Product information

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

EN ISO 9001 certified company

Instruction for use

Phospholipid Screen IgG/IgM

Immunometric Enzyme Immunoassay for the quantitative determination of the sum of autoantibodies against Cardiolipin, Phosphatidyl Serine, Phosphatidyl Inositol, Phosphatidic Acid and β2-Glycoprotein I (IgG and/or IgM class)

CE

REF **DE7470**

Σ **96 Tests**

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

CONTENTS

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

NAME AND INTENDED USE

The DEMEDITEC Phospholipid Screen IgG/IgM assay is a quantitative enzyme immunoassay (EIA) intended to screen for the presence of IgG and IgM class autoantibodies against cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and beta-2-glycoprotein I in human serum or plasma as an aid in the diagnosis of an increased risk of thrombosis in patients with systemic lupus erythematosus (SLE) or lupus-like disorders.

SUMMARY AND EXPLANATION OF THE TEST

The first study of anti-phospholipid antibodies began in 1906, when Wasserman introduced a serological test for syphilis. In 1942, the active component was found to be a phospholipid, which was designated cardiolipin. In the 1950s it became clear that a number of people had positive tests for syphilis without any evidence of the disease. This phenomenon was referred to as the biological false positive serological test for syphilis. A high prevalence of autoimmune disorders, including systemic lupus erythematosus (SLE) and Sjögren´s syndrome occurred in this group of patients.

The presence of circulating anticoagulants in patients with SLE was first documented in 1952 and was associated with increased risk of paradoxical thrombosis in 1963. The term lupus anticoagulant (LA), first used in 1972, is clearly a misnomer, because LA is more frequently encountered in patients without lupus and is associated with thrombosis rather than abnormal bleeding.

During the last years it became clear that the optimal binding of anti-phospholipid antibodies is depending on a cofactor termed beta-2-glycoprotein I (apolipoprotein H) (β2GPI). β2GPI is a 50 kDa beta-2-globulin occurring in plasma at a level of 200 µg/ml. It has been found that beta-2-Glycoprotein I inhibits the intrinsic coagulation pathway and, therefore, it is involved in the regulation of blood coagulation. β2GPI is associated in vivo with negatively-charged substances, e.g. anionic phospholipids, heparin and lipoproteins. The phospholipid binding region is located on its fifth domain.

Under the acronym "aPL" (anti-phospholipid antibodies) antibodies against negatively-charged phospholipids, such as CL (cardiolipin), LA (lupus anticoagulant), PS (phosphatidyl serine), PI (phosphatidyl inositol) and PA (phosphatidic acid) are summarised. Of these, cardiolipin is the phospholipid most commonly used as antigen to test for aPL by ELISA. Some antisera which bind cardiolipin-coated ELISA plates can also bind to plates coated with other negatively-charged phospholipids, such as phosphatidyl serine (PS), phosphatidyl inositol and phosphatidic acid (PA).

Some investigators have suggested that the use of PS in place of cardiolipin in ELISA tests enables more specific diagnosis. These antigens are less commonly used and their additional use can improve the clinical sensitivity in patient samples with suspected APS (anti-phospholipid-syndrome), but they can't replace the measurement of autoantibodies against cardiolipin.

The Scientific and Standardization Committee of the International Society on Thrombosis and Hemostasis has issued consensus criteria that may be used to help laboratory diagnosis. These criteria have been updated in 2006.

PRINCIPLE OF THE TEST

A mixture of highly purified cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and human beta-2-Glycoprotein I is bound to microwells. Antibodies against these antigens, if present in diluted serum or plasma, bind to the respective antigens. Washing of the microwells removes unspecific serum and plasma components. Horseradish peroxidase (HRP) conjugated anti-human IgG or IgM immunologically detects the bound patient antibodies forming a conjugate/antibody/antigen complex. Washing of the microwells removes unbound conjugate. An enzyme substrate in the presence of bound conjugate hydrolyzes to form a blue colour. The addition of an acid stops the reaction forming a yellow end product. The intensity of this yellow colour is measured photometrically at 450 nm.

