Product information

Information about other products is available at: www.demeditec.com

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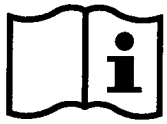

Useŕs Manual

TSH-R-Ab ELISA

Enzyme Immunoassay for the quantitative determination of thyrotropin receptor autoantibodies (TRAb) in human serum

IVD

CE

REF **DE3369**

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Demeditec Diagnostics GmbH • Lise-Meitner-Straße 2 • D-24145 Kiel (Germany)
Phone: +49 (0)431/71922-0 • Fax. +49 (0)431/71922-55
Email: info@demeditec.de • http://www.demeditec.com

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1. INTENDED USE

The Demeditec TSH receptor (TSHR) autoantibody (TRAb) ELISA kit is intended for use by professional persons only for the quantitative determination of TRAb in human serum. Hyperthyroidism in Graves' disease is due to the presence of autoantibodies to the TSHR and measurement of these autoantibodies can be useful in disease diagnosis and management.

2. REFERENCES

1. J. Bolton et al. Measurement of thyroid stimulating hormone receptor autoantibodies by ELISA Clin. Chem.1999 45:2285-2287
2. K. Kamijo. TSH receptor antibody measurement in patients with various thyrotoxicosis and Hashimoto's thyroiditis: a comparison of two two-step assays, coated plate ELISA using porcine TSH receptor and coated tube radioassay using human recombinant TSH receptor. Endocrine Journal 2003 50:113-116
3. B. Rees Smith et al. A new assay for thyrotropin receptor autoantibodies. Thyroid 2004 14: 830-835

3. PATENTS

European Patent 1021721 B1, US Patent 6,844,162 B1 and Japanese Patent 4331403 apply.

4. ASSAY PRINCIPLE

In Demeditec's TRAb ELISA, TRAb in patients' sera, calibrators and controls are allowed to interact with TSHR coated onto ELISA plate wells. After a 2 hour incubation, the samples are discarded leaving TRAb bound to the immobilised TSHR. TSH-Biotin is added in a 2nd incubation step, where it interacts with immobilised TSHR which have not been blocked by the bound TRAb from patient sera, calibrators or controls. The amount of TSH-Biotin bound to the plate is then determined in a 3rd incubation step by addition of Streptavidin Peroxidase (SA-POD), which binds specifically to Biotin. Excess unbound SA-POD is then discarded and the addition of the peroxidase substrate 3,3',5,5'–tetramethylbenzidine (TMB) results in the formation of a blue colour. This reaction is stopped by the addition of stop solution causing the well contents to turn from blue to yellow. The absorbance of the yellow reaction mixture at 450nm is then read using an ELISA plate reader. A lower absorbance indicates the presence of TRAb in a test sample as TRAb inhibits the binding of TSH-Biotin to TSHR coated plate wells. The measuring range is 1 – 40 u/L (NIBSC 90/672).

5. STORAGE AND PREPARATION OF SERUM SAMPLES

Sera to be analysed should be assayed soon after separation or stored, preferably in aliquots, at or below –20^{o}C. 150 µL is sufficient for one assay (duplicate 75 µL determinations). Repeated freeze thawing or increases in storage temperature must be avoided. Incorrect storage of serum samples can lead to loss of TRAb activity. Do not use lipaemic or haemolysed serum samples. Do not use plasma in the assay. When required, thaw test sera at room temperature and mix gently to ensure homogeneity. Centrifuge the serum prior to assay (preferably for 5 minutes at 10-15,000 g in a microfuge) to remove any particulate matter. Please do not omit this centrifugation step for sera that are cloudy or contain particulates.

6. MATERIALS REQUIRED AND NOT SUPPLIED

- Pipettes capable of dispensing 50 µL, 75 µL and 100µL.
- Means of measuring out various volumes to reconstitute or dilute reagents.
- Pure water.
- ELISA Plate reader suitable for 96 well formats and capable of measuring at 450nm.
- ELISA Plate shaker, capable of 500 shakes/min (not an orbital shaker).
- ELISA Plate cover.

7. PREPARATION OF REAGENTS SUPPLIED

Store unopened kits and all kit components (A-K) at 2–8°C.

