

**AESKULISA<sup>®</sup> MMP-3**

*Ref 3168*







|                  |                  |
|------------------|------------------|
| Product Ref.     | <b>3168</b>      |
| Product Desc.    | MMP-3            |
| Versionsnummer:. | 001 : 2014-07-01 |

# Operating manual

## Contents

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|    |   |    |
|----|---|----|
| 1  | Intended purpose .....                        | 1  |
| 2  | Clinical application and test principle ..... | 1  |
| 3  | KIT components.....                           | 2  |
| 4  | Storage and shelf life .....                  | 2  |
| 5  | Instructions and precautions .....            | 3  |
| 6  | Sampling, preparation and storage .....       | 4  |
| 7  | Test execution .....                          | 4  |
| 8  | Quantitative evaluation .....                 | 7  |
| 9  | Technical data .....                          | 8  |
| 10 | Test data/test characteristics .....          | 8  |
| 11 | Literature .....                              | 11 |



## 1 Intended purpose

**AESKULISA<sup>®</sup> MMP-3** is a solid phase enzyme immunoassay with two different monoclonal antibodies against human MMP-3 for the quantitative determination of MMP-3 concentration in human serum.

The test is used to monitor the activity of rheumatoid arthritis.

## 2 Clinical application and test principle

Rheumatoid arthritis (RA) is a chronic inflammatory disease which is primarily characterised by joint inflammation and leads to a loss of joint function and severe disability if the progress of the disease is not tackled in time. **AESKULISA<sup>®</sup> MMP-3** helps to identify RA patients that would benefit from starting aggressive medication therapy early. Moreover, **AESKULISA<sup>®</sup> MMP-3** can be used to control and monitor therapy success.

Matrix metalloproteinase-3 (MMP-3, stromelysin-1) belongs to the family of metalloproteinases. It is predominantly expressed by connective tissue cells and plays an important role in the material conversion processes of the extracellular matrix (ECM). MMP-3 can break down many components of the ECM such as proteoglycans, fibronectin, laminin and various other collagens. As a result of this large range of substrates and the ability to activate other degrading enzymes, including other matrix metalloproteinases, MMP-3 plays a key role in the physiological and pathological processes of tissue remodelling.

MMP-3 is secreted in an inactive form (pro-MMP-3, 52 kDa) and activated by limited proteolysis by endopeptidases. Active MMP-3 (45 kDa and 35 kDa) can be inhibited as a result of binding to tissue inhibitors of matrix metalloproteinases (TIMP) or  $\alpha$ 2-macroglobulin. Regulating MMP-3 activity is necessary to prevent the destruction of the ECM and to preserve the physiological equilibrium in tissue remodelling processes. Accordingly, patients with various pathological conditions such as cancer, atherosclerosis and arthritis have elevated MMP-3 concentrations.

It could be shown that the serum MMP-3 concentration in RA patients is significantly elevated compared with healthy control persons. As a result of the massive inflammation and proliferation of synovial tissue in RA patients, MMP-3 expression and secretion in the synovial fluid increases. The quantity of MMP-3 in the synovial fluid correlates with the MMP-3 concentration in the serum. Serum MMP-3 thereby reflects the inflammation process in the affected joints and is a marker for the activity of the disease. Even at the early stage of the disease the destructive processes in the joints of RA patients can be correlated with elevated MMP-3 concentrations and predicted.

**AESKULISA<sup>®</sup> MMP-3** measures total MMP-3 (pro- and active MMP-3) in human serum and is a tool to assess the risk of developing joint destruction and to monitor disease activity and therapy success in RA patients.

### Test principle

The **1:10** diluted serum samples are incubated in cavities which are coated with a monoclonal anti-human MMP-3 antibody. In this process, MMP-3 from the patient serum binds to the antibody on the plate; unbonded serum components are washed away in the subsequent washing step. A monoclonal anti-human MMP-3 antibody, which is marked with horseradish peroxidase (conjugate), is then added. During incubation, this binds to the previously formed antibody-MMP3-complex. Unbound conjugate is removed in the subsequent washing step. Bonded MMP-3 is detected by an enzymatic colour reaction (blue) of the substrate, which is stopped using diluted acid (sudden colour change to yellow). The intensity of the colour development of the chromogen depends on the amount of conjugate bound to the antibody-MMP-3-complex and is therefore directly proportional to the MMP-3 concentration in the serum.