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

WARNINGS AND PRECAUTIONS

1. All reagents of this kit are strictly intended for in vitro diagnostic use only.
2. Do not interchange kit components from different lots.
3. Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
4. Avoid contact with the TMB (3,3´,5,5´-Tetramethyl-benzidine). If TMB comes into contact with skin, wash thoroughly with water and soap.
5. Avoid contact with the Stop Solution which is acid. If it comes into contact with skin, wash thoroughly with water and seek medical attention.
6. Some kit components (i.e. Controls, Sample buffer and Buffered Wash Solution) contain Sodium Azide as preservative. Sodium Azide (NaN_3) is highly toxic and reactive in pure form. At the product concentrations (0.09%), though not hazardous. Despite the classification as non-hazardous, we strongly recommend using prudent laboratory practices (see 8., 9., 10.)
7. Some kit components contain Proclin 300 as preservative. When disposing reagents containing Proclin 300, flush drains with copious amounts of water to dilute the components below active levels.
8. Wear disposable gloves while handling specimens or kit reagents and wash hands thoroughly afterwards.
9. Do not pipette by mouth.
10. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled.
11. Avoid contact between the buffered peroxide solution and easily oxidised materials; extreme temperature may initiate spontaneous combustion.

Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera. During handling of all kit reagents, controls and serum samples observe the existing legal regulations.

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

CONTENTS OF THE KIT

Package size	96 determ.
Qty.1	Divisible microplate consisting of 12 modules of 8 wells each, coated with a mixture of highly purified phospholipids: cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and saturated with human beta-2-glycoprotein I. Ready to use.
6 vials, 1.5 ml each	Combined anti-phospholipid calibrators in a serum/buffer matrix (PBS, BSA, NaN_3 <0.1% (w/w)) containing IgG: 0; 6.3; 12.5; 25; 50; and 100 GPL U/ml and IgM: 0; 6.3; 12.5; 25; 50; 100 MPL U/ml. Ready to use.
2 vials, 1.5 ml each	Anti-phospholipid controls in a serum/buffer matrix (PBS, BSA, NaN_3 <0.1% (w/w)) positive (1) and negative (2), for the respective concentrations see the enclosed package insert. Ready to use.
1 vial, 20 ml	Sample buffer (Tris, NaN_3 <0.1% (w/w)), yellow, concentrate (5x).
1 vial, 15 ml	Enzyme conjugate solution (PBS, Proclin 300 <0.5% (v/v)), (light red) containing polyclonal rabbit anti-human IgG; labelled with horseradish peroxidase. Ready to use.
1 vial, 15 ml	Enzyme conjugate solution (PBS, PROCLIN 300 <0.5% (v/v)), (light red) containing polyclonal rabbit anti-human-IgM; labelled with horseradish peroxidase. Ready to use.
1 vial, 15 ml	TMB substrate solution. Ready to use.
1 vial, 15 ml	Stop solution (contains acid). Ready to use.
1 vial, 20 ml	Wash solution (PBS, NaN_3 <0.1% (w/w)), concentrate (50x).

STORAGE AND STABILITY

1. Store the kit at 2-8 °C.
2. Keep microplate wells sealed in a dry bag with desiccants.
3. The reagents are stable until expiration of the kit.
4. Do not expose test reagents to heat, sun or strong light during storage and usage.
5. Diluted sample buffer and wash buffer are stable for at least 30 days when stored at 2-8 °C.

MATERIALS REQUIRED

Equipment

- Microplate reader capable of endpoint measurements at 450 nm
- Multi-Channel Dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Data reduction software

Preparation of reagents

- Distilled or deionised water
- Graduated cylinder for 100 and 1000 ml
- Plastic container for storage of the wash solution

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

SPECIMEN COLLECTION, STORAGE AND HANDLING

1. Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
2. Allow blood to clot and separate the serum by centrifugation.
3. Test serum should be clear and non-hemolysed. Contamination by hemolysis or lipemia is best avoided, but does not interfere with this assay.
4. Specimens may be refrigerated at 2-8 °C for up to five days or stored at -20 °C up to six months.
5. Avoid repetitive freezing and thawing of serum samples. This may result in variable loss of autoantibody activity.
6. Testing of heat-inactivated sera is not recommended.

