



**IGFII-Ria**

***KIPMR30***





# IGF-II RIA

Radioimmunoassay for the Quantitative Detection of Insulin-like  
Growth Factor-II

KIPMR30

**IN VITRO DIAGNOSTIC USE**

en

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## PRECAUTIONS

### General

All reagents are for in vitro use only!

In conducting the assay, follow strictly the test protocol. The acquisition, possession and use of the kit are subject to the regulations of the national nuclear regulatory authorities.

Reagents with different lot numbers should not be mixed.

Reagents contain Sodium-Azide as preservative, however, highly diluted (0.02%). Avoid any skin contact.

### First aid procedures:

*Skin contact:* Wash affected area thoroughly with water at least 15 minutes. Discard contaminated cloths and shoes. See a physician.

*Eye contact:* In case of contact with eyes, rinse immediately with plenty of water at least 15 minutes. In order to assure an efficient rinsing spread the eyelids. See a physician.

*Ingestion:* If swallowed, wash out mouth thoroughly with water, provided that the person is conscious. Immediately see a physician.

### **The handling of radioactive and potentially infectious material must comply with the following guidelines:**

The material should be stored and used in a special designated area.

Do not eat, drink or smoke in these areas.

Never pipette the materials with the mouth.

Avoid direct contact with these materials by wearing laboratory coats and disposable gloves.

Spilled material must be wiped off immediately. Clean contaminated areas and equipment with a suitable detergent.

Unused radioactive material and radioactive waste should be disposed according to the recommendations of the national regulatory authorities.

### **Radioactivity**

Before ordering or using radioactive materials, it is necessary to take the appropriate actions to ensure compliance with national regulations governing their use. Local rules in each establishment, which define actions and behaviour in the radioactivity working areas, should also be adhered to. The advice given here does not replace any local rules, instructions or training in the establishment, or advice from the radiation protection advisers. It is important to follow the code of good laboratory practice in addition to the specific precautions relating to the radionuclide I-125 used.

Iodine-125 has a radioactive half-life  $T_{1/2}$  of 60 days and emits 35,5 keV gamma radiation, 27 – 32 keV x-rays and no beta radiation. Shielding is effective done by lead, first half value layer is 0.02 mm lead, reduction to 10 % is made by 0.2 mm.

To reduce the radiation dose time spent handling radioactivity should be minimized (plan ahead), and distance from source of radiation should be maximized (doubling the distance from the source quarters the radiation dose).

Formation of aerosols, e.g. by improper opening and mixing of vials or pipetting of solutions which may cause minute droplets of radioactivity become airborne, is a hazard and should be avoided.

Solutions containing iodine should not be made acidic, because this might lead to the formation of volatile elemental iodine.

As some iodo-compounds can penetrate rubber gloves, it is advisable to wear two pairs, or polyethylene gloves over rubber.

For cleaning of contaminated areas or equipment, the Iodine-125 should be rendered chemically stable by using alkaline sodium thiosulphate solution together with paper or cellulose tissue.

## MATERIALS

### Material provided

The reagents listed below are sufficient for 100 tubes including the calibrator curve.

|                    |                  |                                                                                                            |
|--------------------|------------------|------------------------------------------------------------------------------------------------------------|
| ACID               | BUF              | Acidification Buffer<br>(1 bottle, 12.5 ml, ready for use)                                                 |
| DIL                | BUF              | Dilution Buffer<br>(1 bottle, 125 ml, ready for use)                                                       |
| ASS                | BUF              | Assay Buffer<br>(1 bottle, 30 ml, ready for use)                                                           |
| ANTISERUM          |                  | 1st Antibody (anti-hIGF-II) containing rabbit IgG and recombinant hIGF-I<br>(1 bottle, 11 ml, lyophilized) |
| Ag                 | <sup>125</sup> I | Tracer ( <sup>125</sup> I-IGF-II) (< 3 µCi or < 110 kBq)<br>(1 bottle, 11 ml lyophilized)                  |
| NSB                |                  | Non-specific binding (NSB)<br>(1 vial, 500 µl, lyophilized)                                                |
| CAL                | N                | Calibrators 0-7. (8 vials, 500 µl each, lyophilized)<br>See exact values on the vial labels                |
| CONTROL            | N                | Controls 1-2 (human plasma). (2 vials, 100 µl each, lyophilized)<br>See exact values on the vial labels    |
| 2 <sup>nd</sup> Ab |                  | 2nd Antibody (anti-rabbit immunoglobulin)<br>(1 vial, 1 ml, lyophilized)                                   |
| PEG                |                  | Precipitation Reagent<br>(1 bottle, 55 ml, ready for use after adding 2nd Ab)                              |

### Required Materials Not Provided

- 1) Ice-cold deionized water
- 2) Pipettes: 10 ml, 1 ml, 500 µl, 250 µl, 100 µl, 10 µl;  
100 µl, 500 µl and 1 ml repeating pipettes are recommended.
- 3) Disposable polystyrene or polypropylene tubes. Conical tubes are highly recommended because of the small immunoprecipitates. The use of round-bottom tubes may cause formation of insufficiently compact pellets.
- 4) Vortex mixer
- 5) Centrifuge appropriate for precipitation of immunocomplexes.
- 6) Device for aspiration of liquid supernatant (e.g. connected to a water pump).
- 7) Gamma counter

## ASSAY CHARACTERISTICS AND VALIDATION

The radioimmunoassay for IGF-II uses a specific, high-affinity polyclonal antibody. Its cross-reactivity with IGF-I is less than 0.05%.

The sensitivity of the assay is **0.1 ng/ml**.

The inter-assay variation coefficient has been found to be 7.9% , the intra-assay variation coefficient did not exceed 5.4% (three serum samples containing different concentrations of IGF-II were determined 6 times each in every assay).