### 3 KIT components

| <b>Dilute before use.</b>  |                    |             |                 |   |
|--|--------------------|-------------|-----------------|---|
| Kit component  | Quantity           | Seal colour | Solution colour | Description / content   |
| Sample buffer 5x   | 1 x 20 ml          | White       | Yellow          | 5 x concentrated Tris, NaCl, BSA, sodium azide < 0.1% (preservative)  |
| Wash buffer 50x  | 1 x 20 ml          | White       | Green           | 50 x concentrated Tris, NaCl, Tween 20, sodium azide < 0.1% (preservative)  |
| <b>Ready for use:</b>  |                    |             |                 |   |
| Kit component  | Quantity           | Seal colour | Solution colour | Description / content   |
| Negative control   | 1 x 1.5 ml         | Green       | Colourless      | Purified human MMP-3, BSA, sodium azide < 0.1% (preservative)   |
| Positive control   | 1 x 1.5 ml         | Red         | Yellow          | Purified human MMP-3, BSA, sodium azide < 0.1% (preservative)   |
| Calibrators  | 6 x 1.5 ml         | White       | Yellow*         | Concentration of calibrators: 0, 5, 20, 50, 100, 200 ng/ml. Purified human MMP-3, BSA, sodium azide < 0.1% (preservative) |
| Conjugate  | 1 x 15 ml          | Blue        | Blue            | Anti-human MMP-3 marked with horseradish peroxidase, BSA  |
| TMB substrate  | 1 x 15 ml          | Black       | Colourless      | Stabilised TMB/H <sub>2</sub> O <sub>2</sub>  |
| Stop solution  | 1 x 15 ml          | White       | Colourless      | 1M hydrochloric acid  |
| Microwell strips   | 12 x 8 well strips | N/a         | N/a             | breakable. Coating see point 1.   |
| *colour intensity increases with concentration   |                    |             |                 |   |
| <b>Required materials, not contained in the kit:</b>   |                    |             |                 |   |
| Microtitre plate photometer with optical filter for 450 nm, optionally with reference wave length of 620 nm (600–690 nm). Glaseware (cylinder 100-1000 ml), tubes for dilutions, vortexer, micropipettes (10, 100, 200, 500, 1000 µl) or an adjustable multi-pipette. Washing unit for microtitre plates (300µl multi-pipette or multichannel pipette or automatic wash system), filter paper. Our tests have been developed for using with purified water according to the definition of US Pharmacopoeia (USP 26 - NF 21) and European Pharmacopoeia (Eur. Ph. 4th Ed.). |                    |             |                 |   |

### 4 Storage and shelf life

The kit reagents and the microtitre plate should be stored in their original bottles at 2-8°C/35-46°F. Diluted solutions can be kept for one month at 2-8°C/35-46°F. The expiry dates indicated on the packaging and the labels of the individual components must be observed. Do not use expired kit components. Avoid strong light irradiation on the TMB substrate solution. Always store microtitre plates sealed in the packaging film with dessicant bag.

## 5 Instructions and precautions

### 5.1 Risk to health

**This product may only be used for IN VITRO DIAGNOSTIK.**

It must be used by personnel that have been specifically taught and trained in its use by in vitro-Diagnostika. The reagents contained in this product are not classified as toxic or hazardous to health when used as prescribed, however to ensure maximum safety for the user, please comply with the following:

#### Recommendations and precautions

As individual components of the kit contain potentially hazardous reagents, these may cause skin or eye irritation.

**IMPORTANT:** Calibrators, controls and buffers contain sodium azide ( $\text{NaN}_3$ ) as a preservative.  $\text{NaN}_3$  can have a toxic effect if it is ingested or adsorbed via the skin or eyes.  $\text{NaN}_3$  can form highly explosive metal azides with lead or copper pipes. To avoid azide accumulations, when disposing of these solutions please rinse them away with copious amounts of water. Please observe the decontamination requirements of regional/national regulations.

