

Janvier 2019 – Modèle 026



Cisbio Bioassays

Parc Marcel Boiteux - BP 84175 - 30200 Codolet / France - Tél. 33 (0)4.66.79.67.00



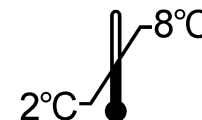
**TESTOSTERONE**

REF













**TESTO-CT2**



IVD



<p><b>Trousse pour le dosage radioimmunologique de la Testostérone dans le sérum</b></p> <p><b>Pour diagnostic In Vitro</b></p> <p>La trousse contient :</p> <table border="0"> <tr> <td>Tubes revêtus</td> <td>2X50 tubes</td> </tr> <tr> <td>Traceur <math>\leq 200</math> kBq</td> <td>1 x 55 mL</td> </tr> <tr> <td>Calibrateur 0</td> <td>1 x qsp 0,5 mL</td> </tr> <tr> <td>Calibrateurs 1 - 5</td> <td>5 x qsp 0,5 mL</td> </tr> <tr> <td>Notice d'utilisation</td> <td>1</td> </tr> </table> <p><b>Attention:</b> Certains réactifs contiennent de l'azoture de sodium</p>	Tubes revêtus	2X50 tubes	Traceur $\leq 200$ kBq	1 x 55 mL	Calibrateur 0	1 x qsp 0,5 mL	Calibrateurs 1 - 5	5 x qsp 0,5 mL	Notice d'utilisation	1	<p><b>Radioimmunoassay kit for the quantitative determination of Testosterone in human serum</b></p> <p><b>For In Vitro diagnostic use</b></p> <p>Kit content :</p> <table border="0"> <tr> <td>Coated tubes</td> <td>2X50 tubes</td> </tr> <tr> <td>Tracer <math>\leq 200</math> kBq</td> <td>1 x 55 mL</td> </tr> <tr> <td>Calibrator 0</td> <td>1 x qs 0.5 mL</td> </tr> <tr> <td>Calibrators 1 - 5</td> <td>5 x qs 0.5 mL</td> </tr> <tr> <td>Instruction for use</td> <td>1</td> </tr> </table> <p><b>Warning:</b> Some reagents contain sodium azide</p>	Coated tubes	2X50 tubes	Tracer $\leq 200$ kBq	1 x 55 mL	Calibrator 0	1 x qs 0.5 mL	Calibrators 1 - 5	5 x qs 0.5 mL	Instruction for use	1	<p><b>Radioimmunassay kit zur Bestimmung von Testosteron in Serum</b></p> <p><b>Zur In Vitro Diagnostik</b></p> <p>Inhalt des Kits :</p> <table border="0"> <tr> <td>Teströhrchen beschichtet</td> <td>2X50 Röhrchen</td> </tr> <tr> <td>Tracer <math>\leq 200</math> kBq</td> <td>1 x 55 mL</td> </tr> <tr> <td>Kalibrator 0</td> <td>1 x qs 0,5 mL</td> </tr> <tr> <td>Kalibratoren 1 – 5</td> <td>5 x qs 0,5 mL</td> </tr> <tr> <td>Gebrauchsinformation</td> <td>1</td> </tr> </table> <p><b>Achtung:</b> Einige Reagenzien enthalten Natriumazid</p>	Teströhrchen beschichtet	2X50 Röhrchen	Tracer $\leq 200$ kBq	1 x 55 mL	Kalibrator 0	1 x qs 0,5 mL	Kalibratoren 1 – 5	5 x qs 0,5 mL	Gebrauchsinformation	1
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<p><b>kit per il dosaggio radioimmunologico del testosterone nel siero</b></p> <p><b>Per uso diagnostico In Vitro</b></p> <p>Contenuto del kit :</p> <table border="0"> <tr> <td>Provette coattate</td> <td>2X50 provette</td> </tr> <tr> <td>Tracciante <math>\leq 200</math> kBq</td> <td>1 x 55 mL</td> </tr> <tr> <td>Calibratore 0</td> <td>1 xq.b a 0,5 mL</td> </tr> <tr> <td>calibratori 1 – 5</td> <td>5 xq.b a 0,5 mL</td> </tr> <tr> <td>Istruzioni per l'uso</td> <td>1</td> </tr> </table> <p><b>Attenzione:</b> Alcuni reagenti contengono sodio azide</p>	Provette coattate	2X50 provette	Tracciante $\leq 200$ kBq	1 x 55 mL	Calibratore 0	1 xq.b a 0,5 mL	calibratori 1 – 5	5 xq.b a 0,5 mL	Istruzioni per l'uso	1	<p><b>Equipo inmunorradiométrico para la determinación cuantitativa de testosterona en suero</b></p> <p><b>Para uso de diagnóstico In Vitro</b></p> <p>Contenido del equipo :</p> <table border="0"> <tr> <td>Tubos recubiertos</td> <td>2X50 tubos</td> </tr> <tr> <td>Trazador <math>\leq 200</math> kBq</td> <td>1 x 55 mL</td> </tr> <tr> <td>Calibrador 0</td> <td>1 x csp 0,5 mL</td> </tr> <tr> <td>calibradores 1 – 5</td> <td>5 x csp 0,5 mL</td> </tr> <tr> <td>Instrucciones de uso</td> <td>1</td> </tr> </table> <p><b>Precauciones:</b> Algunos reactivos contienen azida sódica</p>	Tubos recubiertos	2X50 tubos	Trazador $\leq 200$ kBq	1 x 55 mL	Calibrador 0	1 x csp 0,5 mL	calibradores 1 – 5	5 x csp 0,5 mL	Instrucciones de uso	1	<p><b>Κιτ Radioimmunoassay για τον ποσοτικό προσδιορισμό της τεστοστερόνης σε ανθρώπινο ορό</b></p> <p><b>Για διαγνωστική χρήση in vitro</b></p> <p>Περιεχόμενα της τυποποιημένης συσκευασίας</p> <table border="0"> <tr> <td>Επικαλυμμένοι σωλήνες</td> <td>2X50 σωλήνων</td> </tr> <tr> <td>Ιχνηθέτης <math>\leq 200</math> kBq</td> <td>1 x 55 mL</td> </tr> <tr> <td>Πρότυπο 0</td> <td>1 x qs 0,5 mL</td> </tr> <tr> <td>Πρότυπα 1 – 5</td> <td>5 x qs 0,5 mL</td> </tr> <tr> <td>Οδηγίες χρήσεως</td> <td>1</td> </tr> </table> <p><b>Προσοχή:</b> Ορισμένα αντιδραστήρια περιέχουν αζίδιο νατρίου</p>	Επικαλυμμένοι σωλήνες	2X50 σωλήνων	Ιχνηθέτης $\leq 200$ kBq	1 x 55 mL	Πρότυπο 0	1 x qs 0,5 mL	Πρότυπα 1 – 5	5 x qs 0,5 mL	Οδηγίες χρήσεως	1
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	FRA	ENG	DEU	ITA	SPA	ELL	SWE	POL	HUN	BUL	SRB
	<b>Explication des symboles</b>	<b>Explanation of symbols</b>	<b>Erläuterung der Symbole</b>	<b>Spiegazione dei simboli</b>	<b>Significado de los símbolos</b>	<b>Επεξήγηση των συμβόλων του</b>	<b>Symbol förklaring</b>	<b>Wyjaśnienie symboli</b>	<b>Jelmagyarázat</b>	<b>Обяснение на символите</b>	<b>Objašnjenje simbola</b>
	Conforme aux normes européennes	European conformity	CE-Konformitätskennzeichnung	Conformita europea	Conformidad europea	European conformity	Förenlig med europeiska normer	Zgodne z normami europejskimi	Megfelel az európai szabványoknak	Европейската съответствие	Evropska usaglašenost
	T° limite de stockage	Storage temperature limitation	Limitierung der Lagertemperatur	Limiti per la temperatura di conservazione	Limites de temperatura de almacenamiento	Περιορισμός θερμοκρασίας φύλαξης	T°-gräns vid förvaring	Graniczna temperatura przechowywania	Tárolási hőmérséklet határ	Ограничаване на температурата на съхранение	Ograničenje temperature za čuvanje
	N° de lot	Batch code	Chargencode	codice lotto	Código de lote	Κωδικός παρτίδας	Lotnr.	Numer partii	Gyártási szám	номер	Šifra serije
	Utiliser jusqu'au	Use by	Verwendbar bis	utilizzare entro	Consumir antes de	Ημερομ. λήξης	Används senast	Zużyć do	Felhasználható az alábbi dátumig :	Срок валидност на	Upotrebiti do
	Consulter la notice d'utilisation	Consult operating instructions	Das Handbuch zu Rate ziehen	consultare le istruzioni per l'USO	Consultar las instrucciones de manejo o funcionamiento	Ανατρέξτε στις οδηγίες λειτουργίας	Läs bruksanvisning en	Patrz dołączona ulotka	Olvassa el a használati utasítást	Консултирайте инструкциите за работа	Pogledajte uputstvo za upotrebu
	Diagnostic In Vitro	In Vitro Diagnostic device	In-Vitro Diagnostische Anwendung	Dispositivo Diagnostico In Vitro	Dispositivo de diagnóstico In Vitro	διαγνωστική συσκευή In Vitro	In vitro-diagnos	Diagnostyka In Vitro	In vitro diagnosztika	За ин витро диагностика устройство	Uređaj za dijagnostiku <i>in vitro</i>
	Fabriqué par	Manufactured by	Hergestellt von	Prodotto da	Fabricado por	Κατασκευάζεται από την	Tillverkad av	Wyprodukowan e przez	Gyártja:	Произведено от	Proizveo
	Référence	Catalogue number	Katalog Nr.	N. catalogo	Número de catálogo	Αριθμός καταλόγου	Referens	Wzorzec	Referenciakészít mény	Каталожен номер	Kataloški broj
	Nombre de tubes	Number of determinations	Anzahl der Bestimmungen	Numero di determinazioni	Número de determinaciones	Αριθμός προσδιορισμών	Antal rör	Liczba próbowek	A kémcsövek száma	Брой определяния	Broj određivanja
	Tubes revêtus	Coated tubes	beschichtete Röhrchen	Provette coattate	Tubos recubiertos	Επιστρωμένα σωληνάρια	Belagda rör	Probówki powlekane	Bevont kémcsövek	Покритите тръби	Obložene epruvete
	Traceur radioactif	Radioactive tracer	Radioactiver Tracer	Traccianti radioattivo	Trazador radiactivo	Ραδιοενεργός ιχνηθέτης	Radioaktiv tracer	Znacznik radioaktywny	Nyomjelző izotóp	Индикатор	Radioaktivni indikator
	Calibrateur	Calibrator	Kalibrator	Calibratore	Calibrador	Βαθμονομητής	Kalibrator	Kalibrator	Kalibrátor	Калибратор	Kalibrator