## REAGENT STORAGE AND PREPARATION

Upon receipt the kit should be stored at 2 - 8 °C until its expiry date. After reconstitution, the lyophilized reagents should be stored at -20°C. Avoid repeated thawing and freezing. The shelf-life of the components after opening is not affected, if used appropriately.

|                        |                                                                                                                                                                                                                            |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Antiserum</b>       | Reconstitute with 11 ml Assay Buffer.                                                                                                                                                                                      |
| <b>Tracer</b>          | Reconstitute with 11 ml Assay Buffer.                                                                                                                                                                                      |
| <b>NSB</b>             | Reconstitute with 500 µl Assay Buffer.                                                                                                                                                                                     |
| <b>Calibrators 0-7</b> | Reconstitute with 500 µl Dilution Buffer.                                                                                                                                                                                  |
| <b>Controls 1-2</b>    | Reconstitute with 100 µl distilled water. Dilute according to samples with Dilution Buffer (e.g.1:101)                                                                                                                     |
| <b>2nd Antibody</b>    | Reconstitute with 1 ml Assay Buffer to obtain the precipitating solution. Transfer dissolved material to PEG immediately before use. The assay is unaffected by the possible occurrence of turbidity in the final reagent. |

Ensure that the lyophilized materials are completely dissolved on reconstitution. It is recommended to keep reconstituted reagents at room temperature for half an hour and then to mix them vigorously with a Vortex mixer. This is important in particular for the controls 1 and 2 !

## SAMPLE PREPARATION

The stability of IGFBP-bound IGF-II makes sample preparation simple. Serum and Heparin/EDTA plasma levels are comparable. Blood samples may be taken at any time of the day. Whole blood should be processed within a few hours and stored frozen at -20°C until measurement. IGF-II levels are usually not affected by improper handling or storage. They remain stable over several days in normal and in various clinical situations even under conditions of high temperature (37°C). Avoid repeated freezing and thawing cycles, although IGF-levels in normal sera remained unchanged after 10 cycles. Frozen samples are stable over many years. Samples may also be freeze-dried without suffering any loss of activity.

**Serum or plasma samples should be diluted 1 to 30 - 400-fold**, (or even more) depending on the expected values, with the Dilution Buffer. Usually, a dilution of 1 : 100 - 150 is appropriate.

Example: Add 10 µl serum to 1 ml Dilution Buffer (dilution 1: 101).

If very low levels are expected (e.g. in extreme GH deficiency or in GH receptor deficiency), serum or plasma samples may be diluted 1: 20 or less with the Dilution Buffer. Sufficient acidification can be achieved by adding a small volume of Acidification Buffer: 1/10th of the diluted sample volume is sufficient.

Example: Dilute 10 µl serum with 200 µl Dilution Buffer (1: 21). Add 20 µl Acidification Buffer (total dilution 1: 23).

In body fluids other than serum or plasma (e.g. cerebrospinal fluid, ocular vitreous fluid, or urine), or in conditioned cell culture media, IGF-II concentrations may be extremely low. These samples can be directly measured without dilution after adding 1/10th of their volume Acidification Buffer.

Example: add 20 µl Acidification Buffer to 200 µl conditioned cell culture medium (dilution 1:11, dilution factor 11).

According to the common dilution of serum or plasma samples the dilution of the controls (1 and 2) should be about 1:100 with Dilution Buffer.

## ASSAY PROCEDURE

Samples (calibrators and patient specimens) should be assayed in duplicate. For optimal results, accurate pipetting and adherence to the protocol are recommended.

### Flow Chart of Assay Protocol

| #     | Tube                          | Dilution Buffer<br>μl | Calibrators,<br>Controls,<br>Sample<br>μl | NSB<br>μl | Antiserum<br>μl | Tracer<br>μl | Precipitating<br>solution<br>μl |
|-------|-------------------------------|-----------------------|-------------------------------------------|-----------|-----------------|--------------|---------------------------------|
| 1,2   | Total                         | –                     | –                                         | –         | –               | 100          | –                               |
| 3,4   | NSB                           | 100                   | –                                         | 100       | –               | 100          | 500                             |
| 5,6   | B <sub>0</sub> – Calibrator 0 | –                     | 100                                       | –         | 100             | 100          | 500                             |
| 7-20  | Calibrators 1-7               | –                     | 100                                       | –         | 100             | 100          | 500                             |
| 21,22 | Control 1                     | –                     | 100                                       | –         | 100             | 100          | 500                             |
| 23,24 | Control 2                     | –                     | 100                                       | –         | 100             | 100          | 500                             |
| 25,26 | Sample 1                      | –                     | 100                                       | –         | 100             | 100          | 500                             |
| 27,28 | Sample 2                      | –                     | 100                                       | –         | 100             | 100          | 500                             |
| etc.  |                               |                       |                                           |           |                 |              |                                 |

1) Labelling of the assay tubes should be done in the following order:

- 1, 2            total counts, **TC**
- 3, 4            non-specific binding, **NSB**
- 5, 6            zero calibrator (**B<sub>0</sub>**)
- 7, 8            calibrator **1**
- 9, 10          calibrator **2** etc.
- 21, 22        high control **1**
- 23, 24        low control **2**
- 25, 26        etc.duplicates of samples.

- 2) Add **100 μl** of **Dilution Buffer** to tubes 3 and 4.
- 3) Add **100 μl** of **calibrators** to tubes 5 to 20, (zero calibrator to tubes 5 and 6, calibrator **1** (0.4 ng/ml) to tubes 7 and 8, etc).
- 4) Add **100 μl** of diluted **control 1 (high control)** to tubes 21 and 22 and diluted **control 2 (low control)** to tubes 23 and 24.
- 5) Add **100 μl** of diluted (or only acidified) **samples** to tubes 25 and 26, etc.
- 6) Add **100 μl NSB** to tubes 3 and 4.
- 7) Add **100 μl Antiserum** beginning with tube 5.
- 8) Add **100 μl tracer** to all tubes.
- 9) Set aside tubes 1 and 2 (total counts) or mark or seal with a stopper. Steps 10 to 17 may not be performed on tubes 1 and 2.

- 10) Mix tubes with a vortex mixer.
- 11) Incubate tubes at **2 - 8 °C for 2 days**. Incubation of 1 day or more than 2 days will also be appropriate.
- 12) Add **500 µl precipitating solution**, beginning with tube 3. The reagent should be cold (**2 - 8 °C**).
- 13) Mix tubes with a vortex mixer.
- 14) Incubate tubes at **2 - 8 °C for 1 hour**
- 15) Add **1 ml ice-cold distilled water**.
- 16) Centrifuge all tubes except tubes 1 and 2 at least at **3000 x g** for **30 min** at a temperature of **2 - 8 °C**.
- 17) Aspirate the supernatant (except tubes 1 and 2!). The remaining supernatant should not be higher than **2 mm** above the precipitate. Take care that the precipitate remains intact.  
  
