



Leptin-EASIA

KAP2281



Read entire protocol before use.

Leptin-EASIA

I. INTENDED USE

Immunoenzymetric assay for the in vitro quantitative measurement of human Leptin in serum and plasma.

II. GENERAL INFORMATION

- A. Proprietary name :** DIAsource Leptin-EASIA Kit
- B. Catalogue number :** KAP2281 : 96 tests
- C. Manufactured by :** DIAsource ImmunoAssays S.A.
Rue de l'Industrie, 8, B-1400 Nivelles, Belgium.

For technical assistance or ordering information contact :
Tel : +32 (0)67 88.99.99 Fax : +32 (0)67 88.99.96

III. CLINICAL BACKGROUND

A. Biological activities

Leptin, the product of the *ob* gene, is a hormone secreted by adipocytes (1). Animals with mutations in the *ob* gene are obese, diabetic and have reduced activity (2). Administration of recombinant leptin to these animals decreases food intake and causes weight loss. In humans, this type of mutation has not been found.

Human leptin cDNA encodes a 167 amino acid non-glycosylated protein including a 21 AA signal peptide, which is cleaved to give mature human leptin. The human receptor for leptin (OB-R) has been identified (7) as a 1144 amino acid transmembrane glycoprotein. It is expressed in the choroid plexus and in the hypothalamus. Leptin is implicated in an increasing number of endocrine regulations including adiposity (3), satiety, energy homeostasis (4), puberty and fertility (5, 6).

B. Clinical application

Little is known about the physiologic actions of leptin in humans. The availability of a sensitive and specific assay to measure concentrations of leptin in serum and plasma will accelerate our understanding.

IV. PRINCIPLES OF THE METHOD

The DIIAsource Leptin-EASIA is a solid phase Enzyme Amplified Sensitivity Immunoassay performed on microtiterplate. The assay uses monoclonal antibodies (MAbs) directed against distinct epitopes of human Leptin. Calibrators and samples react with the capture monoclonal antibody (MAb 1) coated on microtiter well and with a monoclonal antibody (MAb 2) labelled with horseradish peroxidase (HRP). After an incubation period allowing the formation of a sandwich: coated MAb 1 – human Leptin – MAb 2 – HRP, the microtiterplate is washed to remove unbound enzyme labelled antibody. Bound enzyme-labelled antibody is measured through a chromogenic reaction. Chromogenic solution (TMB ready for use) is added and incubated. The reaction is stopped with the addition of Stop Solution and the microtiterplate is then read at the appropriate wavelength. The amount of substrate turnover is determined colourimetrically by measuring the absorbance, which is proportional to the Leptin concentration. A calibration curve is plotted and Leptin concentration in samples is determined by interpolation from the calibration curve. The use of the EASIA reader (linearity up to 3 OD units) and a sophisticated data reduction method (polychromatic data reduction) result in a high sensitivity in the low range and in an extended calibration range.