**Do not eat, drink or smoke when working with the kit. Do not pipette by mouth, wear disposable gloves.**

The reagents contained in this product of human origin (controls and calibrators) have proven to be negative when testing for the hepatitis B surface antigen (HbsAg), hepatitis C and HIV 1 and 2. Nevertheless, the specified, other or even still unknown or diagnosed pathogens can never be excluded with absolute certainty in products of human origin. For this reason controls, calibrators and patient sera should be classified as potentially infectious and handled in accordance with national law. The product contains components of animal origin as specified in the table of components: Relevant national guidelines should be observed in their handling.

### 5.2 General instructions

If product information, including labelling, is false or incorrect, please contact the manufacturer or the supplier of the kit.

Individual controls, calibrators and conjugates or microtitre plates of different batches should not be interchanged as this may lead to the measurement results being distorted.

Bring all kit components to room temperature (20-26°C/68-78.8°F) before starting the test and mix thoroughly. The prescribed protocol for carrying out the test must be observed.

**Incubation: When processing tests (even using automatic machines) the temperature must not exceed 26°C/78.8°F.**

Never expose the individual kit components to temperatures higher than 37°C/98.6°F.

Always pipette the substrate solution with brand new pipette tips to avoid contamination. Avoid the substrate solution being in contact with strong light. Never pipette the conjugate solution with pipette tips that are contaminated with other reagents.

**A definitive clinical diagnosis should not be made solely based on the results of the performed test but by a doctor, taking into account all clinical findings and laboratory results. The diagnosis should categorically be confirmed using various diagnostic methods.**

## 6 Sampling, preparation and storage

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The use of fresh serum samples is recommended. Blood samples should be taken in accordance with national legislation. Do not use icteric, lipaemic, haemolysed or bacterially contaminated serum samples. If the samples are cloudy, centrifuge the particles at low speed (< 1000 x g). Collect blood samples in clean, dry and empty tubes.

After extraction, serum samples should be used within 8 hours or be sealed and stored for 48 hours at 2-8°C/35-46°F. If longer storage is intended, the samples should be deep-frozen at -20°C/-4°F.

**Plasma samples may not be used in this test!**

## 7 Test execution

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### 7.1 Preparation

#### **Diluting concentrated reagents:**

Dilute concentrated sample buffers 1:5 with distilled water,  
e.g. 20 ml + 80 ml.

Dilute concentrated wash buffers 1:50 with distilled water,  
e.g. 20 ml + 980 ml.

To avoid errors we recommend labelling the lids of the calibrators and controls.

#### **Diluting patient samples:**

Dilute and mix serum samples **1:10** with diluted sample buffer (1x),  
e.g. 450 µl sample buffer + 50 µl serum.

#### **Washing:**

20 ml diluted wash buffer (1x) per 8 cavities or 200 ml per 96 cavities is required,  
e.g. 4 ml concentrate plus 196 ml distilled water.

#### **Automated washing:**

Additional wash buffer quantities should be taken into account for starting up the appliance and for the dead volume.

#### **Manual washing:**

carefully remove liquid by tapping the plate on filter paper. Pipette 300 µl diluted wash buffer in each cavity, wait 20 seconds. Repeat the process twice more.

#### **Microtitre plate:**

Remove unused cavities and store tightly sealed in the packaging film with dessicant bag in a cool place (2-8°C/35-46°F).



## 7.2 Pipetting scheme

We recommend pipetting the calibrators, controls and samples as follows:

|   | 1     | 2     | 3   | 4... |
|---|-------|-------|-----|------|
| A | Cal A | Cal E | P1  |      |
| B | Cal A | Cal E | P1  |      |
| C | Cal B | Cal F | P2  |      |
| D | Cal B | Cal F | P2  |      |
| E | Cal C | PC    | P3  |      |
| F | Cal C | PC    | P3  |      |
| G | Cal D | NC    | ... |      |
| H | Cal D | NC    | ... |      |