**FRA** **Modifications par rapport à la version précédente :**  
Mise à jour du code langue Serbe.

**ENG** **Changes from the previous version:**  
Update of the Serbian language code.

**DEU** **Änderungen gegenüber der Vorgängerversion:**  
Aktualisierung des serbischen Sprachcodes.

**ITA** **Modifiche rispetto alla versione precedente:**  
Aggiornamento del codice della lingua serba.

**SPA** **Los cambios a la versión anterior:**  
Actualización del código de idioma serbio.

**ELL** **Οι αλλαγές από την προηγούμενη έκδοση:**  
Ενημέρωση του κώδικα της σερβικής γλώσσας.

**SWE** **Ändringar från den tidigare versionen:**  
Uppdatering av den serbiska språkkoden.

**POL** **Zmiany w stosunku do poprzedniej wersji:**  
Aktualizacja kodu języka serbskiego.

**HUN** **Változások az előző verzióhoz képest:**  
A szerb nyelvi kód frissítése.

**BUL** **Промени от предишната версия :**  
Актуализиране на кода на сръбския език.

**SRB** **Promeneod prethodne verzije:**  
Ažuriranje koda srpske jezika.

## 1. NAME AND INTENDED USE

**TESTO-CT2** is a radioimmunoassay kit for the quantitative determination of Testosterone in human serum. The kit is intended for professional use.

## 2. INTRODUCTION

Testosterone (MW 288.4) is a steroid hormone mainly synthesized by the Leydig cells of the testes in males and by the ovaries and adrenal cortex in female. Testosterone production in both sexes is regulated mainly by LH. Circulating testosterone is 60% bound to a globulin: Sex Hormone Binding Globulin (SHBG). Only 1% of Testosterone is free, and is referred to as the active form.