V. REAGENTS PROVIDED

Reagents	96 tests Kit	Color Code	Reconstitution			
 Microtiterplate with 96 anti Leptin (monoclonal antibodies) coated wells	96 wells	blue	Ready for use			
<table><tr><td>Ab</td><td>HRP</td></tr></table> Conjugate: HRP labelled anti-Leptin (monoclonal antibodies) in TRIS-Maleate buffer with bovine serum albumin, thymol and ProClin 300 (< 0.05%)	Ab	HRP	1 vial 11 ml	red	Ready for use	
Ab	HRP					
<table><tr><td>CAL</td><td>0</td></tr></table> Zero Calibrator in bovine serum with thymol	CAL	0	1 vial lyophil.	yellow	Add 1 ml distilled water	
CAL	0					
<table><tr><td>CAL</td><td>N</td></tr></table> Calibrator N = 1 to 5 (see exact values on vial labels) in bovine serum with thymol	CAL	N	5 vials lyophil.	yellow	Add 0.5 ml distilled water	
CAL	N					
<table><tr><td>INC</td><td>BUF</td></tr></table> Incubation Buffer: TRIS-Maleate buffer with bovine serum albumin, thymol and ProClin 300 (< 0.05%)	INC	BUF	1 vial 6 ml	black	Ready for use	
INC	BUF					
<table><tr><td>WASH</td><td>SOLN</td><td>CONC</td></tr></table> Wash Solution (Tris-HCl)	WASH	SOLN	CONC	1 vial 10 ml	brown	Dilute 200 x with distilled water (use a magnetic stirrer).
WASH	SOLN	CONC				
<table><tr><td>CONTROL</td><td>N</td></tr></table> Controls - N = 1 or 2 in human plasma with benzamidin and thymol	CONTROL	N	2 vials lyophil.	silver	Add 0.5 ml distilled water	
CONTROL	N					
<table><tr><td>CHROM</td><td>TMB</td></tr></table> Chromogenic TMB Solution	CHROM	TMB	1 vial 25 ml	white	Ready for use	
CHROM	TMB					
<table><tr><td>STOP</td><td>SOLN</td></tr></table> Stop Solution: HCl 2N	STOP	SOLN	1 vial 25 ml	white	Ready for use	
STOP	SOLN					

Note: 1. Use Zero Calibrator for sample dilutions.
2. 1 ng of the calibrator preparation is equivalent to 1 ng of the NIBSC 1st IS 97/594.

VI. SUPPLIES NOT PROVIDED

The following material is required but not provided in the kit:

- High quality distilled water
- Pipettes for delivery of: 50 µl, 100 µl, 500 µl and 1 ml (the use of accurate pipettes with disposable plastic tips is recommended)
- Vortex mixer
- Magnetic stirrer
- Horizontal microtiterplate shaker capable of 700 rpm ± 100 rpm

- Washer for Microtiterplates
- Microtiterplate reader capable of reading at 450 nm, 490 nm and 650 nm (in case of polychromatic reading) or capable of reading at 450 nm and 650 nm (bichromatic reading)
- Optional equipment: The ELISA-AID™ necessary to read the plate according to polychromatic reading (see paragraph XI.A.) can be purchased from Robert Maciels Associates, Inc. Mass. 0.2174 USA.

VII. REAGENT PREPARATION

- Calibrators:** Reconstitute the zero calibrator with 1 ml distilled water and the other calibrators with 0.5 ml distilled water.
- Controls:** Reconstitute the controls with 0.5 ml distilled water.
- Working Wash solution:** Prepare an adequate volume of Working Wash solution by adding 199 volumes of distilled water to 1 volume of Wash Solution (200x). Use a magnetic stirrer to homogenize. Discard unused Working Wash solution at the end of the day.

VIII. STORAGE AND EXPIRATION DATING OF REAGENTS

- § Before opening or reconstitution, all kits components are stable until the expiry date, indicated on the vial label, if kept at 2 to 8°C.
- § Unused strips must be stored, at 2-8°C, in a sealed bag containing a desiccant until expiration date.
- § After reconstitution, calibrators and controls should be frozen immediately after use and kept at -20°C for 3 months. Only one freeze thawing cycle is allowed, discard the calibrators and controls after the second use.
- § The concentrated Wash Solution is stable at room temperature until expiration date.
- § Freshly prepared Working Wash solution should be used on the same day.
- § After its first use, the conjugate is stable until expiry date, if kept in the original well-closed vial at 2 to 8°C.
- § Alterations in physical appearance of kit reagents may indicate instability or deterioration.

IX. SPECIMEN COLLECTION AND PREPARATION

- § Serum must be kept at 2 - 8°C.
- § If the test is not run within 24 hours, storage in aliquots at -20°C is recommended. Avoid subsequent freeze thaw cycles.
- § Prior to use, all samples should be at room temperature. It is recommended to vortex the samples before use.
- § Do not use haemolysed samples.
- § Do not use lipemic samples.