1. **TSH Receptor Coated Wells**
   12 breakapart strips of 8 wells (96 in total) in a frame and sealed in a foil bag. Allow to stand at room temperature (20-25oC) for at least 30 minutes before opening.
   Ensure wells are fitted firmly into frame provided. After opening, return any unused wells to the original foil bag and seal, then place the foil bag in the self-seal plastic bag with desiccant provided. Store at 2-8°C for up to expiry of kit.

2. **Start Buffer**
   10 mL, Ready for use

3. **Calibrators**
   1, 2, 8 and 40 u/L (units are NIBSC 90/672), 4 x 1.0 mL, Ready for use

4. **Negative Control**
   1.0 mL, Ready for use
   Positive Control (See label for range)
   1.0 mL, Ready for use

5. **TSH-Biotin**
   3 vials, Lyophilised, Reconstitute each vial with 4.5 mL reconstitution buffer for TSH-Biotin (6.). When more than one vial is to be used, pool the vials and mix gently before use. Store at 2–8oC for up to expiry of kit.

6. **Reconstitution Buffer for TSH-Biotin**
   15 mL, Ready for use

7. **Streptavidin Peroxidase (SA-POD)**
   0.75 mL, Concentrated
   Dilute 1 in 20 with diluent for SA-POD (8). For example, 0.5mL (7.)+ 9.5mL (8.). Store at 2–8oC for up to expiry of kit.

8. **Diluent for SA-POD**
   15 mL, Ready for use

9. **Peroxidase Substrate (TMB)**
   15 mL, Ready for use

10. **Concentrated Wash Solution**
    100 mL, Concentrated
    Dilute to 1 litre with pure water before use. Store at 2–8oC for up to expiry of kit.

11. **Stop Solution**
    10 mL, Ready for use

8. ASSAY PROCEDURE

Allow all reagents and test samples to stand at room temperature (20-25°C) for at least 30 minutes before use. A repeating Eppendorf type pipette is recommended for steps 1, 5, 8, 10 and 11. Duplicate determinations are strongly recommended for test sera, calibrators and controls.

1. Pipette **75 µL** of start buffer (B) into each well to be used, leaving the last well empty for a blank (see step 12).
2. Pipette **75 µL** of test sera, calibrators (C1-4) and controls (D1 and D2) into respective wells (start with the 40 u/L calibrator and descend down the plate to the negative control and then test sera), leaving the last well blank.
3. Cover the frame and shake the wells for 2 hours at room temperature on an ELISA plate shaker (500 shakes per min.).
4. After incubation, aspirate samples by use of a plate washing machine, or discard the samples by briskly inverting the frame of wells over a suitable receptacle. Wash the wells once with diluted wash solution (J), and aspirate the wash by use of a plate washing machine or discard the wash by briskly inverting the frame of wells over a suitable receptacle. Tap the inverted wells gently on a clean, dry, absorbent surface to remove excess wash solution (only necessary if washing plate by hand).
5. Pipette **100 µL** of reconstituted TSH-Biotin (E) into each well (except blank). Avoid splashing the material out of the wells during addition.
6. Cover the frame, and incubate at room temperature for 25 minutes without shaking.
7. Repeat wash step 4.
8. Pipette **100 µL** of diluted SA-POD (G) into each well (except blank), cover the frame and incubate at room temperature for 20 minutes without shaking.
9. After incubation, aspirate samples by use of a plate washing machine, or discard the samples by briskly inverting the frame of wells over a suitable receptacle. Wash the wells twice with diluted wash solution (J) followed by once with pure water (to remove any foam) and tap the inverted wells gently on a clean, dry, absorbent surface to remove excess wash solution (if a plate washing machine is used, the plate can be washed 3 times with diluted wash solution (J) only).
10. Pipette **100 µL** of TMB (I) into each well (including blank) and incubate in the dark at room temperature for 30 minutes without shaking.
11. Pipette **50 µL** stop solution (K) to each well (including blank) cover the frame and shake for approximately 5 seconds on an ELISA plate shaker. Ensure substrate incubations are the same for each well.
12. Read the absorbance of each well at 450 nm using an ELISA plate reader, blanked against the well containing **100 µL** of TMB (I) and **50 µL** stop solution (K) only.