At puberty, pituitary gonadotrophins increase, stimulating testicular maturation: LH acts directly on the interstitial mesenchymal elements, causing them to secrete testosterone and estrogens, as they are developing into mature Leydig cells. FSH acts on the seminiferous tubules to induce and maintain normal spermatogenesis. At the onset of puberty, testosterone stimulates the development of male sex characteristics (such as external genitalia, accessory sex organs, hair growth, linear growth, voice timbre, psyche, muscle and bone tissue mass) which it will maintain throughout life. The age at which maximum testosterone levels are observed varies from 15-20 to 25 years according to the theories. Testosterone is secreted episodically throughout the day, so that multiple peaks can be observed if frequent samplings are made (maximum peak being around 8.00am).

Testosterone measurement is used in the following cases:

- Delayed puberty and androgen deficiency in men.
- Androgen excess in female (Hirsutism).
- Androgen excess in children.
- Monitoring of endocrine treatment.

The Testosterone measurement is not sufficient in the assessment of gonadal function. In the male it must be supplemented at least with careful clinical examination of the patient, measure of LH, FSH and evaluation of the ejaculate. In females with hirsutism syndrome, additional tests are needed to differentiate between ovarian and adrenal origins of elevated testosterone. These tests may include, quantitative determination of serum cortisol, ACTH, LH and FSH.

## 3. PRINCIPLE

The principle of the assay is based on the competition between the labelled testosterone and testosterone contained in calibrators or specimens to be assayed against a fixed and limited number of anti-testosterone antibody binding sites bound to the solid phase (coated tubes).

After incubation, the unbound tracer is easily removed by a washing step.

The amount of labelled testosterone bound to the antibody is inversely related to the amount of unlabelled testosterone present in the sample.

## 4. REAGENTS

Each kit contains enough reagents for 100 tubes. The expiry date is marked on the external label.

REAGENTS	SYMBOLS	QUANTITY	STORAGE
<b>COATED TUBES:</b> ready to use. Anti-testosterone rabbit polyclonal antibodies coated at the bottom of the tube.	CT	2X50 tubes	2-8°C until the expiry date. Once opened keep the box in the resealable plastic bag with the dessicant bag
<b><sup>125</sup>I-TESTOSTERONE:</b> ready to use. <sup>125</sup> I labelled testosterone, buffer, yellow dye and preservative. ≤ 200 kBq (≤ 5,4μCi)	TRACER	1 55 mL vial	2-8°C until the expiry date.
<b>CALIBRATOR "0":</b> freeze-dried. Human serum, Sodium Azide and preservative.*	CAL	1 vial reconstitute with 0.5 mL distilled water	2-8°C until the expiry date. 2-8°C 12 weeks after reconstitution within the limits of the expiry date of the kit.
<b>CALIBRATORS 1 to 5:</b> freeze-dried. Synthetic testosterone, human serum, sodium azide and preservative. 0.5 - 1.5 - 5 - 15 - 50 nmol/L*	CAL	5 vials reconstitute with 0.5 mL distilled water	2-8°C until the expiry date. 2-8°C 12 weeks after reconstitution within the limits of the expiry date of the kit.

\* Calibrated against an in-house master calibrator set prepared by gravimetry. The values shown above are the target values. Real values of calibrators are indicated on the labels. Calibrator traceability is performed to the reference method, Isotope Dilution Mass spectrometry (IDMS).

## 5. PRECAUTIONS FOR USE

### 5.1. Safety measures

Raw materials of human origin contained in the reagents of this kit have been tested with licensed kits and found negative for the anti-HIV 1, anti-HIV 2, anti-HCV antibodies and the HBs antigen. However as it is impossible to strictly guarantee that such products will not transmit hepatitis, the HIV virus, or any other viral infection, all raw materials of human origin including the samples to be assayed must be treated as potentially infectious.

Do not pipette by mouth.

Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.

Wear disposable gloves while handling kit reagents or specimens and wash hands thoroughly afterwards.

Avoid splashing.

Decontaminate and dispose of specimens and all potentially contaminated materials as if they contained infectious agents. The recommended method of doing this is autoclaving for a minimum of one hour at 121.5°C. Sodium azide may react with lead or copper piping to form highly explosive metal azides. During waste disposal, flush the drains thoroughly to prevent a build-up of these products.

### 5.2. Basic radioprotection rules

This radioactive product may only be received, purchased, stored or used by persons so authorized, and by laboratories covered by such authorization. The solution should under no circumstance be administered to humans or to animals. The purchase, storage, use or exchange of radioactive products are subject to the laws in force in the user's country. The enforcement of the basic rules for handling radioactive products ensures adequate security.

A summary of these is given below :

Radioactive products must be stored in their original containers in a suitable area.

A record of the reception and storage of radioactive products must be kept up to date.

Handling of radioactive products should take place in a suitably-equipped area with restricted access (controlled zone).

Do not eat, drink, smoke or apply cosmetics in a controlled zone. Do not mouth-pipette radioactive solutions.

Avoid any direct contact with all radioactive products by using laboratory coats and protective gloves.

Contaminated laboratory equipment and glassware must be disposed of immediately after contamination to prevent cross-contamination of different isotopes.

Any contamination or radioactive substance loss should be dealt with in accordance with the established procedures.

All radioactive waste disposal must be carried out according to the regulations in force.

### 5.3. Handling precautions

Do not use kit components beyond their expiry date.

Do not mix reagents from different batches.

Avoid any microbial contamination of the reagents or of the water used for washing.

Fully respect the incubation times and the washing instructions indicated.

## 6. SPECIMEN COLLECTION AND PREPARATION

Assay is carried out on sera extracted from venous blood sample, following the normal precautions for venipuncture.

Samples may be stored for up to 12 hours at room temperature or up to 3 days at 2-8 °C . For longer periods they may be separated in aliquots and stored frozen at -20°C for 2 years.

Repeated freezing and thawing should be avoided.

### Dilutions

Samples with suspected high testosterone concentration may be diluted 1 + 1 using 0.9 % NaCl.

It is recommended that disposable plastic tubes be used when carrying out the dilutions.

## 7. ASSAY PROCEDURE

### 7.1. Material required

Precision micropipettes or similar, with disposable tips, capable of dispensing 25 µL, 500 µL and 1 mL. Their calibration should be checked regularly.

Distilled water.

Vortex type mixer.

Parafilm.

Aspirating device.

Water bath (37°C)

Plastic film

Disposable plastic test-tubes (for measurement of total activity)

Gamma scintillation counter calibrated for 125 Iodine.

### 7.2. Reconstitution of the calibrators

Reconstitute the calibrators with 0.5 mL of distilled water. Recap the vial. Mix gently by inversion to assure complete dissolution of the freeze-dried material.

