



DHT-RIA

KIPI9900



DHT-RIA

Radioimmunoassay for the Quantitative Determination of 5 α -Dihydrotestosterone in Human Serum or Plasma

KIP19900

IN VITRO DIAGNOSTIC USE

en

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1. INTENDED USE:

For IN VITRO determination of serum or plasma DHT levels.

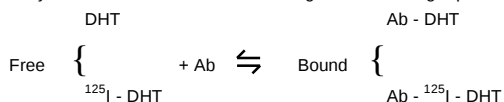
5 α -Dihydrotestosterone (DHT; 17 β -Hydroxy-5 α -androstan-3-one), the most potent naturally-occurring androgen, is produced from testosterone through the action of cholesteryl 5 α -reductase [1]. The concentrations of 5 α -reductase are highest in certain peripheral tissues, including genital skin and hair follicles, and is localized intracellularly in apparent association with the nuclear membrane. DHT exerts its biological action by intracellular binding to the androgen receptor; this complex is then transferred to the nucleus where DNA-binding occurs with resultant effects on DNA transcription [2]. Most of the residual DHT undergoes intracellular metabolism to 3 α -androstenediol and 3 α -androstenediol glucuronide. Only a small proportion of DHT escapes into the peripheral circulation, where it is present primarily complexed to sex-hormone binding globulin [3].

Testosterone causes virilization of the Wolffian ducts during fetal life, while DHT is responsible for the development of the male external genitalia and prostate, and is primarily responsible for the physical changes which occur during male sexual maturation. An autosomal-recessive genetic deficiency of 5 α -reductase, sometimes called male pseudohermaphroditism or pseudovaginal perineoscrotal hypospadias, leads to inadequate differentiation of DHT-dependent peripheral tissues. Male infants with this disorder have ambiguous genitalia and are often raised as females, although significant virilization may occur later in life presumably due to the natural increase in testosterone levels [2].

Measurement of DHT concentrations can be complicated by antibody cross-reactivity to testosterone. The DHT Double Antibody radioimmunoassay utilizes a sample oxidation / extraction procedure to remove most of the testosterone, coupled with a specific immunoassay for DHT.

2. PRINCIPLE OF THE METHOD:

The 5 α dihydrotestosterone (DHT) DA RIA obeys the law of mass action according to the following equation :



The procedure follows the basic principle of radioimmunoassay where there is competition between the radioactive and non-radioactive antigen for a fixed number of antibody binding sites. The amount of (I-125)-labeled analyte bound to the antibody is inversely proportional to the concentration of unlabeled analyte present. The separation of free and bound antigen is achieved by using a double antibody system.

3. MATERIAL PROVIDED AND STORAGE:

Stored at 2 - 8°C, the material can be used up to the expiration date printed on each label.

3.1. CAL

Stock solution in ethyl alcohol, containing 100ng/ml.

Preparation of the curve.

Concentration (pg/ml)	Calibrator (ml)	Buffer (ml)	
2500	Stock : 0.1	3.9	= Cal 7
1000	Stock : 0.1	9.9	= Cal 6
500	Cal 6 : 1.0	1.0	= Cal 5
200	Cal 6 : 0.2	0.8	= Cal 4
100	Cal 6 : 0.1	0.9	= Cal 3
50	Cal 6 : 0.1	1.9	= Cal 2
25	Cal 2 : 0.5	0.5	= Cal 1

The calibrator 0 pg/ml is the diluting buffer.

Store at 2-8°C for up to 3 weeks.

3.2. Ag 125I

DHT ¹²⁵I (yellow)

1 vial, 10.5 ml, containing < 5 μ Ci (< 185 kBq) of ¹²⁵I labelled DHT in protein-based buffer containing sodium azide (< 0.1%) as a preservative. Store at 2-8°C.

3.3. ANTISERUM

Ab DHT

2 vials, 5.2 ml, containing lyophilised anti-DHT rabbit serum (blue coloured) and sodium azide (<0.1%) as a preservative. Reconstitute by adding 5.2 ml of buffer. Store at 2-8°C.

3.4. PEG

1 vial, 105 ml, containing sheep anti-rabbit gamma globulin in a buffer, polyethylene glycol as a precipitating aid and sodium azide (<0.1 %) as a preservative. Store at 2-8°C.

3.5. KMnO₄

1 vial, 5 ml, containing KMnO₄ solution. Store at 2-8°C.

3.6. BUF

1 vial, 100 ml, Phosphate Buffered Saline 0.1M containing sodium azide (<0.1%) as a preservative. Store at 2-8°C.

3.7. CONTROL N

N = 2

2 vials horse serum containing preservative (NaN₃ < 0.1%). The control sera are to be assayed along with the patient samples. The ranges for the control sera are printed on the vial labels.