Depending on local conditions and procedures, the supernatant may also be decanted instead of aspirated.
- 18) Count the activity of all tubes (including tubes 1 and 2) for 1 to 3 min.

#### Extended washing procedure for increased precision

The second incubation step (step 14) is directly followed by step 16 (centrifugation) and step 17 (aspiration). Proceed then with step 15 and add 1 ml of ice-cold water. This should not be done too vigorously in order to keep the precipitate intact. Do not mix! Centrifuge the tubes at **2-8°C at 3000 x g for 5 min.**, aspirate the supernatant, and count the radioactivity of all tubes in the gamma-counter (step 18).

This extended procedure results in a somewhat higher precision and reduces the non-specific binding NSB. The higher precision may be irrelevant for most measurements and should therefore be used only in special cases.

## EVALUATION OF RESULTS

### Establishing the Calibrator Curve

The calibrators provided contain the following concentrations of IGF-II :

| Calibrator | 0   | 1   | 2   | 3   | 4   | 5    | 6    | 7    |
|------------|-----|-----|-----|-----|-----|------|------|------|
| ng/ml      | 0.0 | 0.4 | 0.9 | 2.0 | 4.5 | 10.0 | 22.5 | 50.0 |

1. Calculate the average counts (AC) of each pair of tubes. This gives the values for B
2. Subtract the average counts (AC) of tubes 3 and 4 (non-specific binding NSB) from the average counts of the calibrators, controls and patient samples. This gives the corrected values for B.
3. The corrected value from the zero calibrator (tubes 5 and 6) is  $B_0$ .
4. Calculate the percent bound ( $\% B/B_0$ ):  $\% B/B_0 = B/B_0 \times 100\%$ .
5. Plot  $\% B/B_0$  versus the calibrator concentrations on either semi-logarithmic or logit-log paper. For convenience, it is recommended to use computer assisted data reduction programs.
6. Quality control 1, calculate the non-specific binding NSB in %:

$NSB / \text{Total Counts TC} \times 100\% = (AC \text{ tubes } 3 + 4 / AC \text{ tubes } 1 + 2) \times 100\%$ .  
It should be  $< 5\%$  ( $\%NSB/TC < 5$ ).

Quality control 2, calculate the percent bound of zero calibrator :

$B_0 / \text{Total Counts TC} \times 100\% = ((AC \text{ tubes } 5 + 6 - AC \text{ tubes } 3 + 4) / AC \text{ tubes } 1 + 2) \times 100\%$ .  
It should be  $> 30\%$  ( $\%B_0/TC > 30$ ).

### Evaluation of sample concentrations

Read the concentration value (abscissa) corresponding to the % B/B<sub>0</sub> of the sample as in the example given below:

average counts of NSB: 1353 cpm

average counts of zero calibrator (B<sub>0</sub>): 18183 cpm

average counts of sample: 10036 cpm

$\%B/B_0 = (\text{cpm sample} - \text{NSB}) / (\text{cpm } B_0 - \text{NSB}) \times 100\%$

$= (10036 - 1353) / (18183 - 1353) \times 100\%$

$= 0.516 \times 100\%$

$= 51.6 \%$

For a 51.6 % value on the y-axis (ordinate) a value of 6.63 ng/ml on the x-axis (abscissa) was obtained. Multiply the concentration value, determined graphically or by the aid of a computer program, with the dilution factor.

Example:  $6.63 \times 101 = 670 \text{ ng/ml}$ .

If it is preferred to express the results as nmol/l, the values given as ng/ml should be divided by 7.469 to obtain nmol/l.

Example:  $670 \text{ ng/ml} / 7.469 = 89.7 \text{ nmol/l}$

**Table 1:** Serum levels of IGF-II in ng/ml in healthy subjects at various ages\*

| Percentile  |     |      |      |
|-------------|-----|------|------|
| Age group   | 5th | 50th | 95th |
| Newborns    | 132 | 237  | 430  |
| 1-4 weeks   | 292 | 405  | 561  |
| 1-6 months  | 290 | 459  | 726  |
| 6-12 months | 323 | 485  | 730  |
| 1-3 years   | 320 | 497  | 772  |
| 3-5 years   | 331 | 514  | 767  |
| 5-7 years   | 349 | 532  | 811  |
| 7-9 years   | 361 | 547  | 831  |
| 9-11 years  | 368 | 552  | 828  |
| 11-13 years | 373 | 559  | 838  |
| 13-15 years | 379 | 566  | 845  |
| 15-17 years | 377 | 572  | 868  |
| 20-30 years | 363 | 566  | 882  |
| 30-40 years | 368 | 567  | 874  |
| 40-50 years | 339 | 542  | 866  |
| 50-60 years | 330 | 537  | 874  |
| 60-70 years | 311 | 509  | 833  |

\* Measurement was performed after acid-ethanol extraction, and values were not corrected for recovery. Blum W., Schweizer R.: Insulin-like growth factors and their binding proteins; in Ranke MB (ed): Diagnostics of endocrine function in children and adolescents. Basel, Karger, 2003, pp 166-199.

# Summary of the Assay

| Reagent preparation:                              | Reconstitution            | Dilution                   |
|---------------------------------------------------|---------------------------|----------------------------|
| Antiserum                                         | in 11 ml Assay Buffer     |                            |
| Tracer                                            | in 11 ml Assay Buffer     |                            |
| NSB                                               | in 500 µl Assay Buffer    |                            |
| Calibrators (0-7)                                 | in 500 µl Dilution Buffer |                            |
| Controls (1-2)                                    | in 100 µl distilled water | 1:101 with Dilution Buffer |
| 2.Antibody                                        | in 1 ml Assay Buffer      |                            |
| Mix immediately before use with 55 ml Reagent PEG |                           |                            |
| Dilute Sample with Dilution Buffer e.g. 1:101     |                           |                            |

