



TSH

KAPDB4080



TSH

en

For the direct quantitative determination of Thyroid Stimulating Hormone by enzyme immunoassay in human serum.

KAPDB4080

IN VITRO DIAGNOSTIC

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INTENDED USE

For the direct quantitative determination of Thyroid Stimulating Hormone by enzyme immunoassay in human serum.
For *in vitro* diagnostic use only.

PRINCIPLE OF THE TEST

The principle of the following enzyme immunoassay test follows a typical one-step capture or 'sandwich' type assay. The assay makes use of two highly specific monoclonal antibodies: A monoclonal antibody specific for TSH is immobilized onto the microwell plate and another monoclonal antibody specific for a different region of TSH is conjugated to horse radish peroxidase (HRP). TSH from the sample and calibrators are allowed to bind simultaneously to the plate and to the HRP conjugate. The washing and decanting steps remove any unbound HRP conjugate. After the washing step, the enzyme substrate is added. The enzymatic reaction is terminated by addition of the stopping solution. The absorbance is measured on a microtiter plate reader. The intensity of the colour formed by the enzymatic reaction is directly proportional to the concentration of TSH in the sample.

A set of calibrators is used to plot a calibration curve from which the amount of TSH in patient samples and controls can be directly read.

CLINICAL APPLICATIONS

Thyroid stimulating hormone (TSH) is a glycoprotein hormone secreted by the anterior pituitary gland. TSH has two subunits, namely α and β . The α subunit of TSH is similar to the α subunit found in the LH, FSH and hCG glycoprotein hormones. However, the β subunit is specific and differs from hormone to hormone.

The thyroid hormones are secreted and produced by the thyroid gland. The production of thyroid hormones is under the regulation of TSH. Also, TSH acts as a stimulator of iodide transport and the gland itself is under the positive control of TSH. The concentrations of thyroid hormones control the secretion of TSH, therefore, a negative feedback exists. It is to be noted that the secretion of thyroid hormones are under the direct, positive effect of the sympathetic nervous system. The major protein component of the thyroid gland is thyroglobulin, a glycoprotein of which the secretion in the blood stream is stimulated by TSH. Therefore, TSH plays an important role in the proper function and development of the thyroid gland.

It is recommended to assay both the glycoprotein hormone and the target organ hormones. For example, in primary hypothyroidism the serum level of thyroxine is low while the TSH level is high. In secondary hypothyroidism, both thyroxine and TSH are low. The TSH level is decreased in hyperthyroidism.

Today, with all the sensitive assays available, if there were to be only one test to be prescribed for thyroid function, TSH would be the test. TSH determinations are also helpful to monitor patients who receive thyroxine replacement therapy.

PROCEDURAL CAUTIONS AND WARNINGS

1. Users should have a thorough understanding of this protocol for the successful use of this kit. Reliable performance will only be attained by strict and careful adherence to the instructions provided.
2. Control materials or serum pools should be included in every run at a high and low level for assessing the reliability of results.
3. When the use of water is specified for dilution or reconstitution, use deionized or distilled water.
4. In order to reduce exposure to potentially harmful substances, gloves should be worn when handling kit reagents and human specimens.
5. All kit reagents and specimens should be brought to room temperature and mixed gently but thoroughly before use. Avoid repeated freezing and thawing of reagents and specimens.
6. A calibrator curve must be established for every run.
7. The control should be included in every run and fall within established confidence limits.
8. Improper procedural techniques, imprecise pipetting, incomplete washing as well as improper reagent storage may be indicated when assay values for the control do not reflect established ranges.
9. When reading the microplate, the presence of bubbles in the microwells will affect the optical densities (ODs). Carefully remove any bubbles before performing the reading step.
10. The substrate solution (TMB) is sensitive to light and should remain colourless if properly stored. Instability or contamination may be indicated by the development of a blue colour, in which case it should not be used.

11. When dispensing the substrate and stopping solution, do not use pipettes in which these liquids will come into contact with any metal parts.
12. To prevent contamination of reagents, use a new disposable pipette tip for dispensing each reagent, sample, calibrator and control.
13. Do not mix various lot numbers of kit components within a test and do not use any component beyond the expiration date printed on the label.
14. Kit reagents must be regarded as hazardous waste and disposed of according to national regulations.