X. PROCEDURE

- Handling notes**
Do not use the kit or components beyond expiry date.
Do not mix materials from different kit lots.
Bring all the reagents to room temperature prior to use.
Thoroughly mix all reagents and samples by gentle agitation or swirling.
Perform calibrators, controls and samples in duplicate. Vertical alignment is recommended.
Use a clean plastic container to prepare the Wash Solution.
In order to avoid cross-contamination, use a clean disposable pipette tip for the addition of each reagent and sample.
For the dispensing of the Chromogenic Solution and the Stop Solution avoid pipettes with metal parts.
High precision pipettes or automated pipetting equipment will improve the precision.
Respect the incubation times.
To avoid drift, the time between pipetting of the first calibrator and the last sample must be limited to the time mentioned in section XIII paragraph E (Time delay).
Prepare a calibration curve for each run, do not use data from previous runs.
Dispense the Chromogenic Solution within 15 minutes following the washing of the microtiterplate.
During incubation with Chromogenic Solution, avoid direct sunlight on the microtiterplate.

- Procedure**
 - Select the required number of strips for the run. The unused strips should be resealed in the bag with a desiccant and stored at 2-8°C.
 - Secure the strips into the holding frame.
 - Pipette 50 µl of each Calibrator, Control and Sample into the appropriate wells.
 - Pipette 100 µl of anti-Leptin-HRP conjugate into all the wells.
 - Pipette 50 µl of Incubation Buffer into all the wells

- Incubate for 2 hours at room temperature on a horizontal shaker set at 700 rpm $\pm$ 100 rpm.
- Aspirate the liquid from each well.
- Wash the plate 4 times by:
§ Dispensing 0.4 ml of Wash Solution into each well
§ Aspirating the content of each well
- Pipette 100 μ l of Chromogenic Solution into each well within 15 minutes following the washing step.
- Incubate the microtiterplate for 30 minutes at room temperature on a horizontal shaker set at 700 rpm $\pm$ 100 rpm, avoid direct sunlight.
- Pipette 200 μ l of Stop Solution into each well.
- Read the absorbencies at 450 nm and 490 nm (reference filter 630 nm or 650 nm) within 3 hours and calculate the results as described in section XI.

XI. CALCULATION OF RESULTS

- A. Polychromatic Reading:**
- In this case, the ELISA-AID™ software will do the data processing.
 - The plate is first read at 450 nm against a reference filter set at 650 nm (or 630 nm).
 - A second reading is performed at 490 nm against the same reference filter.
 - The ELISA-AID™ Software will drive the reader automatically and will integrate both readings into a polychromatic model. This technique can generate OD's up to 10.
 - The principle of polychromatic data processing is as follows:
§ X_i = OD at 450 nm
§ Y_i = OD at 490 nm
§ Using a standard unweighted linear regression, the parameters A & B are calculated : $Y = A \cdot X + B$
§ If $X_i < 3$ OD units, then X calculated = X_i
§ If $X_i > 3$ OD units, then X calculated = $(Y_i - B)/A$
§ A 4-parameter logistic curve fitting is used to build up the calibration curve.
§ The Leptin concentration in samples is determined by interpolation on the calibration curve.

- B. Bichromatic Reading**
- Read the plate at 405 nm against a reference filter set at 650 nm (or 630 nm).
 - Calculate the mean of duplicate determinations.
 - On semi-logarithmic or linear graph paper plot the OD values (ordinate) for each calibrator against the corresponding concentration of Leptin (abscissa) and draw a calibration curve through the calibrator points by connecting the plotted points with straight lines.
 - Read the concentration for each control and sample by interpolation on the calibration curve.
 - Computer assisted data reduction will simplify these calculations. If automatic result processing is used, a 4-parameter logistic function curve fitting is recommended.

XII. TYPICAL DATA

The following data are for illustration only and should never be used instead of the real time calibration curve.