N.B.: The reconstituted calibrators should stand at least 30 minutes after reconstitution before proceeding.

### 7.3. Protocol

All reagents should be brought to room temperature (18-25°C) at least 30 minutes before their use. Dispensing of reagents is also carried out at room temperature.

The assay requires the following groups of tubes:

T group, for the total activity determination.

Calibrator groups, to establish the calibrator curve.

Sx groups, for the test samples.

It is recommended to perform the assay in duplicate for the calibrator groups and samples.

Follow the order in which reagents are to be added:

**Dispense** 25 µL of calibrators and samples to be assayed into the corresponding labeled coated tubes.

**Add** 500 µL of <sup>125</sup>I -Testosterone to each tube (and T group).

**Mix** each tube gently with a Vortex-type mixer.

**Cover** tubes with plastic film (parafilm).

**Incubate** 1 hours at 37°C in a water bath.

**Aspirate** liquid from each assay tube (except T tubes).

**Rinse** each coated tube (except T tubes) with 1 mL of distilled water.

**Aspirate** the solution (except T tubes).

**Measure** the remaining radioactivity bound to the tubes with a gamma scintillation counter calibrated for 125 Iodine.

## 8. QUALITY CONTROL

Good laboratory practices require the use of quality control samples in each series of assays to check the quality of the results obtained. All specimens should be treated identically, and result analysis using the appropriate statistical methods is recommended.

## 9. RESULTS

For each group of tubes compute the mean counts.

Calculate B/T value for the CAL0 and calculate B/Bo values for all the calibrators and samples. Draw up the calibration curve by plotting the B/Bo of the calibrators against their concentrations.

Read sample values directly from the calibration curve, and correct the read value for the dilution factor, if necessary. The kit was validated using reference samples measured by gas chromatography mass spectrometry with isotopic dilution.

Conversion nmol/L to ng/mL may be accomplished by :

$$\text{testosterone (ng/mL)} = \text{testosterone (nmol/L)} \times 0.288$$

The forced spline mathematical fitting model is recommended for calibration curve. Other fitting model may give slightly different results.

**Typical calibration curve** (example only) : these data must not be substituted for results obtained in the laboratory.

Groups of Tubes	Mean CPM	B/T x 100	B/Bo x 100	Concentration nmol/L
T	58076	-	-	-
CAL 0 0 nmol/L	33150	57.1	100	-
CAL 1 0.5 nmol/L	28265	-	85.3	-
CAL 2 1.5 nmol/L	23618	-	71.2	-
CAL 3 5 nmol/L	16341	-	49.3	-
CAL 4 15 nmol/L	11088	-	33.4	-
CAL 5 50 nmol/L	5427	-	16.4	-
Sample A	8044	-	24.3	28.5
Sample B	22933	-	69.2	1.6

## 10. PROCEDURAL LIMITATIONS

Strict adherence to the exact procedures described within this package insert and careful technique should be exercised to obtain reliable results with the TESTO-CT2 kit.

The measurement of serum testosterone is not sufficient in the assessment of gonadal function. The testosterone RIA kit measures total unconjugated testosterone, ie protein-bound and non protein-bound. If the carrier plasma proteins ( SHBG, Albumin ) are likely to be abnormally low (eg in liver disease) or high (eg during oestrogen therapy, pregnancy, before puberty, in advanced age males), the respective changes in the fraction of the free testosterone must be considered when the results are interpreted.

Total testosterone values cannot be interpreted accurately in female patients treated with Danazol.

## 11. EXPECTED VALUES

Each laboratory must establish its own range of normal values. Testosterone levels from healthy, fasting individuals obtained utilizing the TESTO-CT2 kit are presented in table below (indicative values) :

	n	Range ( nmol/L )
MALE	87	8.7 - 36.9
FEMALE	175	nd - 3.3

## 12. SPECIFIC CHARACTERISTICS OF THE ASSAY

### 12.1. Imprecision

This was evaluated with samples with different concentrations assayed either 20 times in the same series or once in 10 different series.

Samples	Within-run		Samples	Between-run	
	Mean (nmol/L)	(%) CV		Mean (nmol/L)	(%) CV
1	1.3	8.9	5	3.3	11.6
2	5.4	5.9	6	4.9	8.5
3	16.3	4.6	7	12.9	6.5
4	31.6	3.1	8	28.8	5.2

### 12.2. Recovery test

Known quantities of Testosterone were added into different serum base pools, including both normal male and normal female samples (n = 6). The recovery percentage of Testosterone obtained was 103.0 % +/- 7.2 % (SD), range was 88.0 % – 123.0 %.

### 12.3. Dilution

Samples with high testosterone concentration may be diluted 1 + 1 using 0.9 % NaCl.

### 12.4. Interfering substances

Serum bilirubin concentration  $\leq 340 \mu\text{mol/L}$  does not interfere. Serum hemoglobin concentration  $\leq 2 \text{ g/L}$  does not interfere. The use of highly lipemic samples is not recommended.

### 12.5. Specificity

Determined from equivalent displacement measurements at 50 % binding. The antiserum used in the test shows the following cross-reactions :

Substance	Cross-reactivity %	Concentration nmol/L	Apparent increase nmol/L
Testosterone	100	35	35
5 $\alpha$ -Dihydrotestosterone	2.6	0.6 10	< 0.1 0.26
Methyltestosterone	0.30	3 50	nd 0.15
Androstandione	0.02	4 50	nd nd
5-Androstendiol	0.02	4 50	nd nd
Danazol	0.006	10 1000	nd < 0.1
17 $\beta$ -Estradiol	0.005	0.7 70	nd nd
5 $\alpha$ -Androstandiol-3 $\beta$ , 17 $\beta$	0.008	0.5 5	nd nd
5 $\alpha$ -Androstandiol, 3 $\alpha$ , 17 $\beta$	0.09	1 30	nd < 0.1
Progesterone	0.01	30 1000	nd 0.1
Androstenedione	1.7	5 100	< 0.1 1.7
Cortisol	< 0.001	500 8000	nd < 0.1
Androsterone	0.001	2 30	nd nd
Dehydroepiandrosterone	< 0.001	20 400	nd nd
17OH-Progesterone	0.005	5 1000	nd < 0.1
Dehydroepiandrosteronesulphate	< 0.0001	5000 50000	nd < 0.1

### 12.6. Detection limit

The sensitivity of the method defined as being the detectable concentration equivalent to twice the calibrator deviation of the zero-binding value. Analytical detection limit is lower than 0.1 nmol/L. Functional detection limit is estimated to be 0.3 nmol/L.