## Assay procedure in double determination

| Addition of Reagent [µl]                                                                     |                   |                 |                               |     |           |        |
|----------------------------------------------------------------------------------------------|-------------------|-----------------|-------------------------------|-----|-----------|--------|
| Nr. of Tubes                                                                                 | Contents of Tubes | Dilution Buffer | Calibrators, Controls Samples | NSB | Antiserum | Tracer |
| 1,2                                                                                          | Total             | –               | –                             | –   | –         | 100    |
| 3,4                                                                                          | NSB               | 100             | –                             | 100 | –         | 100    |
| 5,6                                                                                          | B <sub>0</sub>    | –               | 100                           | –   | 100       | 100    |
| 7-20                                                                                         | Calibrators 1-7   | –               | 100                           | –   | 100       | 100    |
| 21,22                                                                                        | High Control      | –               | 100                           | –   | 100       | 100    |
| 23,24                                                                                        | Low Control       | –               | 100                           | –   | 100       | 100    |
| 25,26                                                                                        | Sample 1          | –               | 100                           | –   | 100       | 100    |
| 27,28                                                                                        | Sample 2          | –               | 100                           | –   | 100       | 100    |
| etc.                                                                                         |                   |                 |                               |     |           |        |
| Nr.:1,2 remove until counting the activity.                                                  |                   |                 |                               |     |           |        |
| Mix other tubes with a Vortex-Mixer.                                                         |                   |                 |                               |     |           |        |
| Incubate at 2-8°C, 2 days                                                                    |                   |                 |                               |     |           |        |
| Add 500 µl precipitating buffer (except 1,2).<br>The reagent-mix should be cold (2-8°C).     |                   |                 |                               |     |           |        |
| Mix with Vortex-Mixer.                                                                       |                   |                 |                               |     |           |        |
| Incubate at 2-8°C, 1 h                                                                       |                   |                 |                               |     |           |        |
| Add 1 ml cold distilled water carefully in all tubes (except 1,2)                            |                   |                 |                               |     |           |        |
| Centrifuge at 3000 x g, 30 min at 2-8°C                                                      |                   |                 |                               |     |           |        |
| Aspirate the supernatant<br>(leave 2 mm of the remaining supernatant above the precipitate). |                   |                 |                               |     |           |        |
| Count the activity of all tubes with a Gamma counter.                                        |                   |                 |                               |     |           |        |

Revision Date : 2009-06-05

|  | <u>Used symbols</u>                | <u>Symboles utilisés</u>                  |
|--|------------------------------------|-------------------------------------------|
|  | Consult instructions for use       | Consulter les instructions d'utilisation  |
|  | Storage temperature                | Température de conservation               |
|  | Use by                             | Utiliser jusque                           |
|  | Batch code                         | Numéro de lot                             |
|  | Catalogue number                   | Référence de catalogue                    |
|  | Control                            | Contrôle                                  |
|  | In vitro diagnostic medical device | Dispositif médical de diagnostic in vitro |
|  | Manufacturer                       | Fabricant                                 |
|  | Contains sufficient for <n> tests  | Contenu suffisant pour <n> tests          |
|  | Wash solution concentrated         | Solution de lavage concentrée             |
|  | Zero calibrator                    | Calibrateur zéro                          |
|  | Calibrator #                       | Calibrateur #                             |
|  | Control #                          | Contrôle #                                |
|  | Tracer                             | Traceur                                   |
|  | Tracer                             | Traceur                                   |
|  | Tracer concentrated                | Traceur concentré                         |
|  | Tracer concentrated                | Traceur concentré                         |
|  | Tubes                              | Tubes                                     |
|  | Incubation buffer                  | Tampon d'incubation                       |
|  | Acetonitrile                       | Acétonitrile                              |
|  | Serum                              | Sérum                                     |
|  | Specimen diluent                   | Diluant du spécimen                       |
|  | Dilution buffer                    | Tampon de dilution                        |
|  | Antiserum                          | Antisérum                                 |
|  | Immunoabsorbent                    | Immunoabsorbant                           |
|  | Calibrator diluent                 | Diluant de calibrateur                    |
|  | Reconstitution solution            | Solution de reconstitution                |
|  | Polyethylene glycol                | Glycol Polyéthylène                       |
|  | Extraction solution                | Solution d'extraction                     |
|  | Elution solution                   | Solution d'élution                        |
|  | Bond Elut Silica cartridges        | Cartouches Bond Elut Silica               |
|  | Pre-treatment solution             | Solution de pré-traitement                |
|  | Neutralization solution            | Solution de neutralisation                |
|  | Tracer buffer                      | Tampon traceur                            |
|  | Microtiterplate                    | Microplaque de titration                  |
|  | HRP Conjugate                      | HRP Conjugué                              |
|  | HRP Conjugate                      | HRP Conjugué                              |
|  | HRP Conjugate concentrate          | HRP Conjugué concentré                    |
|  | HRP Conjugate concentrate          | HRP Conjugué concentré                    |
|  | Conjugate buffer                   | Tampon conjugué                           |
|  | Chromogenic TMB concentrate        | Chromogène TMB concentré                  |
|  | Chromogenic TMB solution           | Solution chromogène TMB                   |
|  | Substrate buffer                   | Tampon substrat                           |
|  | Stop solution                      | Solution d'arrêt                          |
|  | Incubation serum                   | Sérum d'incubation                        |
|  | Buffer                             | Tampon                                    |
|  | AP Conjugate                       | AP Conjugué                               |
|  | Substrate PNPP                     | Tampon PNPP                               |
|  | Biotin conjugate concentrate       | Biotine conjugué concentré                |
|  | Avidine HRP concentrate            | Avidine HRP concentré                     |
|  | Assay buffer                       | Tampon de test                            |
|  | Biotin conjugate                   | Biotine conjugué                          |
|  | Specific Antibody                  | Anticorps spécifique                      |
|  | Streptavidin HRP concentrate       | Concentré streptavidine HRP               |
|  | Non-specific binding               | Liant non spécifique                      |
|  | 2nd Antibody                       | Second anticorps                          |
|  | Acidification Buffer               | Tampon d'acidification                    |