Cal A: Calibrator A

Cal B: Calibrator B

Cal C: Calibrator C

Cal D: Calibrator D

Cal E: Calibrator E

Cal F: Calibrator F

PC: Positive control

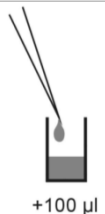

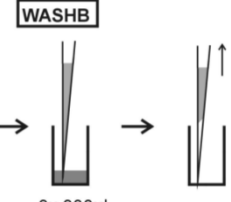
NC: Negative control

P1: Patient 1

P2: Patient 2

P3: Patient 3

## 7.3 Procedure


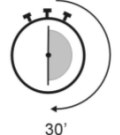
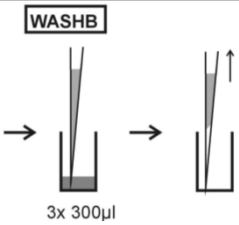
| Step                                       | Description  |
|--|--|
| 1.   | Before starting, ensure that the preparations from section 7.1 have been carried out.  |
| 2.   | Use the following steps in accordance with the intended quantitative interpretation of the results.  |
| <b>Calibrators, controls &amp; samples</b> |  |
| 3.   |  <p>Pipette in each case 100 µl in the provided cavities according to section 7.2:</p> <ul style="list-style-type: none"> <li>• Calibrators (Cal A to Cal F)</li> <li>• Negative control (NC) and positive control (PC) and</li> <li>• Diluted patient samples (P1, P2, ...)</li> </ul> |
| 4.   |  <p>Incubate for 30 minutes at 20-26°C/68-78.8°F.</p>   |
| 5.   |  <p>Wash 3 times in each case with 300 µl 1:50 diluted wash buffer.</p>   |



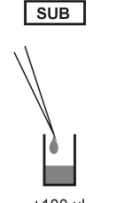
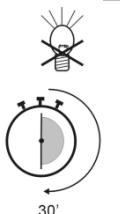


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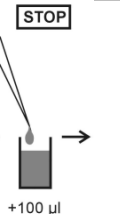
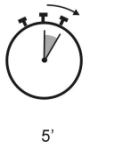
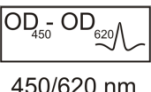
### CONJUGATE

|    |   |   |
|----|---|---|
| 6. |  | Add 100 µl enzyme conjugate solution to each cavity.            |
| 7. |  | Incubate for 30 minutes at 20-26°C/68-78.8°F.                   |
| 8. |  | Wash 3 times in each case with 300 µl 1:50 diluted wash buffer. |

### SUBSTRATE

|     |   |  |
|-----|---|--|
| 9.  |   | Pipette 100 µl TMB substrate solution to each cavity.                                    |
| 10. |  | Incubate for 30 minutes at 20-26°C/68-78.8°F, protect against intense light irradiation. |

### STOP

|     |   |  |
|-----|---|--|
| 11. |  | Pipette 100 µl stop solution per cavity in the sequence of substrate addition.       |
| 12. |  | Incubate for at least 5 minutes.   |
| 13. |   | Shake the plate carefully for 5 seconds.   |
| 14. |  | Measure the optical density at 450 nm within 30 minutes (recommended at 450/620 nm). |

## 8 Quantitative evaluation

The **quantitative evaluation** is based on a standard curve in which the optical density of the calibrators (y-axis) is plotted against the concentration in ng/ml (x-axis). A log-linear plot and a 4-parameter fit is recommended for the evaluation. Using the curve, the MMP-3 concentration in ng/ml is established from the optical density of the sample.

| AESKULISA MMP-3 | Normal range | Borderline    | Positive   |
|-----------------|--------------|---------------|------------|
| Women           | 0 – 20 ng/ml | 20 – 30 ng/ml | > 30 ng/ml |
| Men             | 0 – 40 ng/ml | 40 – 50 ng/ml | > 50 ng/ml |

### Evaluation example

***This example must not be used to interpret patient results!***

| Calibrators MMP-3 | OD 450/620 nm | CV % (variance) |
|-------------------|---------------|-----------------|
| 0 ng/ml           | 0.033         | 2.2             |
| 5 ng/ml           | 0.105         | 4.0             |
| 20 ng/ml          | 0.336         | 1.7             |
| 50 ng/ml          | 0.727         | 1.2             |
| 100 ng/ml         | 1.328         | 1.6             |
| 200 ng/ml         | 2.228         | 3.7             |

### Example calculation

| Patient | Replication (OD) | Mean (OD) | Result (ng/ml) |
|---------|------------------|-----------|----------------|
| P 01    | 0.264/0.258      | 0.261     | 17.2           |
| P 02    | 1.323/1.326      | 1.325     | 97.5           |

Samples that are above the highest calibrator value should be reported as > max. They should be diluted accordingly and be re-evaluated, taking the dilution factor into account. Samples lower than the measurement range should be reported as < min.

