Instructions for Use

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MuSK-Ab ELISA

Enzyme immunoassay for the qualitative and semi-quantitative determination of autoantibodies against muscle-specific receptor tyrosine kinase (MuSK) in human serum.

REF **RE51021**

Σ **96**

2°C 8°C

EU: IVD CE 2797

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REVISION HISTORY OF INSTRUCTIONS FOR USE

Changes from the previous version 2020-01 to actual version 2023-03	
Chapter 1	Additional information
Chapter 2	Additional chapter
Chapter 3	Update to scientific validity
Chapter 5	Additional information
Chapter 6	Update
Chapter 7	Update
Chapter 8	Additional information
Chapter 15	Additional information
Chapter 18	Additional information
Chapter 19	Update literature

1. INTENDED USE

Enzyme immunoassay for the qualitative and semi-quantitative determination of autoantibodies against muscle-specific receptor tyrosine kinase (MuSK) in human serum. The MuSK-Ab assay kit is useful as an aid in the differential diagnosis of Myasthenia Gravis (MG).

2. INTENDED PURPOSE

The MuSK-Ab ELISA is intended for the qualitative and semi-quantitative measurement of autoantibodies against muscle-specific receptor tyrosine kinase (MuSK) from adult patient's serum samples.
The measurement of autoantibodies against MuSK supports the diagnosis of myasthenia gravis (MG), a long-term muscle disease leading to muscle weakness of varying severity. In diagnostics, the determination of autoantibodies against MuSK is used especially in patients who have tested negative for autoantibodies against the acetylcholine receptor (AChR, 70 % of AChR-Ab seronegative patients show autoantibodies against MuSK). The MuSK-Ab ELISA is appropriate as an aid for use in the diagnosis of Myasthenia Gravis. The comprehensive detection of antibodies is necessary for the diagnosis and treatment of MG, therefore, the determination of MuSK antibodies and the determination of autoantibodies against Acetylcholine Receptor (AChR) is usually performed simultaneously. For definition of the myasthenic subgroup further diagnostic investigation is necessary. Subgroup will not be clearly defined using the anti-MuSK antibody ELISA.
The MuSK-Ab ELISA is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding and measured on an absorbance reader. The assay is semi-automated requiring general purpose laboratory instruments and consumables such as absorbance microplate reader/washer, vortexer and pipettes to execute the test. The assay is adaptable by laboratory personnel to automate on open ELISA based liquid handler platforms; however, the programming of the steps and timing required by the manual kit assay test instructions must be strictly adhered to and verified by the laboratory. Test results are calculated from a standard curve and compared to defined cut-off.
The test kit is intended for professional laboratory use by trained personnel. The test kit is not for home or layperson use.

3. SUMMARY AND EXPLANATION

The measurement of autoantibodies against the muscle specific receptor kinase tyrosinase (MuSK) supports the diagnosis of *myasthenia gravis* (MG), a rare but long-term muscle disease leading to muscle weakness of varying severity. Patients with MuSK-associated MG typically have more severe and rapidly progressive clinical symptoms with involvement of the facial, bulbar and respiratory muscle.[1-3]

Myasthenia gravis is an antibody-mediated autoimmune disease of the neuromuscular junction. The examination of patients suspected of MG is usually performed with multiple antibody determinations. In the case of acetylcholine receptor (AChR) seronegativity, the presence of other antibodies such as those against MuSK or Lrp4, can support the diagnosis of an existing MG disease in AChR-seronegative patients.[4,5] Studies emphasized the importance of evaluation of anti-MuSK and anti-LRP4 antibodies also in patients with anti-AChR antibodies.[6]

In approximately 80 % of patients, auto-antibodies to AChR are present. 70 % of AChR-Ab–seronegative MG patients have serum auto-antibodies against the MuSK.[7] The determination of anti-MuSK autoantibodies is an important and essential tool for the diagnosis of MG. The result provides a reliable indication of *myasthenia gravis* disease.