LIMITATIONS

1. All the reagents within the kit are calibrated for the direct determination of TSH in human serum. The kit is not calibrated for the determination of TSH in saliva, plasma or other specimens of human or animal origin.
2. Do not use grossly hemolyzed, grossly lipemic, icteric or improperly stored serum.
3. Any samples or control sera containing azide or thimerosal are not compatible with this kit, as they may lead to false results.
4. Only calibrator 0 may be used to dilute any high serum samples. The use of any other reagent may lead to false results.
5. The results obtained with this kit should never be used as the sole basis for clinical diagnosis. For example, the occurrence of heterophilic antibodies in patients regularly exposed to animals or animal products has the potential of causing interferences in immunological tests. Consequently, the clinical diagnosis should include all aspects of a patient's background including the frequency of exposure to animals/products if false results are suspected.
6. Some individuals may have antibodies to mouse protein that can possibly interfere in this assay. Therefore, the results from any patients who have received preparation of mouse antibodies for diagnosis or therapy should be interpreted with caution.

SAFETY CAUTIONS AND WARNINGS

POTENTIAL BIOHAZARDOUS MATERIAL

Human serum that may be used in the preparation of the calibrators and control has been tested and found to be non-reactive for Hepatitis B surface antigen and has also been tested for the presence of antibodies to HCV and Human Immunodeficiency Virus (HIV) and found to be negative. However no test method can offer complete assurance that HIV, HCV and Hepatitis B virus or any infectious agents are absent. The reagents should be considered a potential biohazard and handled with the same precautions as applied to any blood specimen.

CHEMICAL HAZARDS

Avoid contact with reagents containing TMB, hydrogen peroxide and sulfuric acid. If contacted with any of these reagents, wash with plenty of water. TMB is a suspected carcinogen.

SPECIMEN COLLECTION AND STORAGE

Approximately 0.2 ml of serum is required per duplicate determination. Collect 4-5 ml of blood into an appropriately labelled tube and allow it to clot. Centrifuge and carefully remove the serum layer. Store at 4°C for up to 24 hours or at -10°C or lower if the analyses are to be done at a later date. Consider all human specimens as possible biohazardous materials and take appropriate precautions when handling.

SPECIMEN PRETREATMENT

This assay is a direct system; no specimen pretreatment is necessary.

REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED

1. Precision pipettes to dispense 50, 100, 150 and 300 μ l
2. Disposable pipette tips
3. Distilled or deionized water
4. Plate shaker
5. Microwell plate reader with a filter set at 450nm and an upper OD limit of 3.0 or greater* (see assay procedure step 10).

REAGENTS PROVIDED



Mouse Anti-TSH Antibody Coated Microwell Plate-Break Apart Wells
- Ready To Use.
Contents: One 96 well (12x8) monoclonal antibody-coated microwell plate in a resealable pouch with desiccant.
Storage: Refrigerate at 2-8°C
Stability: 12 months or as indicated on label.

Ab	HRP	CC
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Mouse Anti-TSH Antibody-Horseradish Peroxidase (HRP) Conjugate Concentrate – X50

Contents: Anti-TSH monoclonal antibody-HRP conjugate in a protein-based buffer with a non-mercury preservative.
Volume: 300 µl/vial
Storage: Refrigerate at 2-8°C
Stability: 12 months or as indicated on label.
Preparation: Dilute 1:50 in assay buffer before use (eg. 40 µl of HRP in 2 mL of assay buffer). If the whole plate is to be used dilute 240 µl of HRP in 12 mL of assay buffer. Discard any that is left over.

CAL	N
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TSH Calibrators - Ready To Use. N = 0 to 5

Contents: Six vials containing TSH in a protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with a defined quantity of TSH. 1µIU of the calibrator is equivalent to 1 µIU of the 2nd IIS 80/558.
*Listed below are approximate concentrations, please refer to vial labels for exact concentrations.

