Instructions for Use

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# SARS-CoV-2 S1/RBD IgG Ab ELISA

**The SARS-CoV-2 S1/RBD IgG Ab ELISA is intended for the qualitative and quantitative determination of IgG class antibodies against SARS-CoV-2 in human serum.**

REF **30181829**

Σ **96**

2°C 8°C

EU: IVD CE

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## REVISION HISTORY OF INSTRUCTIONS FOR USE

| Changes from the previous version 2021-02 to actual version 2021-10 | |
|---|---|
| Chapter 3 | Update |
| Chapter 10 | Additional information |
| Chapter 14 | Update and additional data |
| Chapter 15 | Update and additional data |
| Chapter 16 | Update and additional data |
| Symbol page | Layout change |

## 1. INTENDED USE

The SARS-CoV-2 S1/RBD IgG Ab ELISA is intended for the qualitative and quantitative determination of IgG class antibodies against SARS-CoV-2 in human serum. The device serves as an aid in identifying patient's adaptive immune response to SARS-CoV-2 indicating recent or prior infections.

## 2. SUMMARY AND EXPLANATION

End of 2019 a novel respiratory disease emerged in China and soon spread rapidly worldwide. The causative agent was identified as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 belongs to a family of viruses called Coronaviridae, which is characterized by significant genetic variability and high recombination rate. That enables them to be rapidly and easily distributed within human populations causing life-threatening diseases (coronavirus disease 2019, COVID-19).

There is currently no treatment available, research groups are working on development of vaccines and therapeutic drugs.[1]

Symptoms of SARS-COV-2 infection include fever (83 - 99%), cough (59 - 82%), shortness of breath (19 - 55%), and muscle ache (11-44%). The most characteristic symptom is respiratory distress (~ 55%).[1,2] Patients with diseases that affect the immune system have a higher risk of infection.

SARS-CoV-2 is transmitted by droplet infection via coughing or sneezing. Incubation period is up to 14 days, median is 5-10 days.[3] The course of the disease is non-specific and varies widely.[4-6] Virus detection using PCR can be performed in early days of infection, even before detectable antibody response or during early phases of antibody development. IgG antibody level develops during infection and can be detected during active phase of infection, late phase or recurrent infection as well as past infection and at recovery stage of infection.[3]

Serologic testing of IgG-class antibodies directed against SARS-CoV-2 has an essential role in determining the prevalence of this virus. Also regarding pre-screening of individuals prior to admission into vaccine trials and monitoring of temporal immune responses in vaccine recipients, serological testing will play an important role.[7]

Serological tests are not intended to determine the presence of the virus but to detect an immune response of the human body. It is therefore a supplement to methods that can provide additional information compared to direct virus detection (e.g. PCR testing).

## 3. TEST PRINCIPLE

The SARS-CoV-2 S1/RBD IgG Ab ELISA is a solid phase assay based on enzyme-linked immunosorbent (ELISA) principle. The wells are coated with specific SARS-CoV-2 S1/RBD antigen. IgG class antibodies of the human serum sample binding to the antigen coated wells are detected by a secondary enzyme conjugated antibody specific for human IgG. After the substrate reaction the intensity of the color developed can be detected using a microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength 600-650 nm) and is proportional to the amount of IgG-specific antibodies. Results of human serum samples can be determined qualitatively by the cut off control.

