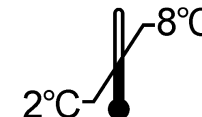
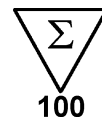


















ESTRADIOL



ESTR-US-CT



<p>Trousse ultrasensible pour le dosage radioimmunologique, sans extraction, de la 17β-Estradiol total dans le sérum ou le plasma humain. Pour diagnostic In Vitro</p> <p>La trousse contient :</p> <table border="0"> <tr><td> Tubes revêtus</td><td> 2X50 tubes</td></tr> <tr><td> Traceur ≤ 85 kBq</td><td> 1 x 6 mL</td></tr> <tr><td> Calibrateurs 0 – 5</td><td> 6 x 2 mL</td></tr> <tr><td> Tampon pour traceur et tampon d'incubation</td><td> 1 x 45 mL</td></tr> <tr><td> Solution de lavage</td><td> 1 x 10 mL</td></tr> <tr><td> Sachet plastique</td><td> 1</td></tr> <tr><td> Notice d'utilisation</td><td> 1</td></tr> </table> <p>Attention: Certains réactifs contiennent de l'azoture de sodium</p>	Tubes revêtus	2X50 tubes	Traceur ≤ 85 kBq	1 x 6 mL	Calibrateurs 0 – 5	6 x 2 mL	Tampon pour traceur et tampon d'incubation	1 x 45 mL	Solution de lavage	1 x 10 mL	Sachet plastique	1	Notice d'utilisation	1	<p>Sensitive radioimmunoassay coated tube kit for the direct quantitative determination of total Estradiol-17β in human serum and plasma. For In Vitro diagnostic use</p> <p>Kit content :</p> <table border="0"> <tr><td> Coated tubes</td><td> 2X50 tubes</td></tr> <tr><td> Tracer ≤ 85 kBq</td><td> 1 x 6 mL</td></tr> <tr><td> Calibrators 0 – 5</td><td> 6 x 2 mL</td></tr> <tr><td> Buffer for tracer and incubation buffer</td><td> 1 x 45 mL</td></tr> <tr><td> Washing solution</td><td> 1 x 10 mL</td></tr> <tr><td> Plastic bag</td><td> 1</td></tr> <tr><td> Instruction for use</td><td> 1</td></tr> </table> <p>Warning: Some reagents contain sodium azide</p>	Coated tubes	2X50 tubes	Tracer ≤ 85 kBq	1 x 6 mL	Calibrators 0 – 5	6 x 2 mL	Buffer for tracer and incubation buffer	1 x 45 mL	Washing solution	1 x 10 mL	Plastic bag	1	Instruction for use	1	<p>Hochsensibler Radioimmunassay zur direkten Bestimmung von total 17β-Estradiol in menschlichem Serum oder Plasma. Zur In Vitro Diagnostik</p> <p>Inhalt des Kits :</p> <table border="0"> <tr><td> Teströhrchen beschichtet</td><td> 2X50 Röhrchen</td></tr> <tr><td> Tracer ≤ 85 kBq</td><td> 1 x 6 mL</td></tr> <tr><td> Kalibratoren 0 – 5</td><td> 6 x 2 mL</td></tr> <tr><td> Puffer</td><td> 1 x 45 mL</td></tr> <tr><td> Waschlösung</td><td> 1 x 10 mL</td></tr> <tr><td> Plastikbeutel</td><td> 1</td></tr> <tr><td> Gebrauchsanleitung</td><td> 1</td></tr> </table> <p>Achtung: Einige Reagenzien enthalten Natriumazid</p>	Teströhrchen beschichtet	2X50 Röhrchen	Tracer ≤ 85 kBq	1 x 6 mL	Kalibratoren 0 – 5	6 x 2 mL	Puffer	1 x 45 mL	Waschlösung	1 x 10 mL	Plastikbeutel	1	Gebrauchsanleitung	1
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	FRA	ENG	DEU	ITA	SPA	SWE	DAN	POL	CES	NOR	SRB
	Explication des symboles	Explanation of symbols	Erläuterung der Symbole	Spiegazione dei simboli	Significado de los símbolos	Symbol förklaring	Symbol forklaring	Wyjaśnienie symboli	Vysvětlení symbolů	Forklaring av symbolene	Objašnjenje simbola