For batch-specific data please see the attached QC certificate. Medical laboratories should perform in-house quality controls with their own controls and/or pooled sera according to national legislation.

It is recommended that each laboratory works out its own normal values, based on its own technology, controls, equipment and patient population.

If the control values do not meet the validation criteria, the test is invalid and must be repeated.

The following technical data should be reviewed: expiry dates of the reagents, storage conditions, pipettes, used equipment, photometer, incubation conditions and washing methods.

If the tested samples reveal unusual values or deviations, or if the validation criteria are not met for inexplicable reasons, please contact the manufacturer or supplier of the kit.

## 9 Technical data

|                           |  |
|---------------------------|--|
| Sample material:          | Serum  |
| Sample volume:            | 100 µl of a 1:10 sample dilution with 1x sample buffer |
| Total incubation period:  | 90 minutes at 20-26°C/68-78.8°F.                       |
| Measurement range:        | 0-200 ng/ml  |
| Analytical sensitivity:   | 5 ng/ml  |
| Storage:                  | at 2-8°C/35-46°F in original bottles.                  |
| Number of determinations: | 96 tests   |

## 10 Test data/test characteristics

### 10.1 Analytical sensitivity

80 tests with the sample buffer in the *AESKULISA*® MMP-3 gave a Limit of Blank of 4 ng/ml, and testing 8 sera at low MMP-3 concentration with 8 repetitions gave a Limit of Detection of 5 ng/ml.

### 10.2 Specificity

The microtitre plates are coated with murine monoclonal antibodies against human MMP-3. Cross reactivities with other antigens could not be detected.

### 10.3 Linearity

For selected sera, a linear relationship between dilution and antibody concentration could be determined in this test. As a result of the heterogeneity of human serum, however, it is not excluded that individual sera display non-linear behaviour.

| Sample no. | Dilution | Measured concentration (ng/ml) | Expected concentration (ng/ml) | Recovery (%) |
|------------|----------|--------------------------------|--------------------------------|--------------|
| 1          | 1 / 10   | 178.4                          | 178.4                          | 100.0        |
|            | 1 / 20   | 86.1                           | 89.2                           | 96.5         |
|            | 1 / 40   | 45.0                           | 43.0                           | 104.6        |
|            | 1 / 80   | 23.2                           | 22.5                           | 103.0        |
| 2          | 1 / 10   | 88.8                           | 88.8                           | 100.0        |
|            | 1 / 20   | 44.1                           | 44.4                           | 99.4         |
|            | 1 / 40   | 22.8                           | 22.1                           | 103.1        |
|            | 1 / 80   | 11.3                           | 11.4                           | 99.5         |

## 10.4 Precision

To control the assay precision, five sera in different regions of the standard curve were used to establish the variance (intra and interassay variance and the lot-to-lot variance), in which the reproducibility was investigated in 5 rounds, each with 8 repetitions. The lot-to-lot variance was investigated, whereby five sera were investigated from 3 different batches in 8 repetitions.

| Intraassay |              |        |
|------------|--------------|--------|
| Sample no. | Mean (ng/ml) | CV (%) |
| 1          | 12.6         | 4.9    |
| 2          | 30.5         | 3.6    |
| 3          | 59.3         | 3.2    |
| 4          | 101.0        | 3.6    |
| 5          | 195.1        | 3.4    |

| Interassay |              |        |
|------------|--------------|--------|
| Sample no. | Mean (ng/ml) | CV (%) |
| 1          | 12.6         | 7.6    |
| 2          | 30.5         | 4.5    |
| 3          | 59.3         | 4.5    |
| 4          | 101.0        | 4.8    |
| 5          | 195.1        | 4.6    |

## 10.5 Calibration

In the absence of an international reference standard, the AESKULISA MMP-3 is calibrated against defined quantities of purified, recombinant human MMP-3 (using SEC-MALS established purity: > 99%). The results are given in ng/ml.