### 12.7. Measurement range

0.3 – 50 nmol/L.

### ASSAY FLOW-CHART

TUBES	Calibrators Samples $\mu\text{L}$	<sup>125</sup> I Testosterone $\mu\text{L}$	Mix --- Cover the tubes --- Incubate 1h at 37°C --- Decant liquid	Distilled water	Decant liquid --- Count
				mL	
T	-	500		-	
Calibrators	25	500	1		
Samples	25	500	1		

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**ES**  
La referencia del producto y el número de lote impresos en la etiqueta del kit constituyen la referencia única del kit y serán necesarios para identificar la versión relevante de las instrucciones de uso correspondientes al producto.

Cómo obtener las instrucciones de uso:

- 1- A través de Internet: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Enviando un correo electrónico a [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Llamando al número correspondiente a su país o zona geográfica que se indica en la tabla siguiente.

Los materiales de origen humano contenidos en los reactivos de este kit se han sometido a ensayo con kits autorizados y han dado un resultado negativo para los anticuerpos anti-VIH 1, anti-VIH 2 y anti-VHC y para el antígeno HBS. Sin embargo, es imposible garantizar completamente que tales productos no transmitan la hepatitis, el VIH o cualquier otra infección vírica. Todos los productos de origen animal y sus derivados han sido obtenidos de animales sanos. Los componentes bovinos proceden de países libres de EEB. Los componentes que contienen sustancias de origen animal o humano deben tratarse como potencialmente infecciosos. Algunos reactivos contienen azida sódica. Algunos reactivos contienen mercurio sódico (solo SHBG-RIACT y ESTR-US-CT).

**PT**  
A referência do produto e o número do lote impressos no rótulo do seu kit constituem a única referência do seu kit e serão necessários para identificar a versão relevante de instruções de utilização associadas ao produto.

Como obter as instruções de utilização:

- 1- Na página da Internet: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Enviando um e-mail para [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Ligando para o número associado ao seu país ou área geográfica que se indica na tabela abaixo.

As matérias-primas de origem humana contidas nos reagentes deste kit foram testadas com kits registados e tiveram resultados negativos para anticorpos anti-VIH 1, anti-VIH 2, anti-VHC o antígeno HBS. No entanto, é impossível garantir absolutamente que estes produtos não transmitirão a hepatite, o vírus VIH ou qualquer outra infeção viral. Todos os produtos e derivados de origem animal foram colhidos de animais saudáveis. Os componentes bovinos têm origem em países onde não foram relatados casos de ESE. Os componentes que contêm substâncias humanas ou animais devem ser tratados como potencialmente infecciosos. Alguns reagentes contêm azida de sódio. Alguns reagentes contêm mercuriato de sódio (apenas SHBG-RIACT e CT-ESTR-U.S.).

**BG**  
Референтната информация и номерът на партидата на продукта, които са отпечатани на етикета на вашия комплект, представяват уникалната референтна информация на вашия комплект и ще се използват, за да се идентифицира съответната версия на инструкциите за употреба, която е свързана с вашия продукт

Как да получите инструкциите за употреба:

- 1- От интернет на адрес: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Като изпратите имейл на [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Като се обадите на телефонния номер, зададен за вашата държава или географска област, от таблицата по-долу

Необработени материали от човешки произход, съдържащи се в реагентите на този комплект, са изследвани с лицензирани комплекти и е установено, че са отрицателни за анти-HIV 1, анти-HIV 2, анти-HCV антигена и HBS антиген. Въпреки това не е възможно категорично да се гарантира, че такива продукти няма да предадат хепатит, вируса на HIV или каквато и да било друга вирусна инфекция. Всички животински продукти и техни деривати са били получени от здрави животни. Говедите компоненти са с произход от дървета, в които BSE не е била докладвана. Компонентите, които съдържат животински или човешки вещества, трябва да бъдат третираны като потенциално инфекциозни. Някои реагенти съдържат натриев азид. Някои реагенти съдържат натриев мертиолат (само SHBG-RIACT и ESTR-US-CT).

**HU**  
A készlet címkéjére nyomtatott termék hivatkozási és tételszám a készlet egyedi hivatkozási száma, amelyre szükség lesz a termékéhez tartozó használati útmutató megfelelő verziójának megkereséséhez.

Hogyan kaphatja meg a használati útmutatót:

- 1- Letöltheti az internetről az alábbi linken: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Küldhet e-mailt a következő címre: [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Felhívhatja az alábbi táblázatban az Ön országának vagy földrajzi régiójának megfelelő számot

A jelen készletben található reagensek által tartalmazott emberi eredetű alapanyagokat engedélyezett készletekkel tesztelték, és anti-HIV 1, anti-HIV 2, anti-HCV antitestekre és a HBS antigénre negatívumok láthatók. Nem garantálható azonban teljes mértékben, hogy ezek a termékek nem okoznak hepatitis, HIV vagy más vírusos fertőzést. Az állati eredetű termékeket és származékokat egészséges állatokból nyerték. A szarvasmarha eredetű szövetek oylan országokból származnak, ahol nem jelentették BSE előfordulását. Az állati vagy emberi eredetű anyagokat tartalmazó összetevőket potenciálisan fertőző anyagként kell kezelni. Egyes reagensek nátrium-azidot tartalmaznak. Egyes reagensek (csak az SHBG-RIACT és az ESTR-US-CT) nátrium-mercaptált tartalmaznak.

**IT**  
Il riferimento del prodotto e il numero di lotto stampati sull'etichetta del kit costituiscono il riferimento univoco del kit e sono necessari per identificare la versione corretta delle istruzioni d'uso associate al prodotto.

Come reperire le istruzioni d'uso:

- 1- Scaricando da internet all'indirizzo: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Inviando un'e-mail a [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Chiamando il numero associato al proprio paese o area geografica nella tabella sottostante

Le materie prime di origine umana contenute nei reagenti di questo kit sono state testate con kit approvati e sono risultate negative agli anticorpi anti-HIV 1, anti-HIV 2, anti-HCV e all'antigene HBS. Tuttavia, non è possibile garantire che tali prodotti non possano trasmettere l'epatite, il virus dell'HIV o qualsiasi altra infezione virale. Tutti i prodotti e i derivati animali sono stati ricavati da animali sani. I componenti bovini provengono da paesi in cui non sono stati segnalati casi di BSE. I componenti contenenti sostanze di origine animale o umana devono essere trattati come potenzialmente infettivi. Alcuni reagenti contengono sodio azide. Alcuni reagenti contengono sodio mercuriato (solo SHBG-RIACT ed ESTR-US-CT).