	Conforme aux normes européennes	European conformity	CE-Konformitätskennzeichnung	Conformità europea	Conformidad europea	Förenlig med europeiska normer	I overensstemmelse med de europæiske standarder	Zgodne z normami europejskimi	Evropská shody	Europeisk konformitet	Evropska usaglašenost
	T° limite de stockage	Storage temperature limitation	Limitierung der Lagertemperatur	Limiti per la temperatura di conservazione	Limites de temperatura de almacenamiento	T°-gräns vid förvaring	T° grænse for opbevaring	Graniczna temperatura przechowywania	Mezní teplota skladování	Lagertemperatur begrensning	Ograničenje temperature za čuvanje
	N° de lot	Batch code	Chargencode	codice lotto	Código de lote	Lotnr.	Lot nr.	Numer partii	Č. šarže	Porsjoner kode	Šifra serije
	Utiliser jusqu'au	Use by	Verwendbar bis	utilizzare entro	Consumir antes de	Används senast	Udløbsdato	Zużyć do	Použitelné do	Bruk ved	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	Läs bruksanvisningen	Se brugsvejledningen	Patrz dołączona ulotka	Přečtěte si návod k použití	Konsulter driftsinstrukser	Pogledajte uputstvo za upotrebu
	Diagnostic In Vitro	In Vitro Diagnostic device	In-VitroDiagnostische Anwendung	Dispositivo Diagnostico In Vitro	Dispositivo de diagnóstico In Vitro	In vitro-diagnos	In vitro diagnose	Diagnostyka In Vitro	Diagnostika in vitro	In Vitro Diagnose innretning	Uređaj za dijagnostiku <i>in vitro</i>
	Fabriqué par	Manufactured by	Hergestellt von	Prodotto da	Fabricado por	Tillverkad av	Fremstillet af	Wyprodukowane przez	Vyrobil	Produsere ved	Proizveo
	Référence	Catalogue number	Katalog Nr.	N. catalogo	Número de catálogo	Referens	Reference	Wzorec	Reference	Katalogiser antall	Kataloški broj
	Nombre de tubes	Number of determinations	Anzahl der Bestimmungen	Numero di determinazioni	Número de determinaciones	Antal rör	Antal glas	Liczba probówek	Počet zkumavek	Antall determinations	Broj određivanja
	Tubes revêtus	Coated tubes	beschichtete Röhrchen	Provette coattate	Tubos recubiertos	Belagda rör	Beklædte glas	Probówki powlekane	potažené zkumavky	Belagt rør	Obložene epruvete
	Traceur radioactif	Radioactive tracer	Radioactiver Tracer	Tracciante radioattivo	Trazador radiactivo	Radioaktiv tracer	Radioaktiv sporstof	Znacznik radioaktywny	Tracer	Radioaktiv tracer	Radioaktivni indikator
	Calibrateur	Calibrator	Kalibrator	Calibratore	Calibrador	Kalibrator	Kalibrator	Kalibrator	Kalibrátor	Calibrator	Kalibrator
	Tampon d'incubation	Incubation buffer	Inkubationspuffer	tampone di incubazione	Tampon	inkubationsbuffert	inkubation buffer	bufor do inkubacji	Pufir	Buffer	Pufer za inkubaciju
	Solution de lavage	Wash solution	Waschlösung	Soluzione di lavaggio	Solución concentrada	Tvättlösning	Vaskeopløsning	Roztwór płuczący	Koncentrovaný roztok	Vaskeløsning	Rastvor za pranje