## 4. WARNINGS AND PRECAUTIONS

1. For *in-vitro diagnostic* use only. For professional use only.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. In case of severe damage of the kit package please contact IBL or your supplier in written form, latest one week after receiving the kit. Do not use damaged components in test runs, but keep safe for complaint related issues.
4. Broken glass may cause injury. Handle glass vessels with caution.
5. Obey lot number and expiry date. Do not mix reagents of different lots. Do not use expired reagents.
6. Follow good laboratory practice and safety guidelines. Wear lab coats, disposable latex gloves and protective glasses where necessary.
7. Reagents of this kit containing hazardous material may cause eye and skin irritations. See MATERIALS SUPPLIED and labels for details. Material Safety Data Sheets for this product are available on the IBL-Homepage or upon request directly from IBL.
8. Chemicals and prepared, used, unused or expired reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
9. The cleaning staff should be guided by the professionals regarding potential hazards and handling.
10. All serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
11. Avoid contact with Stop solution. It may cause skin irritations and burns.
12. All reagents of this kit containing human serum or plasma have been tested and were found negative for anti-HIV I/II, HBsAg and anti-HCV. However, a presence of these or other infectious agents cannot be excluded absolutely. For this reason reagents should be treated as potential biohazards in use and for disposal.
13. Some reagents contain ProClin 300 as preservative. In case of contact with eyes or skin, flush immediately with water. When disposing reagents, flush with a large volume of water to avoid built-up.
14. The device contains material of animal origin, which is certified apparently free of infectious or contagious diseases and injurious parasites. Still the material should be handled with extreme caution.

## 5. STORAGE AND STABILITY

The kit is shipped at ambient temperature and should be stored at 2-8°C. Keep away from heat or direct sunlight. The storage and stability of specimens and prepared reagents is stated in the corresponding chapters.

The microtiter strips are stable up to the indicated expiry date after the kit is opened. Make sure that the opened bag is tightly closed when stored at 2-8°C.

## 6. SPECIMEN COLLECTION AND STORAGE

**Specimen**
Serum

**Specimen collection**
The usual precautions for venipuncture should be observed. It is important to preserve the chemical integrity of a blood specimen from the moment it is collected until it is assayed. Do not use grossly hemolytic, icteric or grossly lipemic specimens. Samples appearing turbid should be centrifuged before testing to remove any particulate material.

**Sample Collection Device**
No special requirements.

**Specimen storage**
Samples can be stored at 2-8°C for 7 days.
It is recommended to freeze samples and store at -80°C for long time storage (< 6 months).
Avoid repeated freeze-thaw cycles. Keep away from heat or direct sunlight.

## 7. MATERIALS SUPPLIED

| Quantity | Symbol | Component |
|---|---|---|
| 1 x 12x8 | **MTP** | **Microtiter Plate** Break apart strips.<br>Coated with SARS-Cov-2 S1/RBD antigen |
| 1 x 100 mL | **DILBUF** | **Diluent Buffer** Ready to use.<br>Contains: ProClin 300. Blue colored. |
| 1 x 15 mL | **ENZCONJ** | **Enzyme Conjugate**, Ready to use.<br>Contains: goat anti-human IgG and ProClin 300. |
| 4 x 1.0 mL | **CAL A-D** | **Standard A-D** Ready to use.<br>0; 10; 40; 120 U/mL Standard B = cut-off standard<br>Contains: recombinant anti-SARS-CoV-2 IgG antibody, stabilizers |
| 1 x 1 mL | **CONTROL +** | **Positive Control** Ready to use.<br>Contains: recombinant anti-SARS-CoV-2 IgG antibody, stabilizers<br>Concentrations / acceptable ranges see QC certificate. |
| 1 x 1 mL | **CONTROL -** | **Negative Control** Ready to use.<br>Contains: recombinant anti-SARS-CoV-2 IgG antibody, stabilizers<br>Concentrations / acceptable ranges see QC certificate. |
| 1 x 15 mL | **TMB SUBS** | **TMB Substrate Solution** Ready to use.<br>Contains: TMB, Buffer, stabilizers. |
| 1 x 15 mL | **TMB STOP** | **TMB Stop Solution** Ready to use.<br>Contains: 0.5 M $H_2SO_4$. |
| 1 x 100 mL | **WASHBUF** **CONC** | **Wash Buffer** Concentrate (10x) |
| 2 x | **FOIL** | **Adhesive Foil** |

## 8. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipettes (Multipette Eppendorf or similar devices, < 3 % CV).
   Volume: 2 – 20µL; 100µL; 200µL; 1000 µL
2. Tubes for sample dilution (Polypropylene (PP) or glass)
3. Vortex mixer
4. 8-Channel Micropipettor with reagent reservoirs
5. Wash bottle, automated or semi-automated microtiter plate washing system
6. Incubator +37°C
7. Microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength 600-650 nm)
8. Bidistilled or deionised water
9. Paper towels, pipette tips and timer