|  | <u>Gebruikte symbolen</u>                    | <u>Gebrauchte Symbolen</u>  |
|--|----------------------------------------------|-----------------------------|
|  | Raadpleeg de gebruiksaanwijzing              | Gebrauchsanweisung beachten |
|  | Bewaartemperatuur                            | Lagern bei                  |
|  | Houdbaar tot                                 | Verwendbar bis              |
|  | Lotnummer                                    | Chargenbezeichnung          |
|  | Catalogusnummer                              | Bestellnummer               |
|  | Controle                                     | Kontrolle                   |
|  | Medisch hulpmiddel voor in-vitro diagnostiek | In Vitro Diagnostikum       |
|  | Fabrikant                                    | Hersteller                  |
|  | Inhoud voldoende voor <n> testen             | Ausreichend für <n> Ansätze |
|  | Wasoplossing, geconcentreerd                 | Waschlösung-Konzentrat      |
|  | Nulkalibrator                                | Null kalibrator             |
|  | Kalibrator #                                 | Kalibrator #                |
|  | Controle #                                   | Kontrolle #                 |
|  | Tracer                                       | Tracer                      |
|  | Tracer                                       | Tracer                      |
|  | Tracer geconcentreerd                        | Tracer Konzentrat           |
|  | Tracer geconcentreerd                        | Tracer Konzentrat           |
|  | Buisjes                                      | Röhrchen                    |
|  | Incubatiebuffer                              | Inkubationspuffer           |
|  | Acetonitrile                                 | Azetonitril                 |
|  | Serum                                        | Humanserum                  |
|  | Specimen diluent                             | Probenverdünner             |
|  | Verdunningsbuffer                            | Verdünnungspuffer           |
|  | Antiserum                                    | Antiserum                   |
|  | Immunoabsorbent                              | Immunadsorbens              |
|  | Kalibratorverdunner                          | Kalibratorverdünnung        |
|  | Reconstitutieoplossing                       | Rekonstitutionslösung       |
|  | Polyethyleen glycol                          | Polyethylenglykol           |
|  | Extractieoplossing                           | Extraktionslösung           |
|  | Elutieoplossing                              | Eluierungslösung            |
|  | Bond Elut Silica kolom                       | Bond Elut Silikakartuschen  |
|  | Pre-behandelingsoplossing                    | Vorbehandlungslösung        |
|  | Neutralisatieoplossing                       | Neutralisierungslösung      |
|  | Tracerbuffer                                 | Tracer-Puffer               |
|  | Microtiterplaat                              | Mikrotiterplatte            |
|  | HRP Conjugaat                                | HRP Konjugat                |
|  | HRP Conjugaat                                | HRP Konjugat                |
|  | HRP Conjugaat geconcentreerd                 | HRP Konjugat Konzentrat     |
|  | HRP Conjugaat geconcentreerd                 | HRP Konjugat Konzentrat     |
|  | Conjugaat buffer                             | Konjugatpuffer              |
|  | Chromogene TMB geconcentreerd                | Chromogenes TMB Konzentrat  |
|  | Chromogene Oplossing TMB                     | Farblösung TMB              |
|  | Substraatbuffer                              | Substratpuffer              |
|  | Stopoplossing                                | Stopplösung                 |
|  | Incubatieserum                               | Inkubationsserum            |
|  | Buffer                                       | Puffer                      |
|  | AP Conjugaat                                 | AP Konjugat                 |
|  | Substraat PNPP                               | Substrat PNPP               |
|  | Geconcentreerd Biotine conjugaat             | Biotin-Konjugat-Konzentrat  |
|  | Geconcentreerd Avidine-HRP conjugaat         | Avidin-HRP-Konzentrat       |
|  | Assay buffer                                 | Assaypuffer                 |
|  | Biotine conjugaat                            | Biotin-Konjugat             |
|  | Specifiek antilichaam                        | Spezifischer Antikörper     |
|  | Streptavidine-HRP concentraat                | HRP Streptavidinkonzentrat  |
|  | Aspecifieke binding                          | Unspezifische Bindung       |
|  | 2de antilichaam                              | Sekundärer Antikörper       |
|  | Verzuringbuffer                              | Ansäuerungspuffer           |

|  | <u><b>Simboli utilizzati</b></u>        | <u><b>Símbolos utilizados</b></u>            |
|--|-----------------------------------------|----------------------------------------------|
|  | Consultare le istruzioni per l'uso      | Consultar las instrucciones de uso           |
|  | Limitazioni di temperatura              | Limitación de temperatura                    |
|  | Utilizzare entro                        | Fecha de caducidad                           |
|  | Numero di lotto                         | Código de lote                               |
|  | Numero di catalogo                      | Número de catálogo                           |
|  | Controllo                               | Control                                      |
|  | Dispositivo medico-diagnostico in vitro | Producto sanitario para diagnóstico in vitro |
|  | Fabbricante                             | Fabricante                                   |
|  | Contenuto sufficiente per <n> saggi     | Contenido suficiente para <n> ensayos        |
|  | Tampone di lavaggio concentrato         | Solución de lavado concentrada               |
|  | Calibratore zero                        | Calibrador cero                              |
|  | Standard #                              | Calibrador #                                 |
|  | Controllo #                             | Control #                                    |
|  | Marcato                                 | Trazador                                     |
|  | Marcato                                 | Trazador                                     |
|  | Marcato concentrato                     | Trazador concentrada                         |
|  | Marcato concentrato                     | Trazador concentrada                         |
|  | Provette                                | Tubos                                        |
|  | Tampone incubazione                     | Tampón de incubación                         |
|  | Acetonitrile                            | Acetonitrilo                                 |
|  | Siero                                   | Suero                                        |
|  | Diluente campione                       | Diluyente de Muestra                         |
|  | Tampone diluizione                      | Tampón de dilución                           |
|  | Antisiero                               | Antisuero                                    |
|  | Immunoassorbente                        | Inmunoadsorbente                             |
|  | Diluente calibratore                    | Diluyente de calibrador                      |
|  | Soluzione di ricostituzione             | Solución de Reconstitución                   |
|  | Polietilenglicole                       | Glicol Polietileno                           |
|  | Soluzione di estrazione                 | Solución de extracción                       |
|  | Soluzione di eluizione                  | Solución de elución                          |
|  | Cartucce di silice bond elut            | Cartuchos Bond Elut Silica                   |
|  | Soluzione di pretrattamento             | Solución de Pre-tratamiento                  |
|  | Soluzione di neutralizzazione           | Solución de Neutralización                   |
|  | Tracer Buffer                           | Tampón de trazador                           |
|  | Piastra di microtitolazione             | Placa de microvaloración                     |
|  | HRP Coniugato                           | HRP Conjugado                                |
|  | HRP Coniugato                           | HRP Conjugado                                |
|  | HRP Coniugato concentrato               | HRP Conjugado concentrada                    |
|  | HRP Coniugato concentrato               | HRP Conjugado concentrada                    |
|  | Buffer coniugato                        | Tampón de Conjugado                          |
|  | Cromogena TMB concentrato               | Cromógena TMB concentrada                    |
|  | Soluzione cromogena TMB                 | Solución Cromógena TMB                       |
|  | Tampone substrato                       | Tampón de sustrato                           |
|  | Soluzione di arresto                    | Solución de Parada                           |
|  | Incubazione con siero                   | Suero de Incubación                          |
|  | Buffer                                  | Tampón                                       |
|  | AP Coniugato                            | AP Conjugado                                 |
|  | Substrato PNPP                          | Sustrato PNPP                                |
|  | Concentrato coniugato con biotina       | Concentrado de conjugado de biotina          |
|  | Concentrato avidina HRP                 | Concentrado avidina-HRP                      |
|  | Soluzione tampone per test              | Tampón de ensayo                             |
|  | Coniugato con biotina                   | Conjugado de biotina                         |
|  | Anticorpo Specifico                     | Anticuerpo específico                        |
|  | Streptavidina-HRP concentrata           | Estreptavidina-HRP Concentrado               |
|  | Legame non-specifico                    | Unión no específica                          |
|  | 2° Anticorpo                            | Segundo anticuerpo                           |
|  | Tampone Acidificante                    | Tampón de Acidificación                      |