FRA

Modifications par rapport à la version précédente :
Modification code langue Serbe.

ENG

Changes from the previous version:
Modification Serbian language code.

DEU

Änderungen gegenüber der Vorgängerversion:
Änderung serbischer Sprachcode.

ITA

Modifiche rispetto alla versione precedente:
Modifica codice lingua serba.

SPA

Cambios desde la versión anterior:
Modificación del código de idioma serbio.

SWE

Ändringar från den föregående versionen:
Ändring serbisk språkkod.

DAN

Ændringer fra den tidligere version:
Ændring Serbisk sprogkode.

POL

Zmiany w stosunku do poprzedniej wersji:
Modyfikacja kodu języka serbskiego.

CES

Změny od předchozí verze:
Modifikace srbského jazykového kódu..

NOR

Endringer fra den foregående versjon:
Modifikasjon serbisk språkkode.

SRB

Promene od prethodne verzije:
Izmjena kod srpske jezika.

1. NAME AND INTENDED USE

ESTR-US-CT is a highly sensitive radioimmunoassay coated tube kit for the direct quantitative determination of total Estradiol-17 β in human serum or plasma.

The kit is intended for professional use.

2. INTRODUCTION

2.1 Physiological background

A steroid hormone, estradiol-17 β is the most active oestrogen in the peripheral circulation. It is mainly produced in the ovary by the Graafian follicle.

A small amount is also produced by the adrenal cortex and by different tissues via the peripheral transformation of estrone and testosterone. In non-pregnant women, the estradiol-17 β concentration varies with the menstrual cycle, the highest values generally occurring one day before ovulation.

This retro-control influence is vital in triggering the mid-cycle LH peak and therefore the ovulation. In the peripheral circulation, estradiol-17 β is mainly present bound to proteins, the two most important being SHBG and albumin. The free form is physiologically active.

2.2 Clinical indications

The use of a highly sensitive estradiol-17 β assay is necessary for young girls, peri- and post-menopausal women, and men. It is useful for testing young girls when precocious puberty is suspected. In post-menopausal women, concentrations of estradiol-17 β are very low, similar to those found in men.

This low post-menopausal concentration increases the risk of osteoporosis and atherosclerosis, indicating the possible need for a hormone replacement therapy (HRT). In men, assays are useful in the investigation of feminizing syndromes (gynecomastia, estrogen-secreting tumors). Serum assays are a helpful tool for establishing the etiology of an amenorrhoea and/or sterility and in investigating estrogen-secreting tumors in women.

Finally, it is useful in monitoring ovulation induction.

3. PRINCIPLE

The principle of the assay is based on a two step technique, using a solid phase.

In the first step, calibrators and samples are incubated in tubes coated with a high affinity anti-Estradiol antibody. After incubation, an amount of hormone proportional to the concentration of the Estradiol fraction present in the sample is bound to the bottom of the tubes.

In the second step, a ¹²⁵I-Estradiol solution is added in the tube to saturate the remaining free antibody sites. Any unbound tracer is then removed.

The quantity of labelled Estradiol bound to the antibody is inversely related to the amount of unlabelled Estradiol 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
COATED TUBES: ready to use. Rabbit anti-Estradiol antibodies coated at the bottom of the tube.	CT	2X50 tubes	2-8°C until the expiry date. Unused coated tubes removed from their bags should be stored in plastic bag supplied with the kit.
¹²⁵I-ESTRADIOL: concentrated solution. ¹²⁵ I labelled ESTRADIOL, buffer, dye, and preservative. ≤ 85 kBq (≤ 2.3 μ Ci).	TRACER	1 6 mL vial	2-8°C until the expiry date. 2-8°C up to 8 weeks after dilution within the limits of the expiry date of the kit. Return the tracer to 2-8°C immediately after use.
CALIBRATOR 0: ready to use. Bovine serum, preservative and sodium azide.	CAL	1 2 mL vial	2-8°C until the expiry date.
CALIBRATORS 1 to 5: ready to use. Estradiol, human serum, preservative and sodium azide. 10 - 25 - 100 - 500 - 2000 pmol/L (*)	CAL	5 2 mL vials	2-8°C until the expiry date.
BUFFER: to be used for tracer dilution and incubation buffer: ready to use. Buffer and preservative.	BUF	1 45 mL vial	2-8°C until the expiry date.
WASHING SOLUTION: concentrated solution Distilled water, detergent.	TWEEN 20	1 10 mL vial	2-8°C until the expiry date After dilution store in a sealed container up to maximum 15 days within the limits of the expiry date of the kit (2-8°C).
PLASTIC BAG		1	

(*) 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 circumstances 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.

Do not contaminate kit components and pipette tips with oestradiol from an external source (e.g. hormone gel).

Follow reasonable precautions to avoid introduction of significant quantities of microorganisms.

Fully respect the incubation times and the washing instructions.