## 9. PROCEDURE NOTES

1. Any improper handling of samples or modification of the test procedure may influence the results. The indicated pipetting volumes, incubation times, temperatures and pre-treatment steps have to be performed strictly according to the instructions. Use calibrated pipettes and devices only.
2. Once the test has been started, all steps should be completed without interruption. Make sure that required reagents, materials and devices are prepared ready at the appropriate time. Allow all reagents and specimens to reach room temperature (18-25°C) and gently swirl each vial of liquid reagent and sample before use. Mix reagents without foaming.
3. Avoid contamination of reagents, pipettes and wells/tubes. Use new disposable plastic pipette tips for each component and specimen. Do not interchange caps. Always cap not used vials. Do not reuse wells/tubes or reagents.
4. It is advised to determine duplicates to be able to identify potential pipetting errors.
5. Use a pipetting scheme to verify an appropriate plate layout.
6. Incubation time affects results. All wells should be handled in the same order and time sequences. It is recommended to use an 8-channel Micropipettor for pipetting of solutions in all wells.
7. Microtiter plate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multichannel pipette or an automatic microtiter plate washing system. Do not allow the wells to dry between incubations. Do not scratch coated wells during rinsing and aspiration. Rinse and fill all reagents with care. While rinsing, check that all wells are filled precisely with Wash Buffer, and that there are no residues in the wells.

8. Humidity affects the coated wells/tubes. Do not open the pouch until it reaches room temperature. Unused wells/tubes should be returned immediately to the resealed pouch including the desiccant.
9. Each test run needs a standard curve.

## 10. PRE-TEST SETUP INSTRUCTIONS

### 10.1. Preparation of concentrated components

**The contents of the kit for 96 determinations can be divided into 3 separate runs.**

The volumes stated below are for one run with all strips (96 determinations).

| Dilute / dissolve | Component | with | Diluent | Relation | Remarks | Storage | Stability |
|---|---|---|---|---|---|---|---|
| 100 mL | **WASHBUF** **CONC** | 900 mL | bidist. water | 1:10 | Mix vigorously. | 2-8°C | 8 weeks |

### 10.2. Dilution of Samples

| Sample | to be diluted | with | Relation | Remarks |
|---|---|---|---|---|
| **Serum** | generally | **DILBUF** | 1:101 | e.g. 5 µL + 500 µL or<br>e.g. 10 µL + 1000 µL |

Samples containing concentrations higher than the highest standard have to be diluted further.

As antibody concentrations after vaccination can significantly increase above the highest kit standard (CAL D = 120 U/mL) further sample dilution is required to obtain reliable quantitative results. Recommended sample dilution is between 1:101 and 1:2001 depending on the time point of measurement after vaccination.

## 11. TEST PROCEDURE

| | |
|---|---|
| **1.** | Pipette **100 µL** of each **Standard, Control** and diluted **sample** into the respective wells of the microtiter plate. |
| **2.** | Cover plate with adhesive foil. **Incubate 1 hour** at **+37°C.** |
| **3.** | Remove adhesive foil. Discard incubation solution. Wash plate **3 x** with **250 µL** diluted **Wash Buffer**.<br>Remove excess solution by tapping the inverted plate on a paper towel.<br>Automatic microtiter plate washers should be adjusted to overflow mode. |
| **4.** | Pipette **100 µL Enzyme conjugate** into each well. |
| **5.** | Cover plate with adhesive foil. **Incubate 1 hour** at **+37°C.** |
| **6.** | Remove adhesive foil. Discard incubation solution. Wash plate **3 x** with **250 µL** diluted **Wash Buffer**.<br>Remove excess solution by tapping the inverted plate on a paper towel.<br>Automatic microtiter plate washers should be adjusted to overflow mode. |
| **7.** | Pipette **100 µL** of **TMB Substrate Solution** into each well. |
| **8.** | **Incubate 15 minutes** at **18-25°C** (room temperature) |
| **9.** | Stop the substrate reaction by adding **100 µL** of **TMB Stop Solution** into each well.<br>Briefly mix contents by gently shaking the plate. Color changes from blue to yellow. |
| **10.** | **Measure** optical density with a photometer at **450 nm** (Reference-wavelength: 600-650 nm) within **15 minutes** after pipetting the Stop Solution. |

## 12. AUTOMATION

Automated protocols can be provided for open ELISA systems: Freedom EVOlyzer®, ThunderBolt® and DSX®. For more information please contact: ProductSupport.IBL@tecan.com

For the use of products on automated instruments it is absolutely necessary to perform and maintain a validation according to legal requirements. A successful validation of the process is a prerequisite for diagnostic use. The responsibility for the implementation and documentation of validation in accordance with the country-specific requirements is assumed by the organization or institution.

## 13. QUALITY CONTROL

The test results are only valid if the test has been performed following the instructions. Moreover, the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or comparable standards/laws. User and/or laboratory must have a validated system to get diagnosis according to GLP. All kit controls must be found within the acceptable ranges as stated on the labels and the QC certificate. If the criteria are not met, the run is not valid and should be repeated. Each laboratory should use known samples as further controls.

In case of any deviation the following technical issues should be proven: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, incubation conditions and washing methods.

It is recommended to participate at appropriate quality assessment trials.

## 14. CALCULATION OF RESULTS

The evaluation of the test can be performed either qualitatively or quantitatively.

### 14.1. Qualitative Calculation

The cut-off value is given by the optical density (OD) of the Standard B (cut-off standard). The cut-off index (COI) is calculated from the mean optical densities of the sample and cut-off value. If the optical density of the sample is within a range of 10 % around the cut-off value (grey zone), the sample has to be considered as borderline. Samples with higher ODs are positive, samples with lower ODs are negative.
Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

**Typical Example**:
Cut-off = OD (Standard B, cut-off standard) = 0.200
Sample OD = 0.600
Cut-off index (COI): 0.600 / 0.200 = 3. The sample has to be considered positive.

### 14.2. Quantitative Evaluation

The obtained OD of the standards (y-axis, linear) are plotted against their concentration (x-axis, logarithmic) either on semi-logarithmic graph paper or using an automated method. A good fit is provided with cubic spline, 4 Parameter Logistics or Logit-Log.
For the calculation of the standard curve, apply each signal of the standards (one obvious outlier of duplicates might be omitted and the more plausible single value might be used).

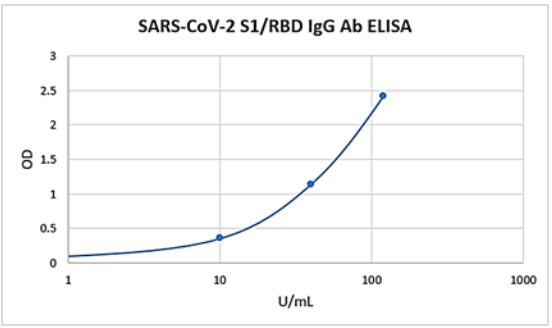
The concentration of the samples can be read directly from the standard curve.

Samples showing concentrations above the highest standard have to be diluted as described in PRE-TEST SETUP INSTRUCTIONS and re-assayed.

In case of diluted samples the values have to be multiplied with the corresponding dilution factor.

**Typical Calibration Curve**
(Example. Do not use for calculation!)

| Standard | U/mL | $OD_{Mean}$ |
|---|---|---|
| A | 0 | 0.025 |
| B | 10 | 0.357 |
| C | 40 | 1.138 |
| D | 120 | 2.425 |




Measuring Range: from 1.6 U/mL (LoQ) to 120 U/mL (Standard D)

| Method | Range | Interpretation |
|---|---|---|
| Quantitative (Standard curve) | < 9 U/mL | negative |
| | 9 – 11 U/mL | borderline |
| | > 11 U/mL | positive |
| Qualitative (Cut-off Index, COI) | < 0.9 | negative |
| | 0.9 – 1.1 | borderline |
| | > 1.1 | positive |

The results themselves should not be the only reason for any therapeutical consequences. They have to be correlated to other clinical observations and diagnostic tests.

### 14.3. International reference standards / harmonisation of results

The following international available reference standards were tested and found positive in the SARS-CoV-2 S1/RBD IgG Ab ELISA.