## 10.6 Recovery

Recovery was determined by adding various, defined quantities of recombinant human MMP-3 to different human sera. The following recovery rates were established by means of linear regression:

| Serum sample | % recovery | Coefficient of determination R <sup>2</sup> |
|--------------|------------|---|
| 1            | 101.4      | 0.9934                                      |
| 2            | 91.8       | 0.9938                                      |
| 3            | 88.5       | 0.9923                                      |

## 10.7 Clinical evaluation

### MMP-3 in healthy people

To determine the normal range the MMP-3 values in a total of 156 serum samples of healthy blood donors (46 women and 110 men) were determined.

| AESKULISA MMP-3 | Number | Min (ng/ml) | Max (ng/ml) | Med (ng/ml) | 95 percentile |
|-----------------|--------|-------------|-------------|-------------|---------------|
| Healthy men     | 110    | 8.9         | 56.6        | 25.3        | 41.9          |
| Healthy women   | 46     | 5.1         | 32.5        | 14.2        | 29.7          |

The normal ranges are determined from the established values as follows:

| <b>AESKULISA MMP-3</b> | <b>Normal range</b> | <b>Borderline</b> | <b>Positive results</b> |
|------------------------|---------------------|-------------------|-------------------------|
| Women                  | 0 - 20 ng/ml        | 20-30 ng/ml       | > 30 ng/ml              |
| Men                    | 0 - 40 ng/ml        | 40-50 ng/ml       | > 50 ng/ml              |

### **MMP-3 in various autoimmune diseases compared with rheumatoid arthritis and in healthy people**

A total of 627 serum samples (see table for composition) were tested for their MMP-3 concentration. The table summarises the results:

| <b>Disease</b>       | <b>Number</b> | <b>Min (ng/ml)</b> | <b>Max (ng/ml)</b> | <b>Med (ng/ml)</b> | <b>Pos</b>  | <b>Neg</b>  |
|----------------------|---------------|--------------------|--------------------|--------------------|-------------|-------------|
| Spondylarthritis     | 80            | 0.0                | 287.4              | 14.3               | 29 (36.3%)  | 51 (63.8%)  |
| Coeliac disease      | 15            | 5.9                | 22.8               | 12.6               | 1 (6.7%)    | 14 (93.3%)  |
| Coeliac disease + DH | 32            | 8.5                | 142.4              | 28.3               | 19 (59.4%)  | 13 (40.6%)  |
| SLE                  | 24            | 14.5               | 200.8              | 46.2               | 22 (91.7%)  | 2 (8.3%)    |
| Vasculitis           | 117           | 5.2                | 283.5              | 47.9               | 97 (82.9%)  | 20 (17.1%)  |
| Healthy              | 156           | 8.9                | 56.6               | 22.0               | 3 (1.9%)    | 153 (98.1%) |
| Rheumatoid arthritis | 203           | 0.7                | 280.2              | 33.2               | 139 (68.5%) | 64 (31.5%)  |








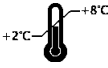












SLE = systemic lupus erythematoses, DH = dermatitis herpetiformis

As described in literature, elevated MMP-3 concentrations are found in different inflammatory diseases. MMP-3 is therefore not suitable to diagnose rheumatoid arthritis. MMP-3 is a marker for the activity of rheumatoid arthritis. The MMP-3 concentrations of RA patients correlate to the individual disease activity.