6. SPECIMEN COLLECTION AND PREPARATION

The assay is performed on human sera or plasma (heparin or EDTA). Do not use citrate plasma samples. Haemolyzed or hyperlipemic samples should not be used. If the test is to be carried out within two days, the samples must be refrigerated at 2-8°C. Otherwise, they should be divided into aliquots, and stored deep frozen (-20°C) until needed (maximum 1 month). They must be thawed only just before using. Do not refreeze samples for later use.

Dilution

If elevated Estradiol levels are suspected, a diluent (ref: 1DIL-ESTR-US) is available on request (2 mL vial). A set of 5 additional diluent vials can be ordered separately under the reference: 5DIL-ESTR-US. It is recommended that disposable plastic tubes be used when carrying out the dilutions.

7. ASSAY PROCEDURE

7.1 Equipment and products required but not provided

Precision micropipettes or similar, with disposable tips, capable of dispensing 100 µL, 200 µL, 250 µL and 2 mL. Their calibrations should be checked regularly.

Reagent dispenser 1 mL (for washing)

Distilled water.

Diluent for dilution of elevated Estradiol levels ref: 1DIL-ESTR-US (2 mL vial), or 5DIL-ESTR-US (5 x 2 mL vials).

Vortex type mixer.

Absorbent paper.

Water bath (37°C).

Parafilm (optional).

Disposable plastic test-tubes.

Gamma scintillation counter calibrated for 125 Iodine.

7.2. Tracer dilution

Dilute the tracer 2.5 times with the buffer (e.g. 1 ml tracer + 1.5 mL buffer). Recap the vial. Mix gently to ensure complete dilution.

It is recommended that only the required volume of tracer be diluted at any time.

It must be refrigerated immediately after use.

7.3. Dilution of the washing solution

Dilute 1/333 the concentrated washing solution with distilled water (1.5 mL in 498.5 mL of distilled water to a final volume of 500 mL water).

Cap the vial and mix.

7.4. Protocol

All reagents must 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 calibration curve.

Sx groups, for the test samples.

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

Strictly respect the order in which reagents should be added.

Dispense 200 µL of calibrators and samples to be assayed into the corresponding labeled coated tubes.

Add 250 µL of buffer to each tube (except T group).

Mix each tube gently with a Vortex-type mixer.

Incubate 1 hour at 37°C after covering the tubes with plastic film.

Add 100 µL of ¹²⁵I -Estradiol to each tube (and T group). Return the remaining tracer to the refrigerator.

Mix each tube gently with a Vortex-type mixer.

Cover the tubes with plastic film and **Incubate** 1 hour at 37°C.

Decant liquid from each assay tube and **tap** the head of each tube firmly onto absorbent paper.

Wash once with 1 mL of washing solution (except T tubes), shaking the rack by hand.

Empty the tubes and tap firmly onto absorbent paper. Let the tubes stand upside down at least 5 min. (except T tubes).

Measure (for at least 2 minutes) 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.

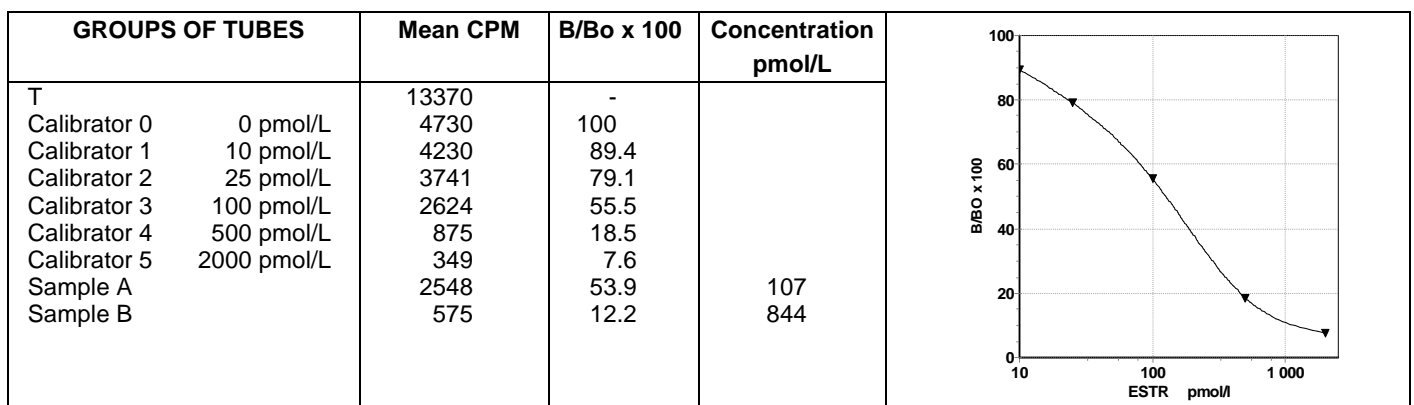
9. RESULTS

For each group of tubes, compute the mean counts. Calculate B/Bo values. Draw up the calibration curve in semi-log 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.