- EURM-017 and EURM-018, Joint Research Centre, European Commission
- NIBSC code 20/136, first WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human) assigned potency 1000 BAU/mL

For harmonization of quantitative results the concentration generated in U/mL (IBL assay) can be converted in BAU/mL (binding units per mL) based on the calibration with first WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human) NIBSC code: 20/136 with the following equation:
1.00 U/mL = 1.86 BAU/mL

## 15. LIMITATIONS OF THE PROCEDURE

Specimen collection and storage have a significant effect on the test results. See SPECIMEN COLLECTION AND STORAGE for details.
For cross-reactivities, see PERFORMANCE.

| | Substance | Concentration |
|---|---|---|
| The following substances do not have a significant effect on the test results up to the below stated concentrations (+/- 20%). | Hemoglobin | 8.0 mg/mL |
| | Bilirubin | 1.0 mg/mL |
| | Triglyceride | 45.5 mg/mL |
| | Sodium azide | 1% (w/w) |
| | Human serum albumin | 50 mg/mL |

## 16. PERFORMANCE

### 16.1. Analytical Specificity (Cross Reactivity)

No cross-reactivity was found to the common coronaviruses HCoV-HKU1, HCoV-NL63, HCoV-OC43 and HCoV-229E and to anti-Haemophilus influenzae IgG, anti-Influenza B IgG, anti-Influenza A IgG, anti-Respiratory Syncytial Virus (RSV) IgG and anti-Hepatitis B surface Antigen (HBs). Cross reactivity was detected for anti-Hepatitis C Virus (HCV) and Antinuclear Antibodies (ANA), cross reactivity to other infectious diseases antibodies or coronavirus antibodies cannot be completely excluded.

Out of 151 true negative serum samples a single sample was detected false positive.

### 16.2. Evaluation of Detection Capability

#### Limit of Blank (LoB)

The LoB study was performed with five different blank samples with two kit lots. As blank sample the zero calibrator (Standard A) was used, measured in four replicates per sample on three days resulting in 60 observations per lot. Limit of Blank = 0.5 U/mL.

#### Limit of Detection (LoD)

The LoD study was performed with five different blank samples and five different low concentrated samples using two kit lots, measured in four replicates per sample on three days resulting in 60 observations per lot. Limit of Detection = 1.2 U/mL.

#### Limit of Quantitation (LoQ)

The LoQ study was performed with five low and medium concentrated serum samples with different concentration levels, measured in four replicates per run with two kit lots on three days resulting in a total of 60 observations per lot. Limit of Quantitation = 1.6 U/mL (with an accuracy of 20%).

### 16.3. Linearity

Recovery in dilution was done with two samples close to the upper concentration range of the assay and two negative samples. The positive samples were mixed and diluted serially with the negative samples resulting in a total of 11 dilutions for two sample pools.

The relation between the expected and the measured concentrations did not significantly deviate from linearity over the studied range (3.4 – 142.7 U/mL). The mean recovery of the diluted sample pool 1 was 100% (range 95 – 105%) and the mean recovery of the diluted sample pool 2 was 96% (range 83 – 101%).

### 16.4. Precision

The intra- and inter-assay study was conducted during 20 days of testing using one reagent lot. Two runs were performed per day with a panel of seven serum samples. Each sample was run in duplicate.

The intra-assay precision showed a mean CV of 7.7% in a range of 5.4% - 9.3% (U/mL) and a mean CV of 6.4% in a range of 5.2% - 8.0% (COI).

The inter-assay precision showed a mean CV of 15.3% in a range of 12.9% - 17.0% (U/mL) and a mean CV of 13.2% in a range of 12.0% - 14.5% (COI).

The between-lot variation study was conducted during 5 days of testing using 3 reagent lots. Each lot was tested in one run per day with a panel of six serum samples. Each sample was tested in five replicates per run.

The between-lot precision showed a mean CV of 15.7% and a range of 11.0% - 19.5% (U/mL) and a mean CV of 15.3% and a range of 9.8% - 19.3% (COI).