|  | <u><b>Símbolos utilizados</b></u>          | <u><b>Använda symboler</b></u>        |
|--|--------------------------------------------|---------------------------------------|
|  | Consulte instruções de utilização          | Läs instruktionerna före användning   |
|  | Temperatura de conservação                 | Förvaringstemperatur                  |
|  | Utilizar antes de                          | Används av                            |
|  | Código de lote                             | Lotnummer                             |
|  | Número de catálogo                         | Katalognummer                         |
|  | Controlo                                   | Kontroll                              |
|  | Dispositivo médico de diagnóstico in vitro | In vitro diagnostiskt kit             |
|  | Fabricante                                 | Tillverkare                           |
|  | Conteúdo suficiente para <n> testes        | Innehållet räcker till <n> prover     |
|  | Solução de lavagem concentrada             | Tvättlösning, koncentrerad            |
|  | Calibrador zero                            | Nollkalibrerare                       |
|  | Calibrador #                               | Kalibrator #                          |
|  | Controlo #                                 | Kontroll #                            |
|  | Marcador                                   | Radioisotop, antigen                  |
|  | Marcador                                   | Radioisotop, antikropp                |
|  | Marcador concentrada                       | Radioisotop, antigen koncentrerad     |
|  | Marcador concentrada                       | Radioisotop, antikropp koncentrerad   |
|  | Tubos                                      | Rör                                   |
|  | Tampão de incubação                        | Inkuberingsbuffert                    |
|  | Acetonitrilo                               | Acetonitril                           |
|  | Soro                                       | Serum                                 |
|  | Diluidor de espécimes                      | Spädningsbuffert för prover           |
|  | Tampão de diluição                         | Spädningsbuffert                      |
|  | Anti-soro                                  | Antiserum                             |
|  | Imunoadsorvente                            | Immunoadsorberare                     |
|  | Diluyente do calibrador                    | Kalibratordiluent                     |
|  | Solução de Reconstituição                  | Rekonstitutionslösning                |
|  | Polietileno-glicol                         | Polyetylen glykol                     |
|  | Solução de Extração                        | Extraktionslösning                    |
|  | Solução de Eluição                         | Elueringslösning                      |
|  | Cartuchos de sílica Bond Elut              | Silikonpatroner för elueringsbindning |
|  | Solução de pré-tratamento                  | Förbehandlingslösning                 |
|  | Solução de neutralização                   | Neutraliseringslösning                |
|  | Tampão Marcador                            | Tracerbuffert                         |
|  | Placa de micro titulação                   | Microtiterplatta                      |
|  | HRP Conjugação                             | HRP-konjugat                          |
|  | HRP Conjugação                             | HRP-konjugat                          |
|  | HRP Conjugação concentrada                 | HRP-konjugat-koncentrat               |
|  | HRP Conjugação concentrada                 | HRP-konjugat-koncentrat               |
|  | Conjuge o tampão                           | Konjugatbuffert                       |
|  | Cromogénica TMB concentrada                | Kromogeniskt TMB-koncentrat           |
|  | Solução Cromogénica TMB                    | Kromogenisk TMB-lösning               |
|  | Tampão de substrato                        | Substratbuffert                       |
|  | Solução de Paragem                         | Stopplösning                          |
|  | Soro de incubação                          | Inkubationsserum                      |
|  | Tampão                                     | Buffert                               |
|  | AP Conjugação                              | AP-konjugat                           |
|  | Substrato PNPP                             | Substrat-PNPP                         |
|  | Concentrado conjugado de biotina           | Biotinkonjugat koncentrat             |
|  | Concentrado HRP de avidina                 | Avidin HRP-koncentrat                 |
|  | Tampão de ensaio                           | Provbuffert                           |
|  | Conjugado de biotina                       | Biotinkonjugat                        |
|  | Anticorpo específico                       | -                                     |
|  | Estreptavidina HRP concentrado             | -                                     |
|  | Ligações não específicas                   | -                                     |
|  | Anticorpo secundário                       | -                                     |
|  | Tampão de acidificação                     | -                                     |