Conversion to pg/mL may be accomplished by using the following equation: Estradiol (pg/mL) = Estradiol (pmol/L) x 0.2724

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

Typical calibration curve (example of results): this data must not be substituted for results obtained in the laboratory.



10. PROCEDURAL LIMITATIONS

Strict following of the procedures described in this package insert and careful handling of the reagents will enable reliable results to be obtained with the **ESTR-US-CT** kit.

Do not attempt to extrapolate sample values beyond the last calibrator. Dilute the samples and re-assay.

11. EXPECTED VALUES

Each laboratory must establish its own range of normal values.

Estradiol values were followed during one menstrual cycle in 25 healthy, normally menstruating women. The ovulation days were established by measuring the LH value of each sample. Day 0 is the day of the LH peak. Results are shown in table below:

Phases	Days from the	n	Mean (pmol/L)	Range (pmol/L)
--------	---------------	---	---------------	----------------

	LH peak			
Follicular phase	-8	10	150	105-217
	-4	15	343	207-1000
Mid-cycle	-1	24	709	416-1399
Luteal phase	9	17	399	165-788

Serum Estradiol values were also measured in samples from 42 post-menopausal women without hormone replacement therapy, 42 pre-pubertal girls and 117 apparently healthy men. Results are shown in the tables below:

Group	Age	n	Mean (pmol/L)	Range (pmol/L)
Women				
Postmenopausal women	47-66 years	42	26	11-50
Pre-pubertal girls	3-5 years	42	17	ND-36

Men	
n =	117
Mean =	117 pmol/L
Reference interval*	34-226 pmol/L
Confidence intervals	90%
Lower reference limit	23 – 51 pmol/L
Upper reference limit	191 – 266 pmol/L

ND = non detectable

* Reference interval = 2.5 and 97.5th percentiles.

12. SPECIFIC CHARACTERISTICS OF THE ASSAY

12.1. Precision

This was evaluated using 8 samples with different concentrations assayed 10 times in the same series or in duplicate in 10 different series.

Samples	Within-run		Samples	Between-run	
	Mean value (pmol/L)	CV (%)		Mean value (pmol/L)	CV (%)
1	17	18.1	5	12	17.6
2	87	2.8	6	94	5.8
3	311	3.5	7	260	8.1
4	1021	5	8	1799	9.7

12.2. Recovery test

Known quantities of Estradiol were added to different serum pools. The recovery percentages of ESTR-US-CT obtained were in the range from 88% to 117%, with a mean value of 102%.

12.3. Specificity

This was determined from equivalent displacement measurements at 50% binding. The antiserum used in the test showed the following cross-reactions:

Compound	Cross reactivity (%)	Compound	Cross reactivity (%)
Estradiol	100	Estrone-glucuronide, sodium salt	0.004
Equilenin	8.9	Norethisterone acetate	0.002
Ethinylestradiol	1.4	Mesterolone	0.002
Equilin	1.1	Norgestrel	0.001
Estrone	0.97	Estradiol-3, 17-disulphate, disodium salt	<0.001
16-Oxoestradiol	0.86	Estradiol-17-sulphate, sodium salt	<0.001
Estradiol-3-glucuronide, sodium salt	0.61	Testosterone	< 0.001
Estriol	0.44	Cortisol	< 0.001
16-hydroxyestrone	0.26	Cortisone	< 0.001
Estradiol-17-glucuronide, sodium salt	0.25	Ethisterone	< 0.001
Estradiol-17-valerate	0.16	Danazol	< 0.001
Progesterone	< 0.05	3,17-Beta-D-glucuroconjugate	0.007
Corticosterone	0.02	Androstenediol	< 0.0003
Estradiol-3-sulfate	0.02	Oestrone-3-Beta-D-glucuronide	0.0003
2-hydroxyestradiol	0.01	Oestrone-3-sulfate	<0.0003
Norethisterone	0.01	17 α -Estradiol	0.005

The Tamoxifen and Fulvestrant (FASLODEX®) drugs at a respective concentration of 8 μ g / mL and 25ng /mL do not interfere with the ESTR-US-CT assay.

