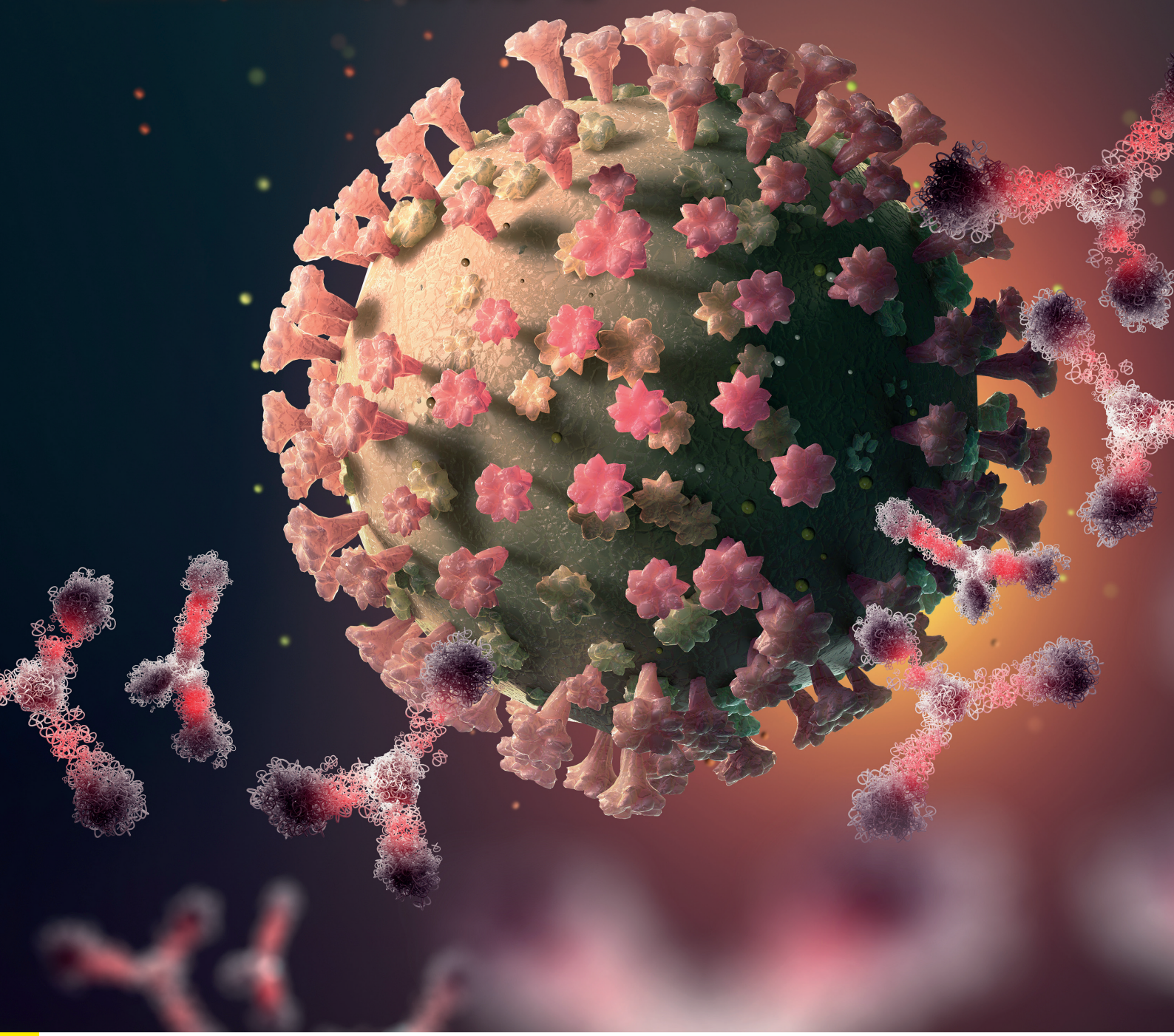
SARS-CoV-2 UTAB FS

Universally applicable IT assay for total antibodies in COVID-19



DiaSys. Total confidence in patient results.
Member of IFCC Task Force on COVID-19.
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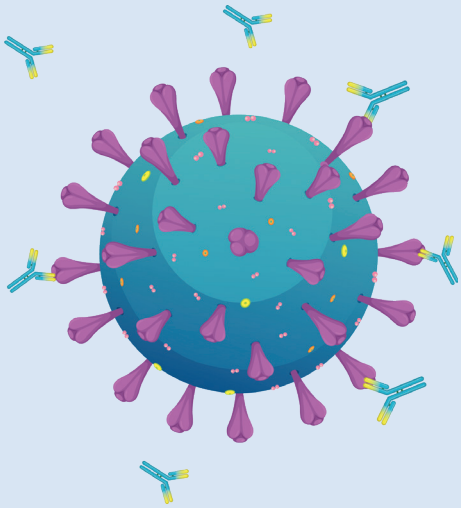
Clinical significance