Before use, reconstitute the contents of the controls with 2 ml of distilled water. Mix gently to avoid foaming. Wait at least 15 minutes after reconstitution before dispensing. After reconstitution, the solutions are stable for 3 weeks at 2-8°C. or for a longer period if stored at -20°C.

All reagents and samples must be allowed to reach room temperature and mixed thoroughly by gentle inversion before use.

4. MATERIAL REQUIRED BUT NOT PROVIDED :

- Refrigerator (2-8°C).
- 12 x 75 mm plastic and glass test tubes.
- Test tube rack for 12 x 75 mm tubes.
- Precision pipette to deliver 100 μ l.
- Precision repeating pipette to deliver 100 μ l, 200 μ l, 500 μ l and 1 ml.
- Controlled-temperature water bath, 37 $\pm$ 2°C.
- Centrifuge (preferably refrigerated) capable of 1500 x g.
- Absorbent material for blotting tubes.
- Gamma counter.
- Semi-log (linear-log) graph paper.
- Vortex mixer.
- Diethyl ether HPLC grade
- Hexane HPLC grade
- Ethanol HPLC grade

5. METHODOLOGY

5.1. Collection and handling of blood samples:

The blood sample may be collected into a dry tube or one containing an anticoagulant. If heparin is used, only the minimum required should be added to avoid clotting.

After separation from the red blood cells, plasma or serum samples may be assayed immediately, within 24 hours if stored at 2 - 8°C, or later, after period up to several months if stored at -20°C. Repeating freezing and thawing must be avoided.

5.2. Preparation of the samples:

1. Extract 300 μ l of serum or plasma and controls by adding 3 ml of Diethyl Ether in **glass** tubes (duplicate).
2. Vortex or shake for 2 minutes.
3. Centrifuge. The recommend speed is 1000 g for 5 minutes.
4. Freeze aqueous layer in a freezer.
5. Transfer solvent into glass tubes and evaporate to dryness.
6. Add 0.5 ml of buffer and vortex for 30 seconds.
7. Add 50 μ l of the oxidation solution (KMnO₄)
8. Incubate at 37°C for 20 minutes.
9. Extract DHT by adding 3 ml of a mixture of Hexane:Ethanol (98:2). Vortex or shake for 2 minutes. Centrifuge. The recommend speed is 1000 g for 5 minutes.
10. Transfer 2 ml of the organic layer into glass tubes and evaporate to dryness.

The tubes are now ready for the RIA determination.

5.3. Assay procedure:

Reagents stored at 2° - 8° C. must be brought at room temperature prior to use. Do not mix reagents of different lots. Label the tubes for T (Total Counts), calibrators, samples and control sera.

Perform the assay in duplicate. Calibrators, controls and samples must be assayed at the same time.

1. Label and arrange tubes in duplicate for total counts, non-specific binding, calibrators, controls and unknowns.
2. Add 200 μ l of the Buffer into extracted tubes and incubate for 20 minutes at room temperature. Vortex now and again.
3. Add 200 μ l of the prepared calibrators into glass tubes.

4. Add 100 µl of the antibody anti-DHT to all tubes except Total counts and NSB.
5. Add 100 µl of DHT ¹²⁵I Reagent to each tube.
6. Vortex, cover and incubate all tubes at 37°C for 1 hour.
7. Add 1 ml of Precipitating Reagent to all tubes except the Total Count tubes and immediately vortex all tubes. THE PRECIPITATING REAGENT MUST BE MIXED THOROUGHLY BEFORE USE.
8. Incubate at room temperature for 10 to 15 minutes.
9. Centrifuge all tubes except the Total Count tubes for 15 minutes at 1500 x g.
10. Aspirate or decant and discard the supernatant by inverting the tubes. Blot the tubes to remove any droplets adhering to the rim before returning the tubes to the upright position.
11. Count the pellet remaining in the tubes in a gamma counter for one minute.
12. Construct a calibration curve for each test run as described below.

5.4. Data processing:

Determine the mean count rate for each set of duplicate tubes.
Calculate the ratio B/B0 as follows:

$$B/B0 \% = [\text{Cal or Sample cpm} / B0 (\text{Cal 0}) \text{cpm}] \times 100$$

Draw the calibration curve on semi logarithmic paper by plotting the ratio B/B0 % (linear scale) obtained for each calibrator versus its respective concentration expressed in pg/ml (logarithmic scale). DHT concentrations in samples may be read directly from the calibration curve.

If a computer is used to calculate the results, the data can be fitted to the appropriate equation: 4 PL weighted.

