

# TruLab SARS-CoV-2 Level 2

## Order Information

Cat. No. 5 1760 99 10 046 Level 2 Kit size 3 x 1 mL

## Intended Use

Assayed quality control material for monitoring the analytical performance of quantitative in vitro determination of SARS-CoV-2 total antibodies on photometric systems.

## Description

TruLab SARS-CoV-2 Level 2 is a liquid-stable control based on human plasma. TruLab SARS-CoV-2 Level 2 is a pathological control.

## Storage

The control both opened and unopened must be stored at 2 – 8°C. Avoid contamination and protect from light. Do not freeze.

## Stability

Unopened: up to the date of expiry indicated on the kit  
Opened: 1 month

Proper storage and handling of this product must be observed.

## Warnings and Precautions

1. TruLab SARS-CoV-2 is based on heat-inactivated human material. Each individual blood donation used for production of TruLab SARS-CoV-2 was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
2. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only.

## Waste Management

Refer to local legal requirements.

## Preparation

The control is liquid and ready to use.

## Materials Required

General laboratory equipment

## Procedure

Please refer to the reagent package insert for instructions for use.

## Assay Values

The assay values have been determined using DiaSys SARS-CoV-2 UTAB FS, calibrated by DiaSys TruCal SARS-CoV-2. Assay values may vary with different reagents and methods used. The assay values listed below are specific for this lot number of control only.

## Literature

1. Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
2. Clinical and Laboratory Standards Institute. Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44 A4.
3. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29 A4.



DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim Germany  
www.diasys-diagnostics.com

	Lot No.	Expiry Date	Target Value	Range
TruLab SARS-CoV-2 Level 2	30765	2021-08-31	65.4 AU/mL	52.3 - 78.5 AU/mL