Coronavirus disease 2019 (COVID-19) is caused by **S**evere **A**cute **R**espiratory **S**yndrome coronavirus 2 (**SARS**-CoV-2). Transmission of COVID-19 occurs primarily through respiratory droplets as in cold and influenza. It is generally assumed that the virus takes approx. 2 to 14 days to incubate. SARS-CoV-2 viral load is associated with the appearance of clinical symptoms like cough, myalgia, or headache; however, a significant ratio of infected individuals remain asymptomatic or exhibit mild symptoms.

The antibody response to SARS-CoV-2 infection targets a variety of viral proteins, including the spike (S) and nucleocapsid (N) protein. The spike protein is crucial for attachment as the receptor-binding domain of the viral spike protein (S1-RBD) mediates the viral entry into the host cells by binding to the ACE-2 receptor. Since the RBD contains multiple dominant neutralizing epitopes and most of the identified neutralizing antibodies are specific to the RBD of the SARS-CoV-2 spike protein, the RBD serves as significant target for vaccine development in COVID-19.

Importance of antibody testing in COVID-19



Serological assays are of critical importance to determine seroprevalence and previous exposure to the virus. Antibody determination should be performed at least two weeks after the onset of symptoms to detect previous SARS-CoV-2 infection. Vaccine-related testing for antibodies is becoming increasingly important as it provides valuable information on vaccine efficacy: it supports the determination of an antibody threshold for immunity and enables the tracking of antibody levels following vaccination.

Innovative method

The particle enhanced immunoturbidimetric DiaSys SARS-CoV-2 UTAB FS assay detects total antibodies targeting the RBD of the spike protein. It has been scientifically proven that these antibodies effectively neutralize SARS-CoV-2 by blocking the ACE2 binding site.

SARS-CoV-2 total antibody concentration present in the sample is determined photometrically by antigen-antibody reaction between human SARS-CoV-2 antibodies and the RBD of the SARS-CoV-2 spike protein.

Key features

- Quantitative assay for total antibody detection in COVID-19
- High throughput PETIA (Particle enhanced immunoturbidimetric assay)
- Designed to detect antibodies directed against SARS-CoV-2 S1-RBD
- Liquid-stable, ready-to-use reagent with dedicated calibrators and controls

Superiority of SARS-CoV-2 UTAB FS

The variety of available antibody assays, which can only be used on the manufacturers' platforms, represents a major challenge for patient follow-up as they provide considerably deviating results. A possible change in the assay procedure requires parallel measurements with both methods to verify the results.

Benefit from the ready-to-use reagent SARS-CoV-2 UTAB FS which is universally applicable on almost all common clinical chemistry analyzers and provide comparable results – no matter which instrument.

Sensitivity	**98.0% (CI 95%, 89.6 - 100%)**
Specificity	**98.7% (CI 95%, 95.3 - 99.8%)**
Clinical performance	**The negative predictive value (NPV) is 99.3 % (CI 95%, 95.5 – 99.9%). The positive predictive value (PPV) is 96.2% (CI 95%, 86.3 – 99.0%).**
Prozone limit (High-Dose-Hook effect)	**No High-Dose-Hook effect observed for antibody concentrations up to 1000 AU/mL**
Measuring range	**1.5 – 150 AU/mL**
Interference	**Endogenous substances show no significant interference**

* Results are given as arbitrary units per milliliter (AU/mL)

Order information

Cat. no.	Kit size	
1 7508 99 10 935	2 x 15 mL + 1 x 10 mL	SARS-CoV-2 UTAB FS R1 + R2
1 7500 99 10 058	4 x 1 mL	TruCal SARS-CoV-2
5 1750 99 10 046	3 x 1 mL	TruLab SARS-CoV-2 Level 1
5 1760 99 10 046	3 x 1 mL	TruLab SARS-CoV-2 Level 2
1 7501 99 10 021	6 x 25 mL	SARS-CoV-2 Sample Dilution Matrix

Leading technology in fluid-stable reagents from DiaSys

- 30 years experience in development and production of clinical chemistry tests
- Premium service in technics, applications and after sales
- Quality products made in Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf life and onboard stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

Handed over by:

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February 2021