|  | <u><b>Επεξήγηση συμβόλων</b></u>                 | <u><b>Anvendte symboler</b></u>               |
|--|--------------------------------------------------|-----------------------------------------------|
|  | Συμβουλευτείτε τις οδηγίες χρήσης                | Læs brugsvejledningen                         |
|  | Θερμοκρασία αποθήκευσης                          | Opbevaringstemperatur                         |
|  | Ημερομηνία λήξης                                 | Anvend inden                                  |
|  | Αριθμός παρτίδας                                 | Batchkode                                     |
|  | Αριθμός καταλόγου                                | Katalognummer                                 |
|  | Πρότυπο ελέγχου                                  | Kontrol                                       |
|  | In Vitro Διαγνωστικό Ιατροτεχνολογικό προϊόν     | Medicinsk udstyr til in vitro-diagnosticering |
|  | Κατασκευαστής                                    | Fabrikant                                     |
|  | Περιεχόμενο επαρκές για «n» εξετάσεις            | Indeholder nok til <n> test                   |
|  | Συμπυκνωμένο διάλυμα έκπλυσης                    | Koncentreret vaskeopløsning                   |
|  | Μηδενικός βαθμονομητής                           | Nul-kalibrator                                |
|  | Βαθμονομητής #                                   | Kalibrator nr.                                |
|  | Ορός ελέγχου #                                   | Kontrol nr.                                   |
|  | Ιχνηθέτης                                        | Markør                                        |
|  | Ιχνηθέτης                                        | Markør                                        |
|  | Χρωμογόνος Ιχνηθέτης                             | Koncentreret markør                           |
|  | Χρωμογόνος Ιχνηθέτης                             | Koncentreret markør                           |
|  | Σοληνάρια                                        | Tuber                                         |
|  | Ρυθμιστικό διάλυμα επώασης                       | Inkubationsbuffer                             |
|  | Ακετονιτρίλιο                                    | Acetonitril                                   |
|  | Ορός                                             | Serum                                         |
|  | Διάλυμα αραίωσης δειγμάτων                       | Prøvediluent                                  |
|  | Ρυθμιστικό διάλυμα αραίωσης                      | Fortyndingsbuffer                             |
|  | Αντιορός                                         | Antiserum                                     |
|  | Ανοσοπροσροφητικό                                | Immonoadsorbent                               |
|  | Αραιωτικό βαθμονομητών                           | Kalibratordiluent                             |
|  | Διάλυμα ανασύστασης                              | Rekonstitueringsopløsning                     |
|  | Πολυαιθυλενογλυκόλη                              | Polyetylenglykol                              |
|  | Διάλυμα εκχύλισης                                | Ekstraktionsopløsning                         |
|  | Διάλυμα έκλουσης                                 | Elueringsopløsning                            |
|  | Φύσιγγες πυριτίου Bond Elut                      | Patroner med bindingselueringssilica          |
|  | Διάλυμα προεπεξεργασίας                          | Forbehandlingsopløsning                       |
|  | Διάλυμα εξουδετέρωσης                            | Neutraliseringsopløsning                      |
|  | Ρυθμιστικό διάλυμα                               | Markørbuffer                                  |
|  | Πλάκα μικροτιτλοδότησης                          | Mikrotiterplade                               |
|  | HRP Σύζευγμα                                     | HRP-konjugat                                  |
|  | HRP Σύζευγμα                                     | HRP-konjugat                                  |
|  | Χρωμογόνος HRP Σύζευγμα                          | HRP-konjugat-koncentreret                     |
|  | Χρωμογόνος HRP Σύζευγμα                          | HRP-konjugat-koncentreret                     |
|  | Ρυθμιστικό διάλυμα συζεύγματος                   | Konjugatbuffer                                |
|  | Χρωμογόνος TMB                                   | Kromogen TMB-koncentreret                     |
|  | Διάλυμα χρωμογόνου TMB                           | Kromogen TMB-opløsning                        |
|  | Ρυθμιστικό διάλυμα υποστρώματος                  | Substratbuffer                                |
|  | Ανασχετικό αντιδραστήριο                         | Stopopløsning                                 |
|  | Ορός επώασης                                     | Inkubationsserum                              |
|  | Ρυθμιστικό διάλυμα                               | Buffer                                        |
|  | AP Σύζευγμα                                      | AP-konjugat                                   |
|  | PNPP υποστρώματος                                | Substrat PNPP                                 |
|  | Συμπυκνωμένο αντιδραστήριο συζευγμένο με βιοτίνη | Biotin konjugat koncentrat                    |
|  | Συμπυκνωμένο διάλυμα αβιδίνης-HRP                | Avidin HRP koncentrat                         |
|  | Ρυθμιστικό διάλυμα προσδιορισμού                 | Prøvebuffer                                   |
|  | αντιδραστήριο συζευγμένο με βιοτίνη              | Biotin konjugat                               |
|  | Ειδικό Αντίσωμα                                  | -                                             |
|  | Συμπυκνωμένη στρεπταβιδίνη συνεξευγμένη με HRP   | -                                             |
|  | μη-ειδική δέσμευση                               | -                                             |
|  | 2ο Αντίσωμα                                      | -                                             |
|  | Ρυθμιστικό Διάλυμα όξινο                         | -                                             |

|  | <b><u>Stosowane symbole</u></b>                   | <b><u>Használt szimbólumok</u></b>      |
|--|---------------------------------------------------|-----------------------------------------|
|  | Przed zastosowaniem zapoznać się z instrukcją     | Olvassa el a használati útmutatót       |
|  | Temperatura przechowywania                        | Tárolási hőmérséklet                    |
|  | Zużyć przed                                       | Lejáratí idő                            |
|  | Kod serii                                         | Gyártási kód                            |
|  | Numer katalogowy                                  | Katalógus szám                          |
|  | Kontrola                                          | Kontrol                                 |
|  | Urządzenie medyczne do diagnostyki in vitro       | In vitro diagnosztikai eszköz           |
|  | Producent                                         | Gyártó                                  |
|  | Zawartość wystarczająca do <n> testów             | Tartalma <n> teszt elvégzésére elegendő |
|  | Roztwór płuczący stężony                          | Mosó folyadék koncentrátum              |
|  | Kalibrator zerowy                                 | Zero kalibrátor                         |
|  | Kalibrator nr                                     | Kalibrátor #                            |
|  | Kontrola nr                                       | Kontrol #                               |
|  | Znacznik izotopowy                                | Nyomjelző izotóp                        |
|  | Znacznik izotopowy                                | Nyomjelző izotóp                        |
|  | Znacznik izotopowy stężony                        | Nyomjelző izotóp koncentrátum           |
|  | Znacznik izotopowy stężony                        | Nyomjelző izotóp koncentrátum           |
|  | Probówki                                          | Csővek                                  |
|  | Wymagana inkubacja buforu                         | Inkubáló puffer                         |
|  | Acetonitryl                                       | Acetonitril                             |
|  | Surowica                                          | Szérum                                  |
|  | Rozcieńczalnik próbki                             | Mintahígító                             |
|  | Bufor do rozcieńczania                            | Hígító puffer                           |
|  | Antysurowica                                      | Antiszérum                              |
|  | Immunoabsorbent                                   | Immunadszorbens                         |
|  | Rozcieńczalnik kalibratora                        | Kalibrátor hígító                       |
|  | Roztwór do rozcieńczania                          | Mintaelőkészítő oldat                   |
|  | Glikol poli(oksy)etylenowy                        | Polietilén glikol                       |
|  | Roztwór ekstrakcyjny                              | Extrakciós oldat                        |
|  | Roztwór elucyjny                                  | Eluáló oldat                            |
|  | Kolumny krzemionkowe Bond Elut                    | Bond Elut Silica szilikagél patronok    |
|  | Roztwór do przygotowania wstępnego                | Előkezelő oldat                         |
|  | Roztwór neutralizujący                            | Semlegesítő oldat                       |
|  | Bufor znacznika                                   | Nyomjelző izotóp hígító puffer          |
|  | mikro płytki                                      | Mikrotiter lemez                        |
|  | Koniugat peroksydazy chrzanowej                   | HRP konjugátum                          |
|  | Koniugat peroksydazy chrzanowej                   | HRP konjugátum                          |
|  | Koncentrat koniugatu peroksydazy chrzanowej       | HRP konjugátum koncentrátum             |
|  | Koncentrat koniugatu peroksydazy chrzanowej       | HRP konjugátum koncentrátum             |
|  | Bufor do koniugacji                               | Konjugátum puffer                       |
|  | Koncentrat chromogenu TMB (czterometylobenzodyny) | Kromogén TMB koncentrátum               |
|  | Roztwór chromogenu TMB (czterometylobenzodyny)    | Kromogén TMB oldat                      |
|  | Bufor substratu                                   | Szubsztrát puffer                       |
|  | Roztwór zatrzymujący reakcję                      | Stop oldat                              |
|  | Wymagana inkubacja surowicy                       | Inkubációs szérum                       |
|  | Bufor                                             | Puffer                                  |
|  | Koniugat AP (fosfatazy alkalicznej)               | AP konjugátum                           |
|  | p-nitrofenylofosforan substratowy                 | Szubsztrát PNPP                         |
|  | Koncentrat koniugatu biotyny                      | Biotin konjugátum koncentrátum          |
|  | Koncentrat peroksydazy chrzanowej z awidyną       | Avidin HRP koncentrátum                 |
|  | Bufor do oznaczania                               | Vizsgálati puffer                       |
|  | Koniugatu biotyny                                 | Biotin konjugátum                       |
|  | Przeciwciało swoiste                              | Specifikus ellenanyag                   |
|  | Koncentrat streptawidyny HRP                      | Sztreptawidin HRP koncentrátum          |
|  | Wiązanie nieswoiste                               | Nem-specifikus kötődés                  |
|  | Drugie przeciwciało                               | Másodlagos ellenanyag                   |
|  | Bufor zakwaszający                                | Savas puffer                            |

|                 | <b><u>Използвани символи</u></b>             |
|-----------------|----------------------------------------------|
|                 | Вижте инструкцията за работа                 |
|                 | Температура на съхранение                    |
|                 | Използвайте с                                |
| <b>LOT</b>      | Партиден код                                 |
| <b>REF</b>      | Каталожен номер                              |
| <b>CONTROL</b>  | Контрол                                      |
| <b>IVD</b>      | Ин витро диагностично медицинско изделие     |
|                 | Производител                                 |
|                 | Съдържание достатъчно за <n> теста           |
| WASH SOLN CONC  | Концентриран измиващ разтвор                 |
| CAL 0           | Нулев калибратор                             |
| CAL N           | Калибратор #                                 |
| CONTROL N       | Контрол #                                    |
| Ag 125I         | Трейсър                                      |
| Ab 125I         | Трейсър                                      |
| Ag 125I CONC    | Концентриран маркер                          |
| Ab 125I CONC    | Концентриран маркер                          |
|                 | Епруветки                                    |
| INC BUF         | Инкубационен буфер                           |
| ACETONITRILE    | Ацетонитрил                                  |
| SERUM           | Серум                                        |
| DIL SPE         | Разредител за пробите                        |
| DIL BUF         | Буфер за разреждане                          |
| ANTISERUM       | Антисерум                                    |
| IMMUNOABSORBENT | Имуноабсорбент                               |
| DIL CAL         | Разредител за калибратора                    |
| REC SOLN        | Пресъздаващ разтвор                          |
| PEG             | Полиетилен гликол                            |
| EXTR SOLN       | Екстрактов разтвор                           |
| ELU SOLN        | Разтвор за елюиране                          |
| GEL             | Силикагелни пълнители                        |
| PRE SOLN        | Пред-лечебен разтвор                         |
| NEUTR SOLN      | Неутрализиращ разтвор                        |
| TRACEUR BUF     | Маркерен буфер                               |
|                 | Микротитърна пластина                        |
| Ab HRP          | HRP конюгат / Конюгат на хрянова пероксидаза |
| Ag HRP          | HRP конюгат / Конюгат на хрянова пероксидаза |
| Ab HRP CONC     | HRP конюгиран концентрат                     |
| Ag HRP CONC     | HRP конюгиран концентрат                     |
| CONJ BUF        | Буфер за конюгата                            |
| CHROM TMB CONC  | Хромогенен ТМВ концентрат                    |
| CHROM TMB       | Хромогенен ТМВ разтвор                       |
| SUB BUF         | Субстратен буфер                             |
| STOP SOLN       | Стоп разтвор                                 |
| INC SER         | Инкубационен серум                           |
| BUF             | Буфер                                        |
| Ab AP           | AP конюгат / конюгат на алкална фосфатаза    |
| SUB PNPP        | Субстрат PNPP / пара нитрофенил фосфат       |
| BIOT CONJ CONC  | Биотин конюгиран концентрат                  |
| AVID HRP CONC   | Авидин HRP концентрат                        |
| ASS BUF         | Буфер за пробите                             |
| Ab BIOT         | Биотин конюгат                               |
| Ab              | специфично антитяло                          |
| SAV HRP CONC    | стрептавидин HRP концентрат                  |
| NSB             | не специфично свързване                      |
| 2nd Ab          | второ антитяло                               |
| ACID BUF        | киселинизиращ буфер                          |