**PL**  
Kod produktu i numer partii wydrukowane na etykiecie zestawu stanowią unikalny numer referencyjny zestawu i będą wymagane do zidentyfikowania odpowiedniej wersji instrukcji użycia powiązanej z produktem.

Jak uzyskać instrukcję użycia:

- 1- Pobierając z witryny: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Wysyłając wiadomość e-mail pod adres [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Dzwońjąc pod odpowiedni numer (kraj/obszar geograficzny) wskazany w poniższej tabeli

Surowce pochodzenia ludzkiego zawarte w odczynnikach dołączonych do zestawu zostały zbadane z wykorzystaniem zatwierdzonych zestawów i ustalono, że są one ujemne pod względem przeciwciał anti-HIV 1, anti-HIV 2, anti-HCV i antygenu HBS. Nie można jednak całkowicie zagwarantować, że takie produkty nie będą przekazywać wirusa zapalenia wątroby, wirusa HIV bądź innych infekcji wirusowych. Wszystkie produkty zwierzęce i od nich pochodne zostały pozyskane od zdrowych osobników. Składniki pochodzące od bydła pozyskano w krajach, gdzie nie zgłaszano przypadków BSE. Składniki zawierające substancje pochodzenia zwierzęcego lub ludzkiego należy traktować jako potencjalnie zaraźliwobórzce. Niektóre odczynniki zawierają azydek sodu. Niektóre odczynniki zawierają Merthiolat (tylko SHBG-RIACT i ESTR-US-CT).

**TR**  
Kit etiketinde yazılan olan ürün referansı ve parti numarası, kitinizin benzersiz referansını oluşturur ve ürününüz ile ilgili talimatların ilgili sürümünü tanımlamak için gereklidir.

Kullanım talimatları nasıl alınır:

- 1- İnternette yüklemek için: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- [iva@cisbio.com](mailto:iva@cisbio.com) adresine bir e-posta gönderilebiliriz
- 3- Aşağıdaki tabloda ülkeniz veya coğrafi alanınız için gösterilen ilgili numarayı arayabilirsiniz

Bu kitin reaktiflerinde bulunan insan kökenli hammaddeler, lisanslı kriter ile test edilmiştir ve bu kriterin anti-HIV 1, anti-HIV 2 ve anti-HCV antikoları ile HBS antijeni açısından bunların negatif olduğu tespit edilmiştir. Ancak bu ürünlerin hepatit, HIV virüsü ya da diğer viral enfeksiyonları bulaştırmayacağı konusunda garanti sunulmamaktadır. Tüm hayvan kaynaklı ürünler ve türevleri, sağlıklı hayvanlardan toplanmıştır. Sığır bileşenleri, BSE'nin bildirilmediği ülkelerden alınmıştır. İnsan veya hayvan kökenli maddeleri içeren bileşenleri bulacağı potansiyelli maddeler olarak yaklaşılmalıdır. Bazı reaktifler sodyum azid içerir. Bazı reaktifler sodyum Merthiolat içerir (yalnızca SHBG-RIACT ve ESTR-US-CT).

**NO**  
Produktreferansen og serienummeret som er trykket på serieetiketten utgjør den entydige referansen til settet du bruker, og vil være nødvendig ved identifisering av den relevante versjonen av bruksanvisningen som er knyttet til produktet ditt.

Hvordan du finner bruksanvisningene:

- 1- På Internett, under [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Ved å sende en e-post til [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Ved å ringe telefonnummeret i tabellen nedenfor som er knyttet til landet ditt eller det geografiske området der du er

Råstoff av menneskelig opprinnelse som dette settet inneholder har blitt testet med lisensierte sett, og funnet negative for antistoffer for anti-HIV 1, anti-HIV 2, anti-HCV og antigener for HBeAg. Det er imidlertid ikke mulig å strengt garantere at slike produkter ikke vil overføre hepatitt, HIV-viruser eller noen andre virusinfeksjoner. Alle dyreprodukter av dervivat har blitt samlet fra dyr eller mennesker fra kveg stammer fra land der det ikke har vært rapportert BSE. Komponenter som inneholder stoffer fra dyr eller mennesker skal behandles som mulig smittefarlig. Noen reagentser inneholder natriumazid. Noen reagentser inneholder natriummerthiolat (bare SHBG-RIACT og ESTR-US-CT).

**SV**  
Modellbeteckning och partinummer tryckt på din utrustningsetikett utgör den unika hänvisningen till ditt utrustning och kommer att krävas för att identifiera den aktuella versionen av bruksanvisningar i samband med din produkt.

Hur man skaffar bruksanvisningen:

- 1- Från internet på: [www.cisbio.com/ivd-pj](http://www.cisbio.com/ivd-pj)
- 2- Genom att skicka ett e-postmeddelande till: [iva@cisbio.com](mailto:iva@cisbio.com)
- 3- Genom att ringa nummeret till landet ditt eller geografiska området i tabellen nedan

Råmaterial från människa i reagenserna i detta kit har testats med licensierade kit och befintliga vara negativa för anti-HIV 1-, anti-HIV 2-, anti-HCV-antikroppar och HBS-antigen. Det är emellertid omöjligt att fullständigt garantera att sådana produkter inte kommer att överföra hepatit, HIV-virus eller andra virusinfektioner. Alla animaliska produkter och derivat har samlat in från friska dyr. Nötreatningskomponenter kommer från länder där BSE inte har rapporterats. Komponenter som innehåller animaliska eller mänskliga ämnen skall behandlas som potentiellt smittfarande. Vissa reagentser innehåller natriumazid. Vissa reagentser innehåller natriummerthiolat (endast SHBG-RIACT och ESTR-US-CT).

EU: +800 135 79 135				non-EU: +31 20 794 7071	
ET	0800 0100567	RQ	0800 895 084	TR	00800 142 064 866
GR	00800 161 220 577 99	SK	0800 606 287	LI	+31 20 796 5692
IS	800 8996	HRV	0800 804 804	MT	+31 20 796 5693
LT	8800 30728				BR 0800 591 1055
					AR, CO, UY, AU, NZ, RU +800 135 79 135



**FR**  
La référence et le numéro de lot imprimés sur l'étiquette de votre kit constituent la référence unique de votre produit. Cette référence unique vous sera demandée pour pouvoir identifier la version des instructions d'utilisation qui doit être associée à votre kit.