### 16.5. Clinical agreement (sensitivity and specificity)

Positive and negative agreement were evaluated in an in-house study using 41 serum samples from patients with previous COVID-19 infection (confirmed positive for SARS-CoV-2 by PCR) and 151 serum samples from patients considered negative (samples collected before December 2019).

The positive sample were collected between 21 and 51 days after suspected date of infection.

| Number of subjects tested | IgG positive results | IgG negative results | Clinical agreement |
|---|---|---|---|
| 41 | 41 | 0 | 100% (sensitivity) |
| 151 | 1 | 150 | 99.3% (specificity) |

### 16.6. Antibody response after vaccination

For evaluation of antibody concentration after vaccination serum samples from 17 donors at different time points before and after vaccination with BioNTech/Pfizer or AstraZeneca vaccine were tested.

| | AstraZeneca | | | BioNtech/Pfizer | | |
|---|---|---|---|---|---|---|
| | Minimum (Um/L) | Median (U/mL) | Maximum (U/mL) | Minimum (Um/L) | Median (U/mL) | Maximum (U/mL) |
| 0 days (before vaccination) | 0.2 | 0.8 | 23.9 | 0.8 | 1.2 | 1.9 |
| 1 -10 days | 0.6 | 1.4 | 21.7 | 1.8 | 1.8 | 1.8 |
| 11 - 20 days | 0.8 | 18.1 | 90.3 | 2.1 | 65.3 | 382 |
| 21 - 40 days | 12.4 | 72.4 | 206 | 7.4 | 149 | 2400 |
| 41 - 60 days | 6.7 | 38.3 | 269 | 97.8 | 1197 | 2204 |
| > 60 days | 6.1 | 57.1 | 147 | 96.2 | 617 | 1478 |

As response to vaccination (BioNTech/Pfizer or AstraZeneca vaccine) an increase in measured concentration could be observed indicating presence of SARS-CoV-2 IgG antibodies against the S1 receptor binding domain.
The IBL SARS-CoV-1 S1/RBD IgG Ab ELISA is suitable to measure and monitor IgG antibody concentrations after vaccination with AstraZeneca or BioNTech/Pfizer Covid-19 vaccine. A statement about long term immunity of a person should not be made based on these results.

## 17. PRODUCT LITERATURE REFERENCES

[1] Tu, Y. F., Chien, C. S., Yarmishyn, A. A., Lin, Y. Y., Luo, Y. H., Lin, Y. T., ... & Wang, M. L. (2020). A review of SARS-CoV-2 and the ongoing clinical trials. International journal of molecular sciences, 21(7), 2657.

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[7] Theel, E. S., Slev, P., Wheeler, S., Couturier, M. R., Wong, S. J., & Kadkhoda, K. (2020). The role of antibody testing for SARS-CoV-2: is there one?. Journal of Clinical Microbiology.

# Symbols / Symbole / Symbôles / Símbolos / Símbolos / Σύμβολα

| | |
|---|---|
| REF | Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.: |
| LOT | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή: |
|  | Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από: |
|  | No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests: / Αριθμός εξετάσεων: |
| CONC | Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα |
| LYO | Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο |
| IVD | In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Dispositivo Médico para Diagnóstico In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση. |
|  | Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Ler as instruções antes de usar. / Leggere le istruzioni prima dell'uso. / Διαβάστε τις οδηγίες πριν την χρήση. |
|  | Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l'abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Manter longe do calor ou luz solar directa. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου. |
|  | Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους: |
|   | Store at: 2-8°C / Lagern bei: 2-8°C / Stocker à: 2-8°C / Almacene a: 2-8°C / Armazenar a: 2-8°C / Conservare a: 2-8°C / Αποθήκευση στους: 2-8°C |
|  | Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός: |
|  | Distributor: / Distributor: / Distributeur: / Distributor: / Distribuidor: / Distributore: / Διανομέας: |
|  | Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή! |
| | Symbols of the kit components see MATERIALS SUPPLIED.<br>Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.<br>Voir MATERIEL FOURNI pour les symbôles des composants du kit.<br>Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.<br>Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.<br>Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.<br>Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ. |

Generic table, not all symbols are present in the product

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

The labelling of hazardous substances is according to European directive.
For further country-specific classifications, please refer to the corresponding safety data sheet.


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