

TruLab SARS-CoV-2 Level 1

Order Information

Cat. No. 5 1750 99 10 046 Level 1 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 automated photometric systems.

Description

TruLab SARS-CoV-2 is a liquid-stable control for SARS-CoV-2 total antibodies based on human material for use with the DiaSys test SARS-CoV-2 UTAB FS.

Level 1 is in the negative range.

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 ready to use.

Materials Required

General laboratory equipment

Procedure

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

Target Values

Target values have been correlated to the first WHO International Standard for anti-SARS-CoV-2 immunoglobulins (human) NIBSC code: 20/136 in a linear regression comparison. The WHO International Standard correlates well with the current standardization of the DiaSys SARS-CoV-2 UTAB FS assay. Since the manufacturer-specific unit AU/mL has been proven to be essentially equivalent to the BAU/mL unit, this unit will now be gradually adapted in all relevant technical documentation.

Target values may vary with reagents and methods used.

Values listed below are valid for the indicated lot only.

Each laboratory should establish corrective action in case of deviations in control recovery.

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.
4. First WHO International Standard Anti-SARS-CoV-2 Immunoglobulin (human). Available at: <https://www.nibsc.org/documents/ifu/20-136.pdf>



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	Lot No.	Expiry Date	Target Value	Range
TruLab SARS-CoV-2 Level 1	32877	2022-12-31	negative	< 10 BAU/mL