- Comment obtenir les instructions d'utilisation:  
1- Sur internet, à l'adresse [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- En envoyant un e-mail à : [iva@cisbio.com](mailto:iva@cisbio.com)  
3- En appelant le numéro associé à votre pays ou à votre zone géographique (voir table ci-dessous):

Les matières premières d'origine humaine contenues dans les réactifs de ce kit ont été testées avec des kits approuvés et ont rendu des résultats négatifs pour la présence d'anticorps anti-HIV 1, anti-HIV 2, anti-HCV et d'antigènes HBs. Cependant, il est impossible de garantir que ces produits ne peuvent pas transmettre l'hépatite, le virus HIV ou d'autres infections virales. Tous les produits d'origine animale, ainsi que leurs dérivés, ont été collectés sur des animaux sains. Les composés bovins proviennent de pays reconnus exempt de BSE. Tous les composés d'origine humaine ou animale doivent être traités avec un potentiellement infectieux. Certains réactifs contiennent de l'azotate de sodium. Certains réactifs contiennent du merthiolate de sodium (SHBG-RIACT et ESTR-US-CT).

**CS**  
Odkaz na produkt a číslo šarže vytlačené na štítku vaší sady jsou jedinečnou referenční vaší sady a budou požadovány k identifikaci relevantní verze návodu k použití spojené s vaším produktem.

- Jak získat návod k použití:  
1- Z internetu na: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- Zasláním e-mailu na [iva@cisbio.com](mailto:iva@cisbio.com)  
3- Zvoláním na telefonní číslo relevantní pro vaši zemi nebo geografickou oblast v tabulce níže

Surové materiály lidského původu obsažené v reagenčních této sadě byly testovány licenčovými sadami s negativním výsledkem pro protilátky anti-HIV 1, anti-HIV 2 a antigen HBs. Nicméně je nemožné striktně zaručit, že takovéto produkty nezabírají přenosu hepatitidy, virusu HIV nebo jiné virové infekce. Všechny zvířecí produkty a deriváty pocházejí ze zdravých zvířat. Hovězí komponenty pocházejí ze zemí, kde nebyla zaznamenána BSE. Se složkami obsahujícími zvířecí nebo lidské látky by mělo být nakládáno jako s potenciálně infekčními. Některé reagenzie obsahují azid sodný. Některé reagenzie obsahují merthiolát sodný (pouze SHBG-RIACT a ESTR-US-CT).

**RU**  
Регистрационный номер продукта и номер партии, напечатанный на маркировке набора, образуют уникальный регистрационный номер набора, который позволяет определить соответствующую версию инструкции по использованию для вашего продукта.

- Получение инструкции по использованию:  
1- Посетите веб-сайт: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- Отправить сообщение электронной почты по адресу [iva@cisbio.com](mailto:iva@cisbio.com)  
3- Позвоните на номер, указанный для вашей страны или географического региона в таблице ниже

Сырье человеческого происхождения, которое содержится в реагентах этого набора, было протестировано с использованием лицензированных наборов. При этом не было обнаружено антител к ВИЧ-1, ВИЧ-2, гепатиту С и антигена HBs. Однако невозможно полностью исключить присутствие гепатита, ВИЧ или любой другой вирусной инфекции в таких продуктах. Все продукты животного происхождения и их производные были получены от здоровых животных. Компоненты, полученные от коров, были взяты в странах без зарегистрированных случаев КТЗ. С компонентами, которые содержат материалы животного или человеческого происхождения, необходимо обращаться как с потенциально инфекционными. Некоторые реагенты содержат азид натрия. Некоторые реагенты содержат мертиолят натрия (только SHBG-RIACT и ESTR-US-CT).

**EN**  
The product reference and lot number printed on your kit label constitute the unique reference of your kit and will be required in order to identify the relevant version of instructions for use associated to your product.

- How to obtain the instructions for use:  
1- From internet under: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- By sending an email at [iva@cisbio.com](mailto:iva@cisbio.com)  
3- By calling the number associated to your country or geographic area in the table below

Raw materials of human origin contained in the reagents of this kit have been tested with licensed kits and found negative for the anti-HIV 1, anti-HIV 2, anti-HCV antibodies and the HBs antigen. However as it is impossible to strictly guarantee that such products will not transmit hepatitis, the HIV virus, or any other viral infection. All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported. Components containing animal or human substances should be treated as potentially infectious. Some reagents contain sodium azide. Some reagents contain sodium Merthiolate (SHBG-RIACT and ESTR-US-CT only).

**DA**  
Den produktreferenc og det lotnummer, der er udskrevet på sættelags label udgør den unikke referenc til dit sæt og er påkrævet for at kunne identificere den relevante version af brugsanvisningen, der er tilknyttet dit produkt.

- Sådan indhentes brugsanvisningen:  
1- På internettet under: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- Ved at sende en e-mail til [iva@cisbio.com](mailto:iva@cisbio.com)  
3- Ved at ringe til det telefonnummer, der er tilknyttet til dit land eller til det geografisk tilknyttede område i tabellen nedenfor

Råmaterier af menneskelig oprindelse, der er indeholdt i reagenserne i dette sæt, er blevet testet med licenserede sæt og fundet negative for anti-HIV 1, anti-HIV 2, anti-HCV-antistoffer og HBs-antigen. Det er imidlertid umuligt fuldstændigt at garantere, at sådanne produkter ikke overfører hepatitis, HIV-virus eller andre virusinfektioner. Alle animalske produkter og derivater er blevet indsamlet fra sunde dyr. Bestanddele fra kvæg stammer fra lande, hvorfra der ikke er indberettet om BSE. Bestanddele, der indeholder animalske eller humane stoffer, bør derfor behandles som potentielt infektive. Nogle reagenser indeholder natriumazid. Nogle reagenser indeholder natrium merthiolat (kun SHBG-RIACT og ESTR-US-CT).

**SK**  
Referenčné označenie produktu a číslo šarže vytlačené na štítku súpravy predstavujú jedinečné referenčné označenie vašej súpravy, ktoré je potrebné na identifikovanie príslušnej verzie návodu na použitie spojeného s týmto produktom.