PROCEDURAL NOTES

1. Do not use kit components beyond their expiration dates.
2. Do not interchange kit components from different lots.
3. All materials must be at room temperature (20-28 °C).
4. Have all reagents and samples ready before start of the assay. Once started, the test must be performed without interruption to get the most reliable and consistent results.
5. Perform the assay steps only in the order indicated.
6. Always use fresh sample dilutions.
7. Pipette all reagents and samples into the bottom of the wells.
8. To avoid carryover contamination, change the tip between samples and different kit controls.
9. It is important to wash microwells thoroughly and remove the last droplets of wash buffer to achieve best results.
10. All incubation steps must be accurately timed.
11. Control sera or pools should routinely be assayed as unknowns to check performance of the reagents and the assay.
12. Do not re-use microplate wells.

For all controls, the respective concentrations are provided on the labels of each vial. Using these concentrations a calibration curve may be calculated to read off the patient results semi-quantitatively.

PREPARATION OF REAGENTS

Preparation of sample buffer

Dilute the contents of each vial of the sample buffer concentrate (5x) with distilled or deionised water to a final volume of 100 ml prior to use. Store refrigerated: stable at 2-8 °C for at least 30 days after preparation or until the expiration date printed on the label.

Preparation of wash solution

Dilute the contents of each vial of the buffered wash solution concentrate (50x) with distilled or de-ionised water to a final volume of 1000 ml prior to use. Store refrigerated: stable at 2-8 °C for at least 30 days after preparation or until the expiration date printed on the label.

Sample preparation

Dilute all samples 1:100 with sample buffer before assay. Therefore combine 10 µl of sample with 990 µl of sample buffer in a polystyrene tube. Mix well. Controls are ready to use and need not be diluted.

TEST PROCEDURE

1. Prepare a sufficient number of microplate modules to accommodate controls and prediluted patient samples.
2. For the determination of one class of autoantibodies pipette **100 µl** of calibrators, controls and prediluted patient samples in duplicate into the wells.
   For determination of both IgG and IgM autoantibodies calibrators, controls and patient samples have to be pipetted fourfold.

	1	*2*	*3*	*4*	*5*	*6*
A	**SA**	**SE**	**P1**	**P5**		
B	**SA**	**SE**	**P1**	**P5**		
C	**SB**	**SF**	**P2**	**P..**		
D	**SB**	**SF**	**P2**	**P..**		
E	**SC**	**C1**	**P3**			
F	**SC**	**C1**	**P3**			
G	**SD**	**C2**	**P4**			
H	**SD**	**C2**	**P4**			

SA-SF: standards A to F
P1, P2…: patient sample 1, 2 ...
C1: positive control
C2: negative control

3. Incubate for 30 minutes at room temperature (20-28 °C)
4. Discard the contents of the microwells and wash 3 times with **300 µl** of wash solution.
5. Dispense **100 µl** of enzyme conjugate (Anti-h-IgG or Anti-h-IgM) into each well.
6. Incubate for 15 minutes at room temperature.
7. Discard the contents of the microwells and wash 3 times with **300 µl** of wash solution.
8. Dispense **100 µl** of TMB substrate solution into each well.
9. Incubate for 15 minutes at room temperature.
10. Add **100 µl** of stop solution to each well of the modules and incubate for 5 minutes at room temperature.
11. Read the optical density at 450 nm and calculate the results. Bi-chromatic measurement with a reference at 600-690 nm is recommended.

The developed colour is stable for at least 30 minutes. Read optical densities during this time.

INTERPRETATION OF RESULTS

Quality Control

This test is only valid if the optical density at 450 nm for positive control (1) and negative control (2) as well as for the calibrator A and F complies with the respective range indicated on the Quality Control Certificate enclosed to each test kit! If any of these criteria is not fulfilled, the results are invalid and the test should be repeated.