Bartoccioni *et al.* reported that in individual cases as well as in the whole population, a correlation between Ab levels and disease severity can be found.[8] The device MuSK-Ab ELISA can be used as a qualitative assay which allows a positive/negative statement using cut-off value. Cut-off of IBL International's device was confirmed through results in peer-reviewed literature. Furthermore the device can be used as semi-quantitative test setup, specified in units, which allows comparison of data of individual patients by follow-up measurements during treatment to observe patient's disease status.

Auto-Ab against MuSK are determined in serum using ELISA technology or immunoprecipitation assay.[3,7] IBL International's MuSK-Ab ELISA correlates well with immunoprecipitation assay (IPA/RIA). ELISA is an adequate replacement for RIA, as the results correlate well but, for example, the use of radioactivity will be avoided. ELISA technology is easily accessible for small and large laboratories and requires less specialized equipment and facility controls.

D-penicillamine can cause anti-AChR and anti-MuSK antibody-positive MG, a rare phenomenon, which is reversed after discontinuation of D-penicillamine treatment.[9]

For definition of the myasthenic subgroup further diagnostic investigation is necessary. Subgroup will not be clearly defined using the anti- MuSK antibody ELISA.

4. TEST PRINCIPLE

Solid phase enzyme-linked immunosorbent assay (ELISA). The wells are coated with antigen. Patient antibodies from the sample bind to the antigen coated wells and are detected by a signal amplification system. The substrate reaction is catalysed via the alkaline phosphatase coupled detection antibody. The intensity of the colour developed is proportional to the amount of patient antibodies detected. Quantitative or qualitative results can be determined by use of a standard curve or the cut-off control, respectively.

5. 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. 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 incidents that have 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. 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.
12. 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.
13. Avoid contact with Stop solution. It may cause skin irritations and burns.

6. STORAGE AND STABILITY

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

The unopened reagents are stable until the expiry date indicated. The kit is stable up to 6 months after the first opening (not exceeding the expiry date) when the Microtiterplate is packed in a tightly closed bag, the bottles are closed with their screw caps and the kit is stored at indicated storage temperature.

7. 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 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 -20°C for long time storage (< 6 months).
Avoid repeated freeze-thaw cycles. Keep away from heat or direct sunlight.

8. MATERIALS SUPPLIED

Quantity	Symbol	Origin	Component
1 x 12 x 8	MTP	BIO	**Microtiter Plate** Break apart strips. MTP (12 strips of 8 wells each). Coated with purified recombinant MuSK protein in solution containing casein. Vacuum dried.
1 x 0.25 mL	ENZCONJ CONC	BIO	**Enzyme Conjugate,** Concentrate (101x) Contains rabbit anti-mouse antibody conjugated to alkaline phosphatase in solution containing bovine serum albumin and < 0.02 % Sodium azide (w/v).
1 x 13 mL	ANTISERUM	BIO	**Antiserum** Ready to use. Contains mouse anti-human antibody in solution containing casein, ≤ 0.1 % ProClin 300 (w/v) and Tween 20. Sediment must be stirred before use, vortex thoroughly and shake vigorously by hand. A turbidity may occur without influence of assay performance and test results.
1 x 5 x 1.2 mL	CAL A-E	BIO BIO	**Standard A-E** Ready to use. 0; 0.4; 2.5; 5; 12 U/mL Contains Antibodies against MuSK (human) in solution containing casein, ≤ 0.1 % ProClin 300 (w/v) and Tween 20.
1 x 1.2 mL	CONTROL +	BIO BIO	**Positive Control** Ready to use. Red colored. Contains Antibodies against MuSK (human) in solution containing casein, ≤ 0.1 % ProClin 300 (w/v) and Tween 20.
1 x 1.2 mL	CONTROL -	BIO BIO	**Negative Control** Ready to use. Green colored. Contains Antibodies against MuSK (human) in solution containing casein, ≤ 0.1 % ProClin 300 (w/v) and Tween 20.
1 x 120 mL	ASSAYBUF	BIO	**Assay Buffer** Ready to use. Red colored. Phosphate buffer containing casein, ≤ 0.1 % ProClin 300 (w/v) and Tween 20. Sediment must be stirred before use, vortex thoroughly and shake vigorously by hand. A turbidity may occur without influence of assay performance and test results.
1 x 100 mL	WASHBUF CONC		**Wash Buffer,** Concentrate (10x) Contains: phosphate buffer and Tween 20.
1 x 13 mL	PNPP SUBS		**PNPP Substrate Solution** Ready to use. Contains: p-nitrophenyl phosphate (PNPP).
1 x 15 mL	PNPP STOP		**PNPP Stop Solution** Ready to use. Contains: 1 M NaOH, 0.25 M EDTA.
4 x	FOIL		**Adhesive Foil**

9. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipettes (Multipette Eppendorf or similar devices, < 3 % CV). Volume: 5; 10; 20; 50; 100; 1000 µL
2. Disposable glass tubes (12 x 75 mm)
3. Polypropylene (PP) tubes (e.g. Sarstedt)
4. Vortex mixer
5. Orbital shaker (500 rpm)
6. 8-Channel Micropipettor with reagent reservoirs
7. Wash bottle, automated or semi-automated microtiter plate washing system
8. Microtiter plate reader capable of reading absorbance at 405 nm (reference wavelength 600 - 650 nm)
9. Bidistilled or deionised water
10. Paper towels, pipette tips and timer

10. 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. Use a pipetting scheme to verify an appropriate plate layout.
5. 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.
6. 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.
7. 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.

11. PRE-TEST SETUP INSTRUCTIONS

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

The volumes stated below are for one run with 4 strips (32 determinations).

11.1. Preparation of lyophilized or concentrated components

Dilute / dissolve	Component		Diluent	Relation	Remarks	Storage	Stability
20 mL	**WASHBUF CONC**	180 mL	bidist. water	1:10	Mix thoroughly	2 - 8°C	8 weeks
40 µL	**ENZCONJ CONC**	4 mL	**ASSAYBUF**	1:101	Mix without foaming	2 - 8°C	48 hours

11.2. Dilution of Samples

Patient sample	to be mixed	with	Relation	Remarks
Serum	generally	**ASSAYBUF**	1:101	e.g. 10 µL + 1000 µL **Dilution has to be made in either glass or polypropylene (PP) tubes.**

12. TEST PROCEDURE

1.	Pipette **100 µL** of each **Standard, Control and diluted patient sample** into the respective wells of the microtiter plate. Cover plate with adhesive foil.
2.	**Incubate** microtiter plate for **60 minutes at 18 - 25°C** (room temperature) on an orbital shaker (500 rpm).
3.	Remove adhesive foil. Discard incubation solution. **Wash** plate **3 x** with **250 µL** of diluted **Wash Buffer.** Remove excess solution by tapping the inverted plate on a paper towel.
4.	Pipette **100 µL** of **Antiserum** in each well. Cover plate with adhesive foil.
5.	**Incubate** microtiter plate for **60 minutes at 18 - 25°C** on an orbital shaker (500 rpm).
6.	Remove adhesive foil. Discard incubation solution. **Wash** plate **3 x** with **250 µL** of diluted **Wash Buffer.** Remove excess solution by tapping the inverted plate on a paper towel.
7.	Pipette **100 µL** of **diluted Enzyme Conjugate** in each well. Cover plate with adhesive foil.
8.	**Incubate** microtiter plate for **60 minutes at 18 - 25°C** on an orbital shaker (500 rpm).
9.	Remove adhesive foil. Discard incubation solution. **Wash** plate **3 x** with **250 µL** of diluted **Wash Buffer.** Remove excess solution by tapping the inverted plate on a paper towel.
10.	For adding of Substrate and Stop Solution use, if available, an 8-channel Micropipettor. Pipetting should be carried out in the same time intervals for Substrate and Stop Solution. Use positive displacement and avoid formation of air bubbles.
11.	Pipette **100 µL PNPP Substrate Solution into each well.** Briefly mix contents by gently shaking the plate.
12.	**Incubate** microtiter plate **for 30 minutes at 18 - 25°C.**
13.	Stop the substrate reaction by adding **100 µL** of **PNPP Stop Solution** into each well**.** Briefly mix contents by gently shaking the plate.
14.	**Measure** optical density with a photometer at **405 nm** (Reference-wavelength: 600 - 650 nm) within **60 minutes** after pipetting of the Stop Solution.