9. RESULT ANALYSIS

A calibration curve can be established by plotting calibrator concentration on the x-axis (log scale) against the absorbance of the calibrators on the y-axis (linear scale). The TRAb concentrations in patients' sera can then be read off the calibration curve [plotted at Demeditec as a spline log/lin curve (smoothing factor = 0)]. Other data reduction systems can be used. Results can also be expressed as inhibition (%I) of TSH binding calculated using the formula;

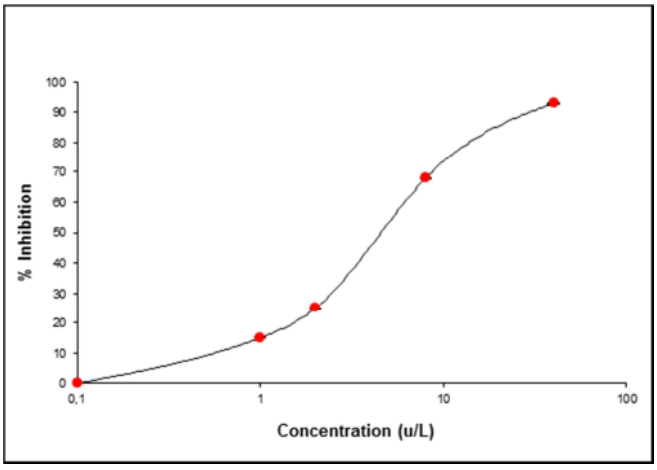
$$100 \times \left(1 - \frac{\text{test sample absorbance at 450 nm}}{\text{negative control (D1) absorbance 450 nm}}\right)$$

Samples with high TRAb concentrations can be diluted in kit negative control (D1). For example, 20 µL of sample plus 180 µL of negative control to give a 10x dilution. Other dilutions (e.g. 100x) can be prepared from a 10x dilution or otherwise as appropriate. Some sera will not dilute in a linear way and we suggest that the dilution giving a value closest to 50% inhibition is used for calculation of TRAb concentration.

TYPICAL RESULTS

(example only, not for use in calculation of actual results)

Sample	A450 (minus blank)	%I	u/L
Negative Control	2.00	0	0
C1	1.70	15	1
C2	1.50	25	2
C3	0.65	68	8
C4	0.15	93	40
Positive Control	1.26	37	3.5



10. ASSAY CUT OFF

Cut off	u/L
Negative	≤1 u/L
Equivocal	1.1 – 1.5 u/L
Positive	>1.5 u/L

11. CLINICAL EVALUATION

10.1 Clinical Specificity
154 Sera from healthy blood donors were assayed in the Demeditec TRAb ELISA kit. 152 (99%) were identified as being negative for TRAb.

10.2 Clinical Sensitivity
50 Sera from patients diagnosed with Graves' disease were assayed using the Demeditec TRAb ELISA kit. 49 (98%) were identified as being positive for TRAb. 1 sample (2%) was identified as being within the equivocal range.

10.3 Functional Sensitivity
A plot of inter assay CV against u/L indicates a 20% CV occurring at 0.60 u/L.

10.4 Lower Detection Limit
The kit negative control was assayed 32 times and the mean and standard deviation calculated. The lower detection limit at 2 standard deviations was 0.21 u/L.

10.5 Inter Assay Precision

Sample	u/L (n=20)	CV (%)
1	3.9	12.9
2	5.4	10.9

10.6 Intra Assay Precision

Sample	u/L (n=25)	CV (%)
1	1.8	7.1
2	7.8	2.2

10.7 Clinical Accuracy
Analysis of sera from patients with autoimmune diseases other than Graves' disease indicated no interference from autoantibodies to thyroglobulin; thyroid peroxidase; glutamic acid decarboxylase; 21-hydroxylase; acetylcholine receptor; dsDNA or from rheumatoid factor.

10.8 Interference
No interference was observed when samples were spiked with the following materials; haemoglobin at 5 mg/mL; bilirubin at 0.2 mg/mL; Intralipid up to 30 mg/mL, human LH up to 10 u/mL; hCG up to 160 u/mL; human FSH up to 70 u/mL and human TSH up to 3 u/L.
The data quoted in these instructions should be used for guidance only. It is recommended that each laboratory include its own panel of control samples in the assay. Each laboratory should establish its own normal and pathological reference ranges for TRAb levels.