Calibrator	Concentration	Volume/Vial
Calibrator 0	0 µIU/mL	2.0 mL
Calibrator 1	0.2 µIU/mL	0.5 mL
Calibrator 2	1 µIU/mL	0.5 mL
Calibrator 3	5 µIU/mL	0.5 mL
Calibrator 4	15 µIU/mL	0.5 mL
Calibrator 5	30 µIU/mL	0.5 mL

Storage: Refrigerate at 2-8°C
Stability: 12 months in unopened vials or as indicated on label. Once opened, the calibrators should be used within 14 days or aliquoted and stored frozen. Avoid multiple freezing and thawing cycles.

CONTROL

Control - Ready To Use.

Contents: One vial containing TSH in a protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with a defined quantity of TSH. Refer to vial label for expected value and acceptable range.
Volume: 0.5 mL/vial
Storage: Refrigerate at 2-8°C
Stability: 12 months in unopened vial or as indicated on label. Once opened, the control should be used within 14 days or aliquoted and stored frozen. Avoid multiple freezing and thawing cycles.

WASH	SOLN	CONC
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Wash Buffer Concentrate – X10

Contents: One bottle containing buffer with a non-ionic detergent and a non-mercury preservative.
Volume: 50 mL/bottle
Storage: Refrigerate at 2-8°C
Stability: 12 months or as indicated on label.
Preparation: Dilute 1:10 in distilled or deionized water before use. If the whole plate is to be used dilute 50 mL of the wash buffer concentrate in 450 mL of water.

ASS	BUF
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Assay Buffer - Ready To Use.

Contents: One vial containing a protein-based buffer with a non-mercury preservative.
Volume: 15 mL/bottle
Storage: Refrigerate at 2-8°C
Stability: 12 months or as indicated on label.

CHROM	TMB
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TMB Substrate - Ready To Use.

Contents: One bottle containing tetramethylbenzidine and hydrogen peroxide in a non-DMF or DMSO containing buffer.
Volume: 16 mL/bottle
Storage: Refrigerate at 2-8°C
Stability: 12 months or as indicated on label.

STOP	SOLN
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Stopping Solution - Ready To Use.

Contents: One vial containing 1M sulfuric acid.
Volume: 6 mL/bottle
Storage: Refrigerate at 2-8°C
Stability: 12 months or as indicated on label.

ASSAY PROCEDURE
Specimen Pretreatment:
None.

All reagents must reach room temperature before use. Calibrators, controls and specimen samples should be assayed in duplicate. Once the procedure has been started, all steps should be completed without interruption.

1. Prepare working solution of the anti-TSH-HRP conjugate and wash buffer.
2. Remove the required number of microwell strips. Reseal the bag and return any unused strips to the refrigerator.
3. Pipette 50 µl of each calibrator, control and specimen sample into correspondingly labelled wells in duplicate.
4. Pipette 100 µl of the conjugate working solution into each well (We recommend using a multichannel pipette).
5. Incubate on a plate shaker (approximately 200 rpm) for 90 minutes at room temperature.
6. Wash the wells 3 times with 300 µl of diluted wash buffer per well and tap the plate firmly against absorbent paper to ensure that it is dry (The use of a washer is recommended).
7. Pipette 150 µl of TMB substrate into each well at timed intervals.
8. Incubate on a plate shaker for 10-15 minutes at room temperature (or until calibrator F attains dark blue colour for desired OD).
9. Pipette 50 µl of stopping solution into each well at the same timed intervals as in step 7.
10. Read the plate on a microwell plate reader at 450 nm within 20 minutes after addition of the stopping solution.

* If the OD exceeds the upper limit of detection or if a 450 nm filter is unavailable, a 415 nm filter may be substituted. The optical densities will be lower, however, this will not affect the results of patient/control samples.

CALCULATIONS

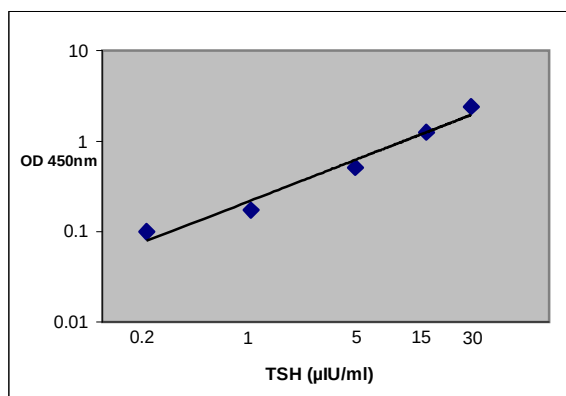
1. Calculate the mean optical density of each calibrator duplicate.
2. Calculate the mean optical density of each unknown duplicate.
3. Subtract the mean absorbance value of the "0" calibrator from the mean absorbance values of the calibrators, control and serum samples.
4. Draw a calibrator curve on log-log paper with the mean optical densities on the Y-axis and the calibrator concentrations on the X-axis. If immunoassay software is being used, a 4-parameter curve is recommended.
5. Read the values of the unknowns directly off the calibrator curve.
6. If a sample reads more than 30 µIU/ml then dilute it with calibrator 0 at a dilution of no more than 1:8. The result obtained should be multiplied by the dilution factor.

TYPICAL TABULATED DATA

Calibrator	OD 1	OD 2	Mean OD	Value (µIU/ml)
0	0.071	0.073	0.072	0
1	0.100	0.099	0.100	0.2
2	0.177	0.171	0.174	1
3	0.492	0.527	0.510	5
4	1.270	1.254	1.262	15
5	2.391	2.421	2.406	30
Unknown	0.446	0.470	0.458	4.3

TYPICAL CALIBRATION CURVE

Sample curve only. **Do not** use to calculate results.



PERFORMANCE CHARACTERISTICS

SENSITIVITY

The lower detection limit is calculated from the calibration curve by determining the resulting concentration of the mean OD of Calibrator 0 (based on 10 replicate analyses) plus 2 SD. Therefore, the sensitivity of the DIAsource Direct TSH ELISA kit is **0.1 µIU/ml**.

SPECIFICITY (CROSS REACTIVITY)

The specificity of the Direct TSH ELISA kit was determined by measuring the apparent TSH values of the following compounds:

Substance	Concentration Range	Apparent TSH Value (µIU/ml)
hCG Calibrated against WHO 1st IS 75/537	10,000-50,000 IU/L	<0.15
hFSH Calibrated against WHO 1st IS 83/575	1000-4000 IU/L	<0.15
hLH Calibrated against WHO 2nd IS 80/552	100-500 IU/L	<0.15

INTRA-ASSAY PRECISION

Three samples were assayed ten times each on the same calibrator curve. The results (in µIU/ml) are tabulated below:

Sample	Mean	SD	CV%
1	0.52	0.07	13.3
2	1.54	0.10	6.4
3	9.27	0.72	7.7

INTER-ASSAY PRECISION

Three samples were assayed ten times over a period of four weeks. The results (in µIU/ml) are tabulated below:

Sample	Mean	SD	CV%
1	0.78	0.07	8.3
2	8.03	0.99	12.3
3	25.42	3.26	12.8

RECOVERY

Spiked samples were prepared by adding defined amounts of TSH to three patient serum samples. The results (in µIU/ml) are tabulated below:

Sample	Obs.Result	Exp.Result	Recovery%
1 Unspiked	1.92	-	-
+0.25	2.31	2.17	106.5
+3.0	5.12	4.92	104.1
+7.5	10.26	9.42	108.9
2 Unspiked	2.01	-	-
+0.25	2.27	2.26	100.4
+3.0	5.10	5.01	101.8
+7.5	9.36	9.51	98.4
3 Unspiked	2.02	-	-
+0.25	2.35	2.27	103.5
+3.0	4.87	5.02	97.0
+7.5	8.57	9.52	90.0

LINEARITY

Three patient serum samples were diluted with calibrator 0. The results (in µIU/ml) are tabulated below:

Sample	Obs.Result	Exp.Result	Recovery%
1	9.36	-	-
1:2	4.53	4.68	96.8
1:4	2.31	2.34	98.7
1:8	1.08	1.17	92.3
2	10.89	-	-
1:2	5.65	5.45	103.7
1:4	2.96	2.72	108.8
1:8	1.32	1.36	97.1
3	11.85	-	-
1:2	6.03	5.93	101.7
1:4	2.43	2.96	82.1
1:8	1.18	1.48	79.7

COMPARATIVE STUDIES

The DIAsource Direct TSH ELISA kit (Kit A) was compared with two other competitors ELISA kits (Kit B and Kit C)

(Kit B). The results (in µIU/ml) are tabulated below:

Group	N	Kit A Mean	Kit B Mean	Kit C Mean
Random Males and Females	27	2.97	3.36	2.89

EXPECTED NORMAL VALUES

As for all clinical assays each laboratory should collect data and establish their own range of expected normal values.

Group	Range (µIU/ml)
Normal	0.3-5
Hyperthyroid	<0.15
Hypothyroid	>5.7

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	<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 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 Extracção	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>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
	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	Polyetylglykol
	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	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
	mikropłytki	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 (czterometylobenzydyny)	Kromogén TMB koncentrátum
	Roztwór chromogenu TMB (czterometylobenzydyny)	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					
	Партиден код					
	Каталожен номер					
	Контрол					
	Ин витро диагностично медицинско изделие					
	Производител					
	Съдържание достатъчно за <n> теста					
<table><tr><td>WASH</td><td>SOLN</td><td>CONC</td></tr></table>	WASH	SOLN	CONC	Концентриран измиващ разтвор		
WASH	SOLN	CONC				
<table><tr><td>CAL</td><td>0</td></tr></table>	CAL	0	Нулев калибратор			
CAL	0					
<table><tr><td>CAL</td><td>N</td></tr></table>	CAL	N	Калибратор #			
CAL	N					
<table><tr><td>CONTROL</td><td>N</td></tr></table>	CONTROL	N	Контрол #			
CONTROL	N					
<table><tr><td>Ag</td><td>125I</td></tr></table>	Ag	125I	Трейсър			
Ag	125I					
<table><tr><td>Ab</td><td>125I</td></tr></table>	Ab	125I	Трейсър			
Ab	125I					
<table><tr><td>Ag</td><td>125I</td><td>CONC</td></tr></table>	Ag	125I	CONC	Концентриран маркер		
Ag	125I	CONC				
<table><tr><td>Ab</td><td>125I</td><td>CONC</td></tr></table>	Ab	125I	CONC	Концентриран маркер		
Ab	125I	CONC				
	Епруветки					
<table><tr><td>INC</td><td>BUF</td></tr></table>	INC	BUF	Инкубационен буфер			
INC	BUF					
<table><tr><td>ACETONITRILE</td></tr></table>	ACETONITRILE	Ацетонитрил				
ACETONITRILE						
<table><tr><td>SERUM</td></tr></table>	SERUM	Серум				
SERUM						
<table><tr><td>DIL</td><td>SPE</td></tr></table>	DIL	SPE	Разредител за пробите			
DIL	SPE					
<table><tr><td>DIL</td><td>BUF</td></tr></table>	DIL	BUF	Буфер за разреждане			
DIL	BUF					
<table><tr><td>ANTISERUM</td></tr></table>	ANTISERUM	Антисерум				
ANTISERUM						
<table><tr><td>IMMUNOABSORBENT</td></tr></table>	IMMUNOABSORBENT	Имуноабсорбент				
IMMUNOABSORBENT						
<table><tr><td>DIL</td><td>CAL</td></tr></table>	DIL	CAL	Разредител за калибратора			
DIL	CAL					
<table><tr><td>REC</td><td>SOLN</td></tr></table>	REC	SOLN	Пресъздаващ разтвор			
REC	SOLN					
<table><tr><td>PEG</td></tr></table>	PEG	Полиетилен гликол				
PEG						
<table><tr><td>EXTR</td><td>SOLN</td></tr></table>	EXTR	SOLN	Екстрактов разтвор			
EXTR	SOLN					
<table><tr><td>ELU</td><td>SOLN</td></tr></table>	ELU	SOLN	Разтвор за елюиране			
ELU	SOLN					
<table><tr><td>GEL</td></tr></table>	GEL	Силикагелни пълнители				
GEL						
<table><tr><td>PRE</td><td>SOLN</td></tr></table>	PRE	SOLN	Пред-лечебен разтвор			
PRE	SOLN					
<table><tr><td>NEUTR</td><td>SOLN</td></tr></table>	NEUTR	SOLN	Неутрализиращ ратвор			
NEUTR	SOLN					
<table><tr><td>TRACEUR</td><td>BUF</td></tr></table>	TRACEUR	BUF	Маркерен буфер			
TRACEUR	BUF					
	Микротитърна пластина					
<table><tr><td>Ab</td><td>HRP</td></tr></table>	Ab	HRP	HRP конюгат / Конюгат на хрянова пероксидаза			
Ab	HRP					
<table><tr><td>Ag</td><td>HRP</td></tr></table>	Ag	HRP	HRP конюгат / Конюгат на хрянова пероксидаза			
Ag	HRP					
<table><tr><td>Ab</td><td>HRP</td><td>CONC</td></tr></table>	Ab	HRP	CONC	HRP конюгиран концентрат		
Ab	HRP	CONC				
<table><tr><td>Ag</td><td>HRP</td><td>CONC</td></tr></table>	Ag	HRP	CONC	HRP конюгиран концентрат		
Ag	HRP	CONC				
<table><tr><td>CONJ</td><td>BUF</td></tr></table>	CONJ	BUF	Буфер за конюгата			
CONJ	BUF					
<table><tr><td>CHROM</td><td>TMB</td><td>CONC</td></tr></table>	CHROM	TMB	CONC	Хромогенен TMB концентрат		
CHROM	TMB	CONC				
<table><tr><td>CHROM</td><td>TMB</td></tr></table>	CHROM	TMB	Хромогенен TMB разтвор			
CHROM	TMB					
<table><tr><td>SUB</td><td>BUF</td></tr></table>	SUB	BUF	Субстратен буфер			
SUB	BUF					
<table><tr><td>STOP</td><td>SOLN</td></tr></table>	STOP	SOLN	Стоп разтвор			
STOP	SOLN					
<table><tr><td>INC</td><td>SER</td></tr></table>	INC	SER	Инкубационен серум			
INC	SER					
<table><tr><td>BUF</td></tr></table>	BUF	Буфер				
BUF						
<table><tr><td>Ab</td><td>AP</td></tr></table>	Ab	AP	AP конюгат / конюгат на алкална фосфатаза			
Ab	AP					
<table><tr><td>SUB</td><td>PNPP</td></tr></table>	SUB	PNPP	Субстрат PNPP / пара нитрофенил фосфат			
SUB	PNPP					
<table><tr><td>BIOT</td><td>CONJ</td><td>CONC</td></tr></table>	BIOT	CONJ	CONC	Биотин конюгиран концентрат		
BIOT	CONJ	CONC				
<table><tr><td>AVID</td><td>HRP</td><td>CONC</td></tr></table>	AVID	HRP	CONC	Авидин HRP концентрат		
AVID	HRP	CONC				
<table><tr><td>ASS</td><td>BUF</td></tr></table>	ASS	BUF	Буфер за пробите			
ASS	BUF					
<table><tr><td>Ab</td><td>BIOT</td></tr></table>	Ab	BIOT	Биотин конюгат			
Ab	BIOT					
<table><tr><td>Ab</td></tr></table>	Ab	специфично анти тяло				
Ab						
<table><tr><td>SAV</td><td>HRP</td><td>CONC</td></tr></table>	SAV	HRP	CONC	стрептавидин HRP концентрат		
SAV	HRP	CONC				
<table><tr><td>NSB</td></tr></table>	NSB	не специфично свързване				
NSB						
<table><tr><td>2nd Ab</td></tr></table>	2nd Ab	второ анти тяло				
2nd Ab						
<table><tr><td>ACID</td><td>BUF</td></tr></table>	ACID	BUF	киселинизиращ буфер			
ACID	BUF					