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

Calculation of results

For the Phospholipid Screen IgG/IgM a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

Recommended Lin-Log Plot

First calculate the averaged optical densities for each calibrator well. Use lin-log graph paper and plot the averaged optical density of each calibrator versus the concentration. Draw the best fitting curve approximating the path of all calibrator points. The calibrator points may also be connected with straight line segments. The concentration of unknowns may then be estimated from the calibration curve by interpolation.

Calculation example

The figures below show typical results for Phospholipid Screen IgG/IgM. These data are intended for illustration only and should not be used to calculate results from another run.

Calibrators										
anti-PL	No	Position	OD 1	OD 2	Mean	Conc. 1	Conc. 2	Mean	decl.Conc.	CV %
IgG	STA	A 1/B 1	0.051	0.049	0.050	0.3	0.1	0.2	0.0	3
IgG	STB	C 1/D 1	0.163	0.160	0.161	6.4	6.3	6.3	6.3	1
IgG	STC	E 1/F 1	0.310	0.273	0.291	12.8	11.2	12.0	12.5	9
IgG	STD	G 1/H 1	0.603	0.630	0.616	25	26	26	25	3
IgG	STE	A 2/B 2	1.122	1.054	1.088	51	47	49	50	4
IgG	STF	C 2/D 2	1.742	1.787	1.765	98	103	101	100	2
IgM	STA	A 7/B 7	0.022	0.021	0.022	0.2	0.1	0.2	0.0	3
IgM	STB	C 7/D 7	0.211	0.205	0.208	6.1	6.0	6.1	6.3	2
IgM	STC	E 7/F 7	0.465	0.462	0.464	13.0	12.9	13.0	12.5	0
IgM	STD	G 7/H 7	0.788	0.879	0.833	23	26	24	25	8
IgM	STE	A 8/B 8	1.411	1.382	1.397	52	50	51	50	1
IgM	STF	C 8/D 8	1.868	1.852	1.860	101	98	99	100	0

Interpretation of results

In a normal range study with serum samples from healthy blood donors the following ranges have been established with the Phospholipid Screen IgG/IgM tests:

	Anti-Phospholipid-Ab	
	IgG [GPL U/ml]	IgM [MPLU/ml]
normal:	< 10	< 10
elevated:	≥ 10	≥ 10

Positive results should be verified concerning the entire clinical status of the patient. Also every decision for therapy should be taken individually.

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

It is recommended that each laboratory establishes its own normal and pathological ranges of Anti-Phospholipid antibodies.

PERFORMANCE CHARACTERISTICS

Parallelism

In dilution experiments sera with high IgG- and IgM-antibody concentrations were diluted with sample buffer and assayed in the Phospholipid Screen IgG/IgM kit. The assay shows linearity over the full measuring range.

Sensitivity

The lower detection limits for Phospholipid Screen IgG and IgM were determined at 0.5 U/ml.

Specificity

The microplate is coated with a mixture of highly purified cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and human beta-2-glycoprotein I. Special coating processes, developed by the manufacturer guarantee for the native immunogenic structure of the phospholipids after immobilisation on the solid phase. The Phospholipid Screen IgG/IgM test kit is specific for autoantibodies directed against phospholipid, beta-2-glycoprotein I or the complex of negatively-charged phospholipids and beta-2-glycoproteinI. No cross reactivity was observed to anti-DNA antibodies and those types of antibodies occurring in syphilis.

Calibration

The assay system is calibrated against the internationally recognized reference sera from E.N. Harris, Louisville, USA, IRP 97/656 and HCAL/EY2C9 since no other international standards are available.

LIMITATIONS OF PROCEDURE

The Phospholipid Screen IgG/IgM ELISA is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated.

INTERFERING SUBSTANCES

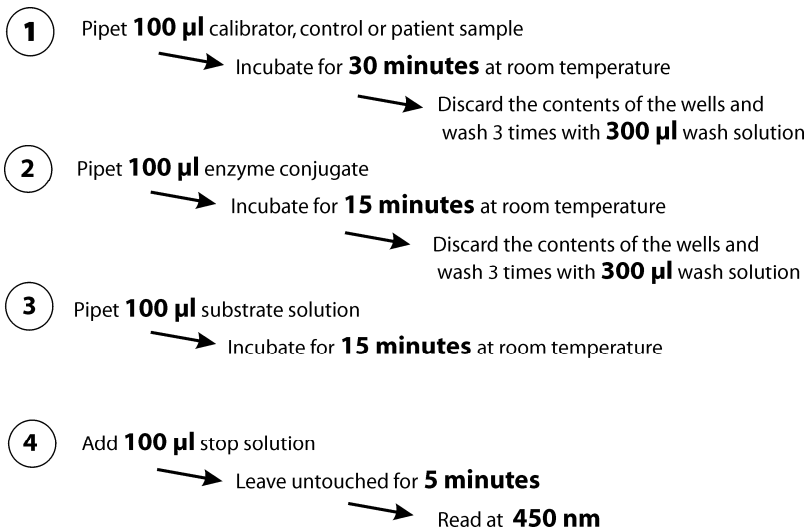
No interference has been observed with haemolytic (up to 1000 mg/dL), lipemic (up to 3 g/dL triglycerides) or bilirubin (up to 40 mg/dL) containing sera. Nor have any interfering effects been observed with the use of anticoagulants. However for practical reasons it is recommended that grossly hemolysed or lipemic samples should be avoided.

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

REFERENCES

1. Hughes, G. R. V., Harris, E. N. and Gharavi, A. E. The Anticardiolipin Syndrome. J. Rheumatol. 1986; 13, 3: 486 - 489.
2. Harris, E. N. et al. Evaluation of the anti-cardiolipin antibody test: report of an international Workshop held 4 April 1986. Clin. Exp. Immunol. 1987; 68: 215 - 222.
3. Miyakis S, Lockshin MD, Atsumi T, Branch DW, Brey RL, Cervera R, Derksen RHWM, de Groot PG, Koike T, Meroni PL, Reber G, Shoenfeld Y, Tincani A, Vlachoyiannopoulos PG, Krilis SA. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). J Thromb Haemost 2006; 4: 295-306.
4. Domke, N. and Siegert, G. Phospholipidantikörper und ihre klinische Bedeutung. Zeitschrift für Klinische Medizin 1988; Heft 16: 1399 - 1401.
5. Pengo, V. et al. Immunological Specificity and Mechanism of Action of IgG Lupus Anticoagulants. Blood 1987; Vol. 70, No 1: 69 - 76.
6. Triplett, D.A. Coagulation Assays for the Lupus Anticoagulant: Review and Critique of Current Methodology. Stroke 1992; Vol. 23,No 2 [suppl I]: I-11 - I-14.
7. Harris, E.N. Serological Detection of Antiphospholipid Antibodies. Stroke 1992; Vol. 23, No 2 [suppl I]: I-3 - I-6.
8. Eilat, D. et al. Evaluation of cross-reaction between anti-DNA and anti-cardiolipin antibodies in SLE and experimental animals. Clin. Exp. Immunol. 1986; 65: 269 - 278.
9. Matsuda, J. et al. Detection of beta-2-Glycoprotein-I dependend Antiphospholipid Antibodies and Anti-beta-2-Glycoprotein-I Antibody in Patients with Systemic Lupus Erythematosus and in Patients with Syphilis. Int. Arch. Allergy Immunol.1994; 103: 239 - 244.
10. Kalunian, K. C. et al. Clinical Significance of a Single Test for Anti-Cardiolipin Antibodies in Patients with Systemic Lupus Erythematosus. Am. J. Med. 1988; Vol. 85: 602 - 608.
11. Al-Momen, A.-K. et al. IgA Antiphospholipid and Adrenal Insufficiency: Is there a link? Thromb. Res. 1991; Vol. 64,No 5: 571 – 578.

INCUBATION SCHEME



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

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 Forschungszwe-cke	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 conser-vation	Temperatura de conservación	Temperatura di conser-vazione
	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

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
RUO				
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilsttrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Distributed by				
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..

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