13. AUTOMATION

Automated protocols can be provided for open ELISA systems: Freedom EVOlyzer®, ThunderBolt® and DSX®. For further 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.

14. 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.

15. CALCULATION OF RESULTS

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

15.1. Qualitative Evaluation

The Cut-off value (CO) 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. Samples higher than the cut-off are positive; lower samples are negative.

Typical Example:
Cut-off = OD (Standard B, Cut-off standard) = 0.23
Sample OD = 0.70
Cut-off index (COI): 0.70 / 0.23 = 3.04. The sample has to be considered positive.

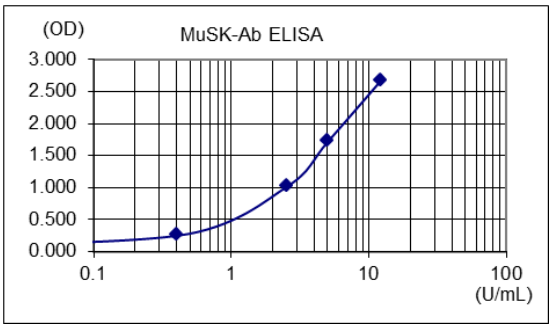
15.2. Semi-Quantitative Evaluation

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 Logisitics 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 from the standard curve.
The initial dilution has been taken into consideration when reading the results from the graph. Results of samples of higher predilution have to be multiplied with the dilution factor.
Samples showing concentrations above the highest standard have to be further diluted with assay buffer and reassayed.

Typical Calibration Curve

(Example. Do not use for calculation!)

Standard	U/mL	OD_{mean}
A	0.0	0.056
B	0.4	0.248
C	2.5	1.008
D	5.0	1.714
E	12	2.654



Measuring Range: 0.22 U/mL to 12 U/mL
(lowest reliable value determined by intra-assay precision to Standard E).

16. INTERPRETATION OF RESULTS

Method	Range	Interpretation
Semi-Quantitative (Standard curve)	> 0.4 U/mL	positive
	< 0.4 U/mL	negative
Qualitative (Cut-off Index, COI)	> 1.0	positive
	< 1.0	negative

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

17. LIMITATIONS OF THE PROCEDURE

Specimen collection and storage have a significant effect on the test results. See SPECIMEN COLLECTION AND STORAGE for details.

Azide and Pro Clin at concentrations > 1.0 %, and thimerosal at concentrations > 0.1 %, interfere in this assay and may lead to false results.

The following blood components do not have a significant effect (+/- 20 % of expected value) on the test results up to the stated concentrations.

Hemoglobin	5.0 mg/mL
Bilirubin	5.0 mg/mL
Triglyceride	91.0 mg/mL

18. PERFORMANCE

Metrological Traceability

For the MuSK-Ab ELISA RE51021 no metrological traceability to SI units is possible.
The calculated maximum uncertainty is 10.7 %.

Method Comparison

A method comparison with a commercially available RIA was performed. 129 positive and negative serum samples were measured and positive and negative results were in accordance (97 %).

Analytical Specificity (Cross Reactivity)

No cross-reactivity was found to: Acetylcholine-Receptor-Ab, LEMS specific-Ab, PR3-Ab (cANCA), MPO-Ab (pANCA), dsDNA-Ab, RF, AMA, ANA and CCP-Ab

Linearity

The linearity study was performed measuring three different samples with different percentage of MuSK-Ab concentrations in a serial dilution with Assay Buffer. The assay showed a linear behaviour up to a 1:32 dilution. The mean recovery of the diluted MuSK-Ab samples was 90.6 % (range 81.2 - 100 %).

Precision

The intra-assay study was conducted by performing three different serum samples in one run, each sample was tested 20 times. The mean intra assay variation CV is 4.6 %, in a range from 3.1 % to 5.8 % for U/mL and 3.1 % (range 2.3 % to 3.7 %) for values calculated with the Cut-off index (COI).

The Inter- Assay Precision was conducted by measuring three different serum samples on five days by four operators. This setup resulted in 11 measurements per sample. The mean inter assay variation CV is 12.7 % in a range 8.5 % to 16.8 % for U/mL and 8.2 % (range 5.3 % to 10.7 %) for values calculated with the Cut-off index (COI).

The between lot study was conducted by performing five serum samples with three different kit lots by three investigators. This setup resulted in 10 measurements per sample. The mean between lot variation CV is 12.3 % (range 8.4 % - 16.2 %) for U/mL and 6.8 % (range 3.0 % to 11.9 %) for values calculated with the Cut-off index (COI).

Diagnostic sensitivity

The diagnostic sensitivity was assessed by measuring 96 MuSK positive samples and calculated to be 95.8 %.

Diagnostic specificity

The diagnostic specificity was assessed by measuring 157 MuSK negative and samples with possible cross-reactive substances and calculated to be 100 %.

19. PRODUCT LITERATURE REFERENCES

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Symbols / Symbole / Symboles / Símbolos / Simboli / Símbolos / Σύμβολα

REF	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.–Cat.: / N.º Cat.: / Αριθμός-Κατ.:
LOT	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lotto n.: / Lote N.º: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Da utilizzare entro:/ Usar até: / Χρησιμοποιείται από:
Σ	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / Quantità dei tests: / N.º de Testes: / Αριθμός εξετάσεων:
CONC	Concentrate / Konzentrat / Concentré / Concentrar / Concentrato / Concentrado / Συμπύκνωμα
LYO	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Liofilizado / Λυοφιλιασμένο
IVD	In Vitro Diagnostic Medical Device / In-vitro-Diagnostikum / Appareil Médical pour Diagnostics In Vitro / Dispositivo Médico para Diagnóstico In Vitro / Dispositivo Medico Diagnostico In vitro / Equipamento Médico de Diagnóstico In Vitro / Ιατρική συσκευή για In-Vitro Διάγνωση
BIO	Contains biological material of human origin / Enthält biologisches Material menschlichen Ursprungs / Contient une substance biologique d'origine humaine / Contiene material biológico de origen humano / Contiene materiale biologico di origine umana / Contém material biológico de origem humana / Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης
BIO	Contains biological material of animal origin / Enthält biologisches Material tierischen Ursprungs / Contient une substance biologique d'origine animale / Contiene material biológico de origen animal / Contiene materiale biologico di origine animale / Contém material biológico de origem animal / Περιέχει βιολογικό υλικό ζωικής προέλευσης
UDI	Unique Device Identification / Eindeutige Gerätekennung / Identifiant de dispositif unique / Identificación única de producto / Identificatore univoco del dispositivo / Identificador de dispositivo único / Μοναδικός αναγνωριστικός κωδικός προϊόντος
	Read instructions before use / Arbeitsanleitung lesen / Lire la fiche technique avant emploi / Lea las instrucciones antes de usar / Leggere le istruzioni prima dell'uso / Ler as instruções antes de usar / 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 / Non esporre ai raggi solari / Manter longe do calor ou luz solar directa / 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: / Armazenar em: / Αποθήκευση στους:
2-8°C	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 / Armazenar em: 2-8°C / Αποθήκευση στους: 2-8°C
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Distributor: / Distributor: / Distributeur: / Distributor: / Distributore: / Distribuidor: / Διανομέας:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Attenzione! / Cuidado! / Προσοχή!
	Symbols of the kit components see MATERIALS SUPPLIED. Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben. Voir MATERIEL FOURNI pour les symbôles des composants du kit. Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS. Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT. Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS. 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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