12. SAFETY CONSIDERATIONS
- This kit is intended for *in vitro* use by professional persons only.
- Follow the instructions carefully.
- Observe expiry dates stated on the labels and the specified stability for coated wells, diluted or reconstituted reagents.
- Refer to Safety Data Sheet for more detailed safety information.
- Material of human origin used in the preparation of the kit has been tested and found non reactive for HIV1 and 2 and HCV antibodies and HBsAg but should, none-the-less, be handled as potentially infectious.
- Wash hands thoroughly if contamination has occurred and before leaving the laboratory. Sterilise all potentially contaminated waste, including test specimens before disposal.
- Material of animal origin used in the preparation of the kit has been obtained from animals certified as healthy but these materials should be handled as potentially infectious.
- Some components contain small quantities of sodium azide as preservative.
- With all kit components, avoid ingestion, inhalation, injection and contact with skin, eyes and clothing.

– Avoid formation of heavy metal azides in the drainage system by flushing any kit component away with copious amounts of water.

ASSAY PLAN

Allow all reagents and samples to reach room temperature (20-25°C) before use.	
Pipette:	**75 µL** Start buffer into each well (except blank)
Pipette:	**75 µL** Calibrators (starting with the highest concentration and descending to lowest), controls, patient sera (except blank)
Incubate	2 Hours at room temperature on an **ELISA plate shaker at 500 shakes/min**
Aspirate/Decant:	Plate
Wash:	Plate once on automatic washer (or wash once, invert and tap dry on absorbent material for manual washing)
Pipette:	**100 µL** TSH-Biotin (reconstituted) into each well (except blank)
Incubate:	25 Minutes at room temperature **without shaking**
Aspirate/Decant:	Plate
Wash:	Plate once as above
Pipette:	**100 µL** SA-POD (diluted 1:20) into each well (except blank)
Incubate:	20 Minutes at room temperature **without shaking**
Aspirate/Decant:	Plate
Wash:	Plate three times on automatic washer (or wash twice, rinse once with pure water and dry on absorbent material for manual washing)
Pipette:	**100 µL** TMB into each well (including blank)
Incubate:	30 Minutes at room temperature **in the dark without shaking**
Pipette:	**50 µL** Stop solution into each well (including blank) and shake for 5 seconds
Read absorbance at 450 nm	
Do not perform the assay at temperatures above 25°C.	

1 EINLEITUNG

Der TSH Receptor Autoantibody ELISA wird zur quantitativen Bestimmung von Thyrotropin-Rezeptor-Autoantikörpern in Humanserum eingesetzt.
Nur für In-vitro Diagnostik.

2 LITERATUR

1. J. Bolton et al. Measurement of thyroid stimulating hormone receptor autoantibodies by ELISA Clin. Chem 1999 45: 2285-2287
2. K Kamijo. TSHR antibody measurement in patients with various thyrotoxicosis and Hashimoto's thyroiditis: a comparison of two two-step assays, coated plate ELISA using porcine TSHR and coated tube radioassay using human recombinant TSHR. Endocrine Journal 2003 50:113-116
3. B. Rees Smith et al. A new assay for thyrotropin receptor autoantibodies. Thyroid 2004 14: 830-835

PATENTE

European Patent 1021721 B1, US Patent 6,844,162 B1 and Japanese Patent 4331403 apply.

3 TESTPRINZIP

Das Testprinzip entnehmen Sie bitte der ausführlichen englischen Anleitung.

4 VORBEREITUNG UND LAGERUNG DER PROBEN

- Das gewonnene Serum sollte möglichst schnell bestimmt werden oder in kleinen Portionen bei -20 °C gelagert werden.
- Pro Bestimmung werden 75 µL Serum benötigt.
- Wiederholte Gefrier/-Auftauzyklen oder eine Erhöhung der Lagertemperatur sollten vermieden werden
- Eine falsche Lagerung der Serumproben kann zu einem Verlust der TRAb-Aktivität führen.
- Lipämische, ikterische und/oder stark hämolysierte Proben sollten nicht verwendet werden.
- Keine Plasmaproben in diesem Test verwenden.
- Aufgetaute Proben sollten vor Testbeginn vorsichtig durchmischt werden, ohne Schaumbildung.
- Serum vor dem Einsatz im Test zentrifugieren (vorzugsweise 5 Minuten bei 10-15,000 g in eine Mikrozentrifuge) um Partikel zu entfernen. Diesen Zentrifugationsschritt auf keinen Fall auslassen, für Seren, die sichtbar trüb oder Partikel-haltig sind.