5.5. Example of a typical assay:

	Contents (pg/ml)	Net average bound counts (cpm)	B/Bo (%)	DHT (ng/ml)
Total counts	-	36935	-	-
NSB	-	888	2.4	-
Cal 0	0	27000	100	-
Cal 1	25	24747	91.4	-
Cal 2	50	23559	86.8	-
Cal 3	100	19816	72.5	-
Cal 4	200	15742	56.9	-
Cal 5	500	9844	34.3	-
Cal 6	1000	6277	20.6	-
Cal 7	2500	3319	9.3	-
Sample 1	-	7750	27	0.6

Example of a typical assay, do not use for calculations

6. PERFORMANCE CHARACTERISTICS:

6.1. Specificity

Steroid	% Cross-reactivity
DHT	100.00
Testosterone	0.19
Estrilol	0.03
Estradiol	0.005
Progesterone	0.004
Free DHEA	N.D.

6.2. Minimum detectable concentration of DHT:

The minimum detectable concentration has been assayed at ± 7 pg/tube (± 20 pg/ml) and corresponds to the concentration given by two standard deviations below the mean cpm of 20 replicate determinations of the zero calibrators.

6.3. Recovery test:

When sera of known DHT contents have their DHT supplemented by addition of DHT in equal volumes (1/1), a satisfactory correlation between theoretical and assayed DHT is obtained.

Added DHT (pg/ml)	0	50	100	200	500	1000
Theoretical	-	180.5	205.5	255.6	405.6	655.6
Assayed DHT (pg/ml)	311.1	185.1	210.5	260.4	429.5	672.8
% recovery	-	102.5	102.4	101.9	105.9	102.6

6.4. Dilution test:

The dilution test indicates that there is immunological identity between the DHT present in the sample and the DHT used to calibrate the calibration curve.

Dilution Factor	1	1/2	1/4	1/8	1/16
Assayed DHT (pg/ml)	737	373.4	192.5	88	52.1
Expected DHT (pg/ml)	-	369	184	92	46

6.5. Reproducibility:

	Within assay variation 10 replicates		Between assay variation 12 replications	
	Mean (pg/ml)	%CV	Mean (pg/ml)	%CV
Pool 1	159.3	6	60.5	18.6
Pool 2	411.6	4.8	201.4	12.3
Pool 3	700.1	4.8	653.9	8.7

7. LIMITATION OF THE PROCEDURE

- 7.1. The results obtained from this or any other diagnostic kit should be used and interpreted only in the context of an overall clinical picture.
- 7.2. Do not use lipemic, haemolyzed, icteric or turbid specimens.

8. EXPECTED VALUES

It is recommended that each laboratory establishes its own reference values.

		DHT (pg/ml)
Males	Pre-puberty	50
	Adult	250 - 1000
Females	Follicular phase	50 - 200
	Luteal phase	100 - 300
	Menopausal	< 100

9. WARNING AND PRECAUTION

For IN VITRO DIAGNOSTIC use only

CAUTION: Radioactive material

This kit contains ¹²⁵I (half-life: 60 days), emitting ionizing X (28 keV) and γ (35.5 keV) radiations.

This radioactive product can be transferred to and used only by authorized persons; purchase, storage, use and exchange of radioactive products are subject to the legislation of the end user's country. In no case the product must be administered to humans or animals.

All radioactive handling should be executed in a designated area, away from regular passage. A logbook for receipt and storage of radioactive materials must be kept in the lab. Laboratory equipment and glassware, which could be contaminated with radioactive substances, should be segregated to prevent cross contamination of different radioisotopes.

Any radioactive spills must be cleaned immediately in accordance with the radiation safety procedures. The radioactive waste must be disposed of following the local regulations and guidelines of the authorities holding jurisdiction over the laboratory. Adherence to the basic rules of radiation safety provides adequate protection.

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

WARNING: Sodium azide

Some components contain sodium azide as preservative agent (NaN₃ < 0.1%). Dispose of the reagents by flushing with large amount of water through the plumbing system.

WARNING: Potentially infectious material

Handle all components (and all patient samples) as if capable of transmitting viral diseases such as hepatitis B and C and the acquired immunodeficiency syndrome (AIDS).

Source material derived from human body fluids or organs and used in the preparation of this kit were tested and found negative for hepatitis B and C surface antigen by immunoassay. However, no known test can guarantee that such material does not contain the causative agent of viral hepatitis.

Likewise, all human materials used in the preparation of this kit were screened for the presence of the HIV-1 and 2 antibodies and found negative by enzyme-immunoassay. However, absence of these antibodies cannot guarantee the absence of the viral agent responsible for the acquired immunodeficiency syndrome.

WARNING: Ethanol

The calibrator stock solution contains ethanol, which is highly flammable.

10. BIBLIOGRAPHY

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2. Pang S, Riddick L: Hirsutism. IN Lifshitz F: *Pediatric Endocrinology, A Clinical Guide, second edition*. Marcel Dekker, New York, 1990, pp. 259-291.
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4. Yalow R, Berson S: Introduction and general considerations. IN: Odell WD, Doughday WH (eds): *Principles of Competitive Protein Binding Assays*. J. B. Lippincott Co., Philadelphia, 1971, pp. 1-19.
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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
	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>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	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>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	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	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

	<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 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