12.4. Detection limit

The detection limit is defined as being the smallest concentration different from the zero with a probability of 95%. It has been assessed as being 5 pmol/L.

12.5. Measurement range

Measurement range: 8-2000 pmol/L

12.6. Interferences

No interference with bilirubin, hemoglobin and SHBG measured up to respective concentrations of equal to 170 µmol/L, 10 g/L and 2000 nmol/L, has been observed. Addition of lipids lowers measured concentrations and therefore, the use of highly lipemic samples is not recommended.

ASSAY FLOW-CHART

Groups of tubes	Calibrators, Samples µL	Buffer µL		125I-Estradiol µL		Washing solution µL	
T	---			100		---	
Calibrators	200	250	Mix --- Incubate 1h at 37°C	100	Mix --- Incubate 1h at 37°C --- Empty the tubes	1000	Empty the tubes --- Measure for <u>at least 2</u> minutes
Samples	200	250		100		1000	

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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
2- Enviando un correo electrónico a 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
2- Enviando um e-mail para 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 contém substâncias humanas ou animais devem ser tratados como potencialmente infecciosos. Alguns reagentes contém azida de sódio. Alguns reagentes contém 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
2- Като изпратите имейл на 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 държави, в които BSE не е била докладвана. Компонентите, които съдържат животински или човешки вещества, трябва да бъдат третирани 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
2- Küldhet e-mailt a következő címre: 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 negatívum találtak. 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 összetevők olyan 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- Scaricandole da internet all'indirizzo: www.cisbio.com/ivd-pj
2- Inviando un'e-mail a 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
2- Wysyłając wiadomość e-mail pod adres 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 ürününüze ilişkin ilgili talimatların ilgili sürümünü tanımlamak için gereklidir.

Kullanım talimatları nasıl alınır:
1- İnternette yüklemek için: www.cisbio.com/ivd-pj
2- 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
2- Ved å sende en e-post til 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 antignener for HBe. Det er imidlertid ikke mulig å strengt garantere at slike produkter ikke vil overføre hepatitt, HIV-viruser eller noen andre virusinfeksjoner. Alle dyreproduktet av derivater 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 må 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 din 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
2- Genom att skicka ett e-postmeddelande till: iva@cisbio.com
3- Genom att ringa nummer till landet ditt eller geografiska området i tabellen nedan

Råmaterial från människa i reagenserna i detta kit har testats med licensierade kit och befintnas 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 samlats in från friska dyr. Nötreatningskomponenter kommer från länder där BSE inte har rapporterats. Komponenter som innehåller animaliska eller mänskliga ämnen skall behandlas som potentiellt smittfarliga. 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
2- En envoyant un e-mail à : 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
2- Zasláním e-mailu na 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- HIV2 a antigen HBs. Nicméně je nemožné striktně zaručit, že takovéto produkty nezabírají přenosu hepatitidy, virus HIV nebo jiné virové infekce. Všechny zvířecí produkty a deriváty pocházejí ze zdravých zvířat. Hovězí komponenty pocházejí ze zemi, 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 merthiolat 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
2- Отправить сообщение электронной почты по адресу iva@cisbio.com
3- Позвоните на номер, указанный для вашей страны или географического региона в таблице ниже

Сырье человеческого происхождения, которое содержится в реактивах 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 КТГ. 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
2- By sending an email at 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 sættets 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
2- Ved at sende en e-mail til 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
2- zasláním e-mailu na adresu: 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 merthiolat 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
2- Per E-Mail an 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
2- Επικοινωνώντας e-mail στο iva@cisbio.com
3- Καλώντας στον αριθμό που αντιστοιχεί 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 χώρας της οποίας δεν έχει αναφερθεί η απογύωση εγκεκριμένα είναι 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
2- Slanjem poruke e-pošte na 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-meriolat (samo SHBG-RIACT i ESTR-US-CT).

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