## 11 Literature

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|   |                                       |   |
|---|---------------------------------------|---|
|     | - Diagnosi in vitro                   | - For in vitro diagnostic use             |
|   | - Pour diagnostic in vitro            | - Para uso diagnóstico in vitro           |
|   | - In Vitro Diagnostikum               | - In Vitro Διαγνωστικό μέσο               |
|   | - Para uso Diagnóstico in vitro       |   |
|    | " Numero d'ordine                     | " Catalogue number                        |
|   | " Référence Catalogue                 | " Numéro de catálogo                      |
|   | " Bestellnummer                       | " Αριθμός παραγγελίας                     |
|   | " Número de catálogo                  |   |
|    | " Descrizione lotto                   | " Lot                                     |
|   | " Lot                                 | " Lote                                    |
|   | " Chargen Bezeichnung                 | " Χαρακτηρισμός παρτίδας                  |
|   | " Lote                                |   |
|    | " Conformità europea                  | " EC Declaration of Conformity            |
|   | " Déclaration CE de Conformité        | " Declaración CE de Conformidad           |
|   | " Europäische Konformität             | " Ευρωπαϊκή συμφωνία                      |
|   | " Declaração CE de Conformidade       |   |
|    | " 96 determinazioni                   | " 96 tests                                |
|   | " 96 tests                            | " 96 pruebas                              |
|   | " 96 Bestimmungen                     | " 96 προσδιορισμοί                        |
|   | " 96 Testes                           |   |
|    | " Rispettare le istruzioni per l'uso  | " See instructions for use                |
|   | " Voir les instructions d'utilisation | " Ver las instrucciones de uso            |
|   | " Gebrauchsanweisung beachten         | " Λάβετε υπόψη τις οδηγίες χρήσης         |
|   | " Ver as instruções de uso            |   |
|    | " Da utilizzarsi entro                | " Use by                                  |
|   | " Utilise avant le                    | " Utilizar antes de                       |
|   | " Verwendbar bis                      | " Χρήση μέχρι                             |
|   | " Utilizar antes de                   |   |
|    | " Conservare a 2-8°C                  | " Store at 2-8°C (35-46°F)                |
|   | " Conserver à 2-8°C                   | " Conservar a 2-8°C                       |
|   | " Lagerung bei 2-8°C                  | " Φυλάσσεται στους 2-8°C                  |
|   | " Conservar entre 2-8°C               |   |
|    | " Prodotto da                         | " Manufactured by                         |
|   | " Fabriqué par                        | " Fabricado por                           |
|   | " Hergestellt von                     | " Κατασκευάζεται από                      |
|   | " Fabricado por                       |   |
|  | " Calibratore cut-off                 | " Cut off Calibrator                      |
|   | " Etalon Seuil                        | " Calibrador de cut-off                   |
|   | " Grenzwert Kalibrator                | " Οριακός ορός Αντιδραστήριο βαθμονόμησης |
|   | " Calibrador de cut-off               |   |
|  | " Controllo positivo                  | " Positive Control                        |
|   | " Contrôle Positif                    | " Control Positivo                        |
|   | " Positiv Kontrolle                   | " Θετικός ορός ελέγχου                    |
|   | " Controllo positivo                  |   |
|  | " Controllo negativo                  | " Negative Control                        |
|   | " Contrôle Négatif                    | " Control Negativo                        |
|   | " Negativ Kontrolle                   | " Αρνητικός ορός ελέγχου                  |
|   | " Controllo negativo                  |   |
|  | " Calibratore                         | " Calibrator                              |
|   | " Etalon                              | " Calibrador                              |
|   | " Kalibrator                          | " Αντιδραστήριο βαθμονόμησης              |
|   | " Calibrador                          |   |
|  | " Recupero                            | " Recovery                                |
|   | " Corrélation                         | " Recuperado                              |
|   | " Wiederfindung                       | " Ανάκτηση                                |
|   | " Recuperação                         |   |
|  | " Coniugato                           | " Conjugate                               |
|   | " Conjugé                             | " Conjugado                               |
|   | " Konjugat                            | " Σύζευγμα                                |
|   | " Conjugado                           |   |
|  | " Micropiastra rivestita              | " Coated microtiter plate                 |
|   | " Microplaque sensibilisée            | " Microplaca sensibilizada                |
|   | " Beschichtete Mikrotiterplatte       | " Επικαλυμμένη μικροπλάκα                 |
|   | " Microplaca revestida                |   |
|  | " Tampone di lavaggio                 | " Wash buffer                             |
|   | " Tampon de lavage                    | " Solución de lavado                      |
|   | " Waschpuffer                         | " Ρυθμιστικό διάλυμα πλύσης               |
|   | " Solução de lavagem                  |   |
|  | " Tampone substrato                   | " Substrate buffer                        |
|   | " Substrat                            | " Tampón sustrato                         |
|   | " Substratpuffer                      | " Ρυθμιστικό διάλυμα υποστρώματος         |
|   | " Substrato                           |   |
|  | " Reagente bloccante                  | " Stop solution                           |
|   | " Solution d'Arrêt                    | " Solución de parada                      |
|   | " Stopreagenz                         | " Αντιδραστήριο διακοπής αντίδρασης       |
|   | " Solução de paragem                  |   |
|  | " Tampone campione                    | " Sample buffer                           |
|   | " Tampon Echantillons                 | " Tampón Muestras                         |
|   | " Probenpuffer                        | " Ρυθμιστικό διάλυμα δειγμάτων            |
|   | " Diluente de amostra                 |   |