5 NICHT IM KIT ENTHALTENE ABER ERFORDERLICHE GERÄTE UND MATERIALIEN

- Kalibrierte variable Präzisions-Mikropipette
- Aqua dest.
- Kalibriertes Mikrotiterplattenlesegerät mit 450 ± 10 nm Filter),
- Mikrotiterplatten-Schüttler (500 U/min), kein Orbital-Schüttler
- Saugfähiges Papier
- Abdeckfolie für die Mikrotiterplatte

6 KIT-KOMPONENTEN UND DEREN ZUBEREITUNG

1. **TSH Receptor Coated Wells**
   96 Wells, 12 x 8 Wells (einzeln brechbar);
   Vor dem Öffnen mindesten 30 Minuten bei Raumtemperatur (20 °C - 25 °C) stehenlassen
   Der einmal geöffnete Folienbeutel sollte stets sehr sorgfältig wieder verschlossen werden.
   Lagerung bei 2 °C - 8 °C für bis zum Verfallsdatum.

2. **Start Buffer**, 10 mL
   Gebrauchsfertig.

3. **Standards**
   1, 2, 8 und 40 U/L (NIBSC 90/672)
   4 x 1,0 mL, Gebrauchsfertig.

4. **Negative Control**, 1.0 mL
   Gebrauchsfertig.

5. **Positive Control** 1,0 mL
   Gebrauchsfertig.
   Kontrollwerte und –bereiche entnehmen Sie bitte dem Fläschchenetikett.

6. **TSH Biotin**, 3 Fläschchen
   Lyophilisiert
   Jedes Fläschchen mit 4,5 mL TSH Biotin Reconstitution Buffer auflösen. Wird mehr als ein Fläschchen benötigt, den Inhalt der Fläschchen poolen und vorsichtig mischen.
   Lagerung: bei 2 °C - 8 °C zum Verfallsdatum des Kits.

7. **TSH Biotin Reconstitution Buffer**, 15 mL
   Gebrauchsfertig.

8. **Streptavidin Peroxidase (SA-POD),** 1 x 0,75 mL
   Konzentrat.
   1 + 19 mit SA-POD -Diluent verdünnen, z.B. 0,5 mL + 9,5 mL.
   Lagerung: Bei 2 °C - 8 °C bis zum Verfallsdatum des Kits.

9. **Diluent for SA-POD** , 15 mL
   Gebrauchsfertig.

10. **Peroxidase Substrate (TMB)**, 15 mL
    Gebrauchsfertig.

11. **Concentrated Wash Solution**, 100 mL
    Konzentrat.
    Vor Gebrauch mit destiliertem Wasser auf 1000 mL auffüllen.
    Lagerung: Bei 2 °C - 8 °C bis zum Verfallsdatum des Kits.

12. **Stop Solution**, 10 mL
    Gebrauchsfertig

7 TESTDURCHFÜHRUNG

Alle Reagenzien und Proben müssen vor Gebrauch auf Raumtemperatur (RT, 20 °C - 25 °C) gebracht und gut durchgemischt werden (mindestens 30 Minuten).