- Ako získať návod na použitie:  
1- z tejto internetovej stránky: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- zasláním e-mailu na adresu: [iva@cisbio.com](mailto:iva@cisbio.com)  
3- telefonátom na číslo pre príslušnú krajinu alebo geografickú oblasť uvedené v nasledujúcej tabuľke

Suroviny ľudského pôvodu nachádzajúce sa v činidlách tejto súpravy boli testované licenčovými súpravami a zistilo sa, že sú negatívne na protilátky proti HIV 1 a HIV 2 a HCV a antigén HBs. Je však nemožné striktné zaručiť, že takéto produkty nebudú prenášať vírus hepatitídy, HIV alebo inú vírusovú infekciu. Všetky produkty a deriváty živočíšneho pôvodu boli odoberaté zo zdravých živočíchov. Zložky pochádzajúce z ošpaných z krajín, kde nebola hlásená infekcia BSE. So zložkami obsahujúcimi živočíšne či ľudské látky sa má zaobchádzať ako s potenciálne infekčnými. Niektoré reagenzie obsahujú azid sodný. Niektoré reagenzie obsahujú merthiolát sodný (len SHBG-RIACT a ESTR-US-CT).

**DE**  
Die auf Ihrem Kit-Etikett aufgedruckte Produktreferenznummer und Chargennummer stellen eine eindeutige Kennzeichnung Ihres Kits dar und sind zur Identifizierung der entsprechenden Version der Gebrauchsanweisung für Ihr Produkt erforderlich

- So erhalten Sie die Gebrauchsanweisung:  
1- Im Internet unter: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- Per E-Mail an [iva@cisbio.com](mailto:iva@cisbio.com)  
3- Telefonisch unter der länderspezifischen Rufnummer aus der Tabelle unten

Die in den Reagenzien dieses Kits enthaltenen Materialien menschlichen Ursprungs wurden mit zugelassenen Kits getestet und waren im Hinblick auf Anti-HIV-1-, Anti-HIV-2-, Anti-HCV-Antikörper und HBs-Antigen negativ. Es kann jedoch nicht zu 100% garantiert werden, dass derartige Produkte keine Überträger von Hepatitis, HIV-Virus oder anderen Virusinfektionen sind. Alle tierischen Produkte und Derivate stammen aus gesunden Tieren. Rinderkomponenten stammen aus BSE-freien Ländern. Komponenten mit tierischen bzw. menschlichen Stoffen sind als potenziell infektiös zu behandeln. Einige Reagenzien enthalten Natriumazid. Einige Reagenzien enthalten Natrium-Merthiolat (nur SHBG-RIACT und ESTR-US-CT).

**EL**  
Ο αριθμός αναφοράς και ο αριθμός παρτίδας του προϊόντος που αναγράφονται στην ετικέτα του kit αποτελούν την μοναδική αναφορά του kit σας και θα απαιτούνται προκειμένου να αναγνωριστεί η σχετική έκδοση των οδηγιών χρήσης που σχετίζονται με το προϊόν σας.

- Πώς να λάβετε τις οδηγίες χρήσης:  
1- Από το Internet στη διεύθυνση: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- Επικοινωνώντας e-mail στο [iva@cisbio.com](mailto:iva@cisbio.com)  
3- Καλώντας στον αριθμό που ανατιστοιχεί στη χώρα ή τη γεωγραφική περιοχή σας, όπως φαίνεται στον πίνακα παρακάτω

Το υλικό ανθρώπινης προέλευσης που περιέχεται στα αντιδραστήρια αυτού του kit έχει ελεγχθεί με εγκεκριμένα kit και έχει επιβεβαιωθεί ως αρνητικό σε αντιώσμια anti-HIV-1, anti-HIV-2, anti-HCV και έναντι του αντιγόνου HBs. Ωστόσο, είναι αδύνατο η πλήρης εγγύηση ότι τα εν λόγω προϊόντα δεν θα μεταδώσουν το ή τις παθήσεις, το HIV ή οποιαδήποτε άλλη ιογενή λοίμωξη. Όλα τα ζωικά προϊόντα και τα παράγωγά έχουν συλλεχθεί από υγιή ζώα. Τα στατιστικά βασισμένα προγράμματα από χώρες της σπείρας δεν έχει αναφερθεί η αποτυχία της εγκεκριμένης από των Βοσείων (ΣΕΒ). Τα στατιστικά που περιέχουν στοιχεία ζωικής ή ανθρώπινης προέλευσης θα πρέπει να υποβληθούν σε χημικό ή πιθανώς μοριακό. Κάποια αντιδραστήρια περιέχουν αζίδιο του νατρίου. Κάποια αντιδραστήρια περιέχουν μερθιολικό νάτριο (sodium Merthiolate) (μόνο SHBG-RIACT και ESTR-US-CT).

**RS**  
Referentni broj i broj šarže odštampani na nalepnici vašeg kompleta predstavljaju jedinstvenu referencu vašeg kompleta i potrebni su radi identifikacije relevantne verzije uputstva za upotrebu priloženog vašeg proizvoda.

- Kako nabaviti uputstvo za upotrebu:  
1- Sa interneta pod: [www.cisbio.com/lvd-pj](http://www.cisbio.com/lvd-pj)  
2- Slanjem poruke e-pošte na [iva@cisbio.com](mailto:iva@cisbio.com)  
3- Pozivanjem broja za vašu zemlju ili geografsku oblast iz tabele u nastavku

Sirovine humanog porekla koje sadrže reagensi iz ovog kita testirane su odobrenim kitovima i potvrđeno je da su negativne na anti-HIV 1, anti-HIV 2, anti-HCV antitela i HB antigen. Međutim, pošto je nemoguće u potpunosti garantovati da takvi proizvodi neće preneti hepatitis, HIV virus, ili bilo koju drugu virusnu infekciju. Svi proizvodi i derivati životinjskog porekla su uzeti sa zdravih životinja. Govede komponente potiču iz zemalja u kojima nije bilo slučajeva BSE. Komponente koje sadrže životinjske ili humane supstance treba da se tretiraju kao potencijalno zarazne. Neki reagensi sadrže natrijum-azid. Neki reagensi sadrže natrijum-merliolat (samo SHBG-RIACT i ESTR-US-CT).

		EU: +800 135 79 135			non-EU: +31 20 794 7071		
ET	0800 0100567	RO	0800 895 084	IR	00800 142 064 866	US	+1 855 236 0910
GR	00800 161 220 577 99	SK	0800 606 287	LI	+31 20 796 5692	CA	+1 855 805 8539
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LT	8800 30728					AR, CO, UY, AU, NZ, RU	+800 135 79 135