Leptin-EASIA		OD units
		Polychromatic model
Calibrator	0 ng/ml	0.019
	0.5 ng/ml	0.058
	1 ng/ml	0.106
	4.8 ng/ml	0.577
	27 ng/ml	3.052
	60 ng/ml	5.368

XIII. PERFORMANCE AND LIMITATIONS

- A. Detection Limit**
Twenty zero calibrators were assayed along with a set of other calibrators. The detection limit, defined as the apparent concentration two standard deviations above the average OD at zero binding, was 0.04 ng/ml.
- B. Specificity**
No significant cross-reaction was observed in presence of 3 μ g/ml of IL-1 α , IL-1 β , IL-4, IL-6, IL-8, IL-10, IL-15, TNF- α , TNF- β , IFN- γ , IP-10, ScF, GRO α , OSM, LIF, MCP-1, RANTES, PDGF, G-CSF, EGF, IL-12, PF4, MIG, C-peptide, IGF-1, IGF-2, Insulin & Glucagon.

C. Precision

INTRA ASSAY				INTER ASSAY			
Serum	N	<X> $\pm$ SD (ng/ml)	CV (%)	Serum	N	<X> $\pm$ SD (ng/ml)	CV (%)
A	10	1.5 $\pm$ 0.2	13.3	A	20	5.9 $\pm$ 0.6	10.2
B	10	9.0 $\pm$ 0.9	10.0	B	20	18.9 $\pm$ 2.4	12.7
C	10	43.4 $\pm$ 1.5	3.5				

SD: Standard Deviation; CV: Coefficient of variation

D. Accuracy

RECOVERY TEST

Sample	Added Leptin (ng/ml)	Theoretical Concent. (ng/ml)	Recovered Leptin (ng/ml)	Recovery (%)
Serum 1	0	7.2	7.6	105.6
	0.5	7.7	7.9	102.6
	2.4	9.6	9.1	94.8
	13.5	20.7	16.9	81.6
	30	37.2	34.5	92.7
Serum 2	0	13.3	12.4	93.2
	0.5	13.8	12.9	93.5
	2.4	15.7	14.5	92.4
	13.5	26.8	24.2	90.3
	30	43.3	38.6	89.1

DILUTION TEST

Sample	Dilution	Theoretical Concent. (ng/ml)	Measured Concent. (ng/ml)
Serum 1	1/1	-	31.8
	1/2	15.9	15.6
	1/4	8.0	7.9
	1/8	4.0	3.9
	1/16	2.0	1.9
	1/32	1.0	0.8
Serum 2	1/1	-	32.8
	1/2	16.4	17.8
	1/4	8.2	8.3
	1/8	4.1	3.7
	1/16	2.1	1.7
	1/32	1.0	0.7

Samples were diluted with zero calibrator

E. Time delay between last calibrator and sample dispensing

As shown hereafter, assay results remain accurate even when a sample is dispensed 40 minutes after the calibrators have been added to the coated wells.

TIME DELAY

Sample ng/ml	0 min	10 min	20 min	30 min	40 min
1	1.0	1.1	1.0	1.0	1.0
2	4.8	5.1	4.8	5.1	5.0
3	19.3	19.7	19.7	19.7	19.4
4	40.9	39.9	38.0	40.8	39.4

F. Hook effect

A sample spiked with 350 ng/ml Leptin gives higher OD's than the last calibrator point.

XIV. INTERNAL QUALITY CONTROL

- § If the results obtained for Control 1 and/or Control 2 are not within the range specified on the vial label, the results cannot be used unless a satisfactory explanation for the discrepancy has been given.

- § If desirable, each laboratory can make its own pools of control samples, which should be kept frozen in aliquots. Controls that contain azide will interfere with the enzymatic reaction and cannot be used.
- § Acceptance criteria for the difference between the duplicate results of the samples should rely on Good Laboratory Practises
- § It is recommended that controls be routinely assayed as unknown samples to measure assay variability. The performance of the assay should be monitored with quality control charts of the controls.
- § It is good practise to check visually the curve fit selected by the computer.

XV. REFERENCE INTERVALS

These values are given only for guidance; each laboratory should establish its own normal range of values.

Women (ages 16 to 80)				
BMI	n	Mean	SD	Range (ng/ml)
14-18	4	0.6	0.1	0.5 – 0.7
18-24	28	3.4	2.3	0.5 – 7.9
25-29	20	8.8	3.3	4.1 – 14.5
30-56	36	23.0	10.0	5.5 – 40.4

Men (ages 15 to 78)				
BMI	n	Mean	SD	Range (ng/ml)
14-18	1	0.5	-	-
18-24	20	1.2	0.9	0.5 – 3.2
25-29	27	4.2	3.9	0.5 – 14.6
30-56	23	10	10.5	2.5 – 42.1

The range is expressed as 2.5% to 97.5% percentiles.

XVI. PRECAUTIONS AND WARNINGS

Safety

For *in vitro* diagnostic use only.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV, anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported. Nevertheless, components containing animal substances should be treated as potentially infectious.

Avoid any skin contact with all reagents, Stop Solution contains HCl. In case of contact, wash thoroughly with water.

Do not smoke, drink, eat or apply cosmetics in the working area. Do not pipette by mouth. Use protective clothing and disposable gloves.

XVII. BIBLIOGRAPHY

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XVIII.SUMMARY OF THE PROTOCOL

	CALIBRATORS (µl)	SAMPLE(S) CONTROLS (µl)
Calibrators (0-5) Samples, Controls	50 -	- 50
Anti-Leptin-HRP Conjugate	100	100
Incubation Buffer	50	50
Incubate for 2 hours at room temperature with continuous shaking at 700 rpm. Aspirate the contents of each well. Wash 4 times with 400 µl of Wash Solution and aspirate.		
Chromogenic Solution (TMB)	100	100
Incubate for 30 min at room temperature with continuous shaking at 700 rpm.		
Stop Solution	200	200
Read on a microtiterplate reader and record the absorbance of each well at 450 nm (and 490 nm) versus 630 (or 650 nm)		

DIAsource Catalogue Nr : KAP2281	P.I. Number : 1700656/en	Revision nr : 090505/1
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Revision date : 2009-05-05

	<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
	Immunoadsorbent	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 Conjuaat	HRP Konjugat
	HRP Conjuaat	HRP Konjugat
	HRP Conjuaat geconcentreerd	HRP Konjugat Konzentrat
	HRP Conjuaat geconcentreerd	HRP Konjugat Konzentrat
	Conjuaat buffer	Konjugatpuffer
	Chromogene TMB geconcentreerd	Chromogenes TMB Konzentrat
	Chromogene Oplossing TMB	Farblösung TMB
	Substraatbuffer	Substratpuffer
	Stopoplossing	Stopplösung
	Incubatieserum	Inkubationsserum
	Buffer	Puffer
	AP Conjuaat	AP Konjugat
	Substraat PNPP	Substrat PNPP
	Geconcentreerd Biotine conjuaat	Biotin-Konjugat-Konzentrat
	Geconcentreerd Avidine-HRP conjuaat	Avidin-HRP-Konzentrat
	Assay buffer	Assaypuffer
	Biotine conjuaat	Biotin-Konjugat
	Specifiek antilichaam	Spezifischer Antikörper
	Streptavidine-HRP concentraat	HRP Streptavidinkonzentrat
	Aspecifieke binding	Unspezifische Bindung
	2de antilichaam	Sekundärer Antikörper
	Verzuringbuffer	Ansäuerungspuffer

	<u>Simboli utilizzati</u>	<u>Símbolos utilizados</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>Símbolos utilizados</u>	<u>Använda symboler</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	Polyetylglykol
	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	Stoplösning
	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>Επεξήγηση συμβόλων</u>	<u>Anvendte symboler</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
	Σωληνάρια	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	-

	<u>Stosowane symbole</u>	<u>Használt szimbólumok</u>
	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	Immunoabsorbens
	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

	<u>Използвани символи</u>
	Вижте инструкцията за работа
	Температура на съхранение
	Използвайте с
LOT	Партиден код
REF	Каталожен номер
CONTROL	Контрол
IVD	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 TMB концентрат
CHROM TMB	Хромогенен TMB 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