1. Je **75 µL** Start Buffer in die benötigten Vertiefungen pipettieren.
2. Je **75 µL** der Testseren, Kontrollen (und Standards) in die entsprechenden Vertiefungen pipettieren.
3. Platte adecken und für 2 Stunden bei RT auf einem ELISA Plattenschüttler (500 U/min) inkubieren.
4. Nach der 2-stündigen Inkubation, schütten Sie den Inhalt der Platte kräftig über einem Waschbecken aus. Waschen Sie die Vertiefung einmal mit Waschpuffer und klopfen Sie die Platte kopfüber auf saugfähigem Papier aus um noch verbleibende Tropfen des Waschpuffers zu entfernen.
5. Vorsichtig **100 µL** des rekonstituierten TSH-Biotin in jede Vertiefung pipettieren.
   Es ist wichtig, ein Herausspritzen der Reagenzien aus den Vertiefungen zu vermeiden.
6. Platte abdecken und 25 Minuten bei RT inkubieren, ohne Schütteln.
7. Waschen wiederholen, wie in Schritt 4.
8. **100 µL** verdünnte Streptavidin-Peroxidase (SA-POD) in jede Vertiefung pipettieren, Platte abdecken und für 20 Minuten bei RT inkubieren, ohne Schütteln.
9. Schütten Sie das SA-POD über einem Becken kräftig aus, waschen Sie zweimal mit Waschpuffer gefolgt von einem Waschschritt mit purem Wasser um verbleibenden Schaum zu entfernen, und klopfen Sie die Vertiefung über Kopf vorsichtig auf saugfähigem Papier aus. Wenn eine Plattenwascheinheit benutzt wird, waschen Sie 3-mal nur mit Waschpuffer (d.h. lassen Sie den Wasser-Waschschritt aus.)
10. **100 µL** Peroxidase Substrat (TMB) in jede Vertiefung pipettieren und für 30 Minuten RT im Dunkeln inkubieren, ohne Schütteln.
11. Stoppen der Substrat-Reaktion durch vorsichtige Zugabe von **50 µL** Stop Solution in jede Vertiefung. Platte abdecken undfür etwa 5 Sekunden auf einem Plattenschüttler schütteln um eine gleichmäßige Durchmischung der Lösung in jeder Vertiefung zu gewährleisten.
    Es ist wichtig, dass die Substrat-Inkubationszeit (d.h. die Zeit vom Zeitpunkt der Zugabe des Substrates bis zur Zugabe der Stopplösung) für jedes Well gleich ist.
12. Die Optische Dichte bei 450 nm mit einem Mikrotiterplatten-Lesegerät bestimmen.
    Gemessen wird gegen einen Leerwert (Blank), dafür werden 100 µL Substrate Lösung plus 50 µL Stopplösung in eine Vertiefung pipettiert.

8 ERGEBNISERMITTLUNG

Die durchschnittlichen Werte der Optischen Dichte (OD) für jedes Set von Standards, Controls und Patientenproben bestimmen.
Eine Standardkurve ermitteln durch Auftragen der mittleren Optischen Dichte jedes Standards gegen die Konzentration, wobei der OD-Wert auf der vertikalen (Y) Achse (lin.) und die Konzentration auf der horizontalen (X) Achse (log.) eingetragen wird.
Unter Verwendung der mittleren OD wird für jede Probe die entsprechende Konzentration aus der Standardkurve ermittelt. Andere Auswertungsfunktionen können verwendet werden.
Die Konzentration der Proben kann direkt von der Standardkurve abgelesen werden.

Wenn die Ergebnisse als Inhibition der TSH Bindung ausgedrückt werden sollen, wird dieser Index kalkuliert mit folgender Formel:

$$100 \times \left[1 - \frac{\text{OD der Probe bei 450 nm}}{\text{OD der Negativ-Kontrolle bei 450 nm}} \right]$$

Wenn in einem ersten Testdurchlauf bei einer Probe eine Konzentration höher als der höchste Standard gefunden wird, kann diese Probe mit *Negative Control* weiter verdünnt und nochmals bestimmt werden. Die Verdünnung muss jedoch bei der Berechnung der Konzentration beachtet werden.

Beispiel einer 1:10 Verdünnung:
20 µL Probe + 180 µL *Negative Control*

Weitere Informationen hierzu entnehmen Sie bitte der englischen Anleitung.

Beispiel für eine Standardkurve
Nachfolgend wird ein typisches Beispiel für eine Standardkurve mit dem Demeditec ELISA gezeigt. Diese Werte sollten nicht zur Berechnung von Patientendaten verwendet werden.

Probe	OD 450 (minus Blank)	%I	U/L
Negative Control	2.00	0	0
C1	1.70	15	1
C2	1.50	25	2
C3	0.65	68	8
C4	0.15	93	40
Positive Control	1.26	37	3.5

9 CUT OFF

Cut off	U/L
Negativ	≤ 1 U/L
Grauzone	1.1 – 1.5 U/L
Positiv	> 1.5 U/L

10 KLINISCHE EVALUIERUNG

Die Daten hierzu entnehmen Sie bitte der ausführlichen englischen Anleitung.

11 SYMBOLS USED WITH DEMEDITEC ASSAYS

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità