BECKMAN COULTER

CE 2797

Estrone Sulfate RIA

Instruction for use in local language is available at beckmancoulter.com/techdocs.

REVISION HISTORY

Previous version: IFU-DSL5400-01	**Current version:** IFU-DSL5400-02
MATERIALS PROVIDED **Calibrators: six 1 mL vials and one 2 mL vial of «zero» calibrator** (ready-to-use) The calibrator vials contain from 0 to approximately 80 ng/mL of estrone sulfate in buffer with proteins (BSA) and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to an internal reference standard. **Control samples: two 1 mL vials** (ready-to-use) The vials contain estrone sulfate in buffer with proteins (BSA) and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to an internal reference standard.	**Calibrators: six 1 mL vials and one 2 mL vial of «zero» calibrator** (ready-to-use) The calibrator vials contain from 0 to approximately 80 ng/mL of estrone sulfate in buffer with proteins (BSA) and sodium azide (<0.1%). The calibrators are traceable to an internal reference standard. The exact concentration is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). **Control samples: two 1 mL vials** (ready-to-use) The vials contain estrone sulfate in buffer with proteins (BSA) and sodium azide (<0.1%). The control samples are traceable to an internal reference standard. The concentration range is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).
Standard curve *(Example of standard curve, do not use for calculation)*	Example of standard curve is given on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). The measured data are indicative only, do not use them for calculation of your results.

REF DSL5400

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

Estrone Sulfate RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of estrone sulfate in human serum and plasma. Measurement of estrone sulfate, as a marker of global estrogenic activity, is intended to be used for monitoring of hormone replacement therapy in postmenopausal women [1].

PRINCIPLE

The radioimmunoassay of estrone sulfate [1,3,5 (10)-estratrien-3-ol-17-one-3-sulfate] is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled estrone sulfate, as a tracer, in presence of polyclonal rabbit antiserum. After incubation, antigen-antibody complex is precipitated by means of second, anti-rabbit antibody, the contents of the tubes are centrifuged and aspirated so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The estrone sulfate concentrations in the samples are obtained by interpolation from the standard curve. The concentration of estrone sulfate in the samples is indirectly proportional to the radioactivity.

WARNING AND PRECAUTIONS

General remarks:

- The vials with calibrators and controls should be opened as shortly as possible to avoid excessive evaporation.
- Do not mix the reagents from kits of different lots.
- A standard curve must be established with each assay.
- It is recommended to perform the assay in duplicate.

Basic rules of radiation safety

The purchase, possession, utilization, and transfer of radioactive material are subject to the regulations of the country of use. Adherence to the basic rules of radiation safety should provide adequate protection:

- No eating, drinking, smoking or application of cosmetics should be carried out in the presence of radioactive materials.
- No pipetting of radioactive solutions by mouth.
- Avoid all contact with radioactive materials by using gloves and laboratory overalls.
- All manipulation of radioactive substances should be done in an appropriate place, distant from corridors and other busy places.

- Radioactive materials should be stored in the container provided in a designated area.
- A record of receipt and storage of all radioactive products should be kept up to date.
- Laboratory equipment and glassware which are subject to contamination should be segregated to prevent cross-contamination of different radioisotopes.
- Each case of radioactive contamination or loss of radioactive material should be resolved according to established procedures.
- Radioactive waste should be handled according to the rules established in the country of use.

Sodium azide

Some reagents contain sodium azide as a preservative. Sodium azide can react with lead, copper or brass to form explosive metal azides. Sodium azide disposal must be in accordance with appropriate local regulations.

Materials of human origin

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

GHS HAZARD CLASSIFICATION

Antiserum	DANGER	
		
	H360	May damage fertility or the unborn child.
	P201	Obtain special instructions before use.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
		Boric Acid 0.1 - 0.3%
		Sodium Borate Decahydrate 0.1 - 0.3%
Tracer	WARNING	
	H316	Causes mild skin irritation.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Acetic Acid 0.1 - < 1%
Precipitating reagent	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum or EDTA plasma are the recommended sample types.
- Allow serum samples to clot completely before centrifugation.
- Serum and plasma samples may be stored in glass tubes at 2-8°C, if the assay is to be performed within 48 hours. For longer storage keep frozen (at < -20°C, 2 months maximum), after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- If samples have concentrations greater than the highest calibrator, they must be diluted into the zero calibrator.

Serum and EDTA plasma values for 15 samples (serum values ranging from 0.81 to 4.35 ng/mL) were compared using the DSL5400 Estrone Sulfate RIA. Results are as follows:

[EDTA-plasma] = 0.9744[serum] + 0.0775

R = 0.9898

MATERIALS PROVIDED

All reagents of the kit are stable until the expiry date indicated on the kit label, if stored at 2-8°C. Expiry dates printed on vial labels apply to the long-term storage of components by the manufacturer only, prior to assembly of the kit. Do not take them into account.

Storage conditions for reagents after opening are indicated in paragraph Procedure.

Antiserum: one 11 mL vial (ready-to-use)

The vial contains rabbit anti-estrone sulfate serum in a buffer with proteins (BSA), sodium azide (<0.1%) and a dye.

^{125}I-Tracer: one 55 mL vial (ready-to-use)

At the time of manufacture, the vial contains 185 kBq of ^{125}I-labeled estrone sulfate in buffer with proteins (BSA), sodium azide (<0.1%) and a dye.

Calibrators: six 1 mL vials and one 2 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 80 ng/mL of estrone sulfate in buffer with proteins (BSA) and sodium azide (<0.1%). The calibrators are traceable to an internal reference standard.

The exact concentration is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).

Control samples: two 1 mL vials (ready-to-use)

The vials contain estrone sulfate in buffer with proteins (BSA) and sodium azide (<0.1%). The control samples are traceable to an internal reference standard.

The concentration range is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).

Precipitating Reagent: one 100 mL bottle (ready-to-use)

The bottle contains goat anti-rabbit gamma globulin serum in a buffer with polyethylene glycol as a precipitating aid and sodium azide (<0.1%).

NOTE: A precipitate may be visible in the reagent. Mix the bottle thoroughly prior to use.

MATERIALS REQUIRED, BUT NOT PROVIDED

In addition to standard laboratory equipment, the following items are required:

- Precision micropipette (100 µL).
- Semi-automatic pipette (100 µL, 500 µL and 1 mL).
- Vortex type mixer.
- Centrifuge (1500 x g, preferably refrigerated).
- Horizontal or orbital shaker.
- Aspiration system.
- A sponge rack for decantation or similar device.
- Absorbent material for blotting tubes.
- Gamma counter set for ^{125}I.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature and mix them thoroughly by gentle inversion before use.

Calibrators and control samples

Once opened, store at 2-8°C for up to 3 weeks, or at < -20°C until expiration date of kit. Avoid repeated freezing and thawing of reagents.

Assay procedure

Step 1 Additions	Step 2 Incubation & Centrifugation	Step 3 Counting
To labeled test tubes add successively:	Incubate 3 hours at 18-25°C with shaking (≥180 rpm).	Aspirate or decant all tubes (except «total cpm» tubes) by simultaneous inversion with a sponge rack into a radioactive waste receptacle.
100 µL of calibrator, control or sample,*	Add 1.0 mL of well mixed Precipitating Reagent to all tubes (except the «total cpm»tubes) and immediately vortex all tubes.	Drain on absorbent material for 1-2 min and gently blot the tubes.
500 µL of tracer, and**	Incubate all tubes for 10-15 min at 18-25°C without shaking.	Count bound cpm (B) and total cpm (T) for 1 minute.
100 µL of antiserum (except the 2 «total cpm» tubes and 2 tubes for NSB). Vortex gently for 1-2 seconds.	Centrifuge all tubes (except the «total cpm» tubes) for 15 min at 1500 x g.***	

* To two NSB tubes add 200 µL of the zero calibrator.

** Add 500 µL of tracer to 2 additional tubes to obtain «total cpm».

***. Preferably refrigerated; approx. 3000 rpm.

RESULTS

Results are obtained from the standard curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

Standard curve

Example of standard curve is given on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). The measured data are indicative only, do not use them for calculation of your results.

The results in the quality control department were calculated using *spline* curve fit with logit of B/T *or* B/B_0 **after subtraction of NSB** on the vertical axis and log of analyte concentration of the calibrators on the horizontal axis.

Other calculation methods may give slightly different results.

Samples

For each sample, locate ratio B/T or B/B_0 **after subtraction of NSB** on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values obtained from healthy subjects are indicative only.

	n	Mean (SD)	Median	Absolute range
			(ng/mL)	
Male	20	1.73 (0.62)	1.66	0.97-3.93
Female				
Folicular phase	31	2.29 (0.88)	2.02	0.79-4.57
Luteal phase	30	3.88 (2.20)	3.10	0.83-8.81
Pregnancy				
1st trimester	30	11.72 (6.15)	10.47	3.09-30.32
2nd trimester	30	17.20 (9.40)	17.02	2.76-36.41
3rd trimester	39	31.54 (23.29)	27.45	5.04-100.2
Oral Contraceptive	27	1.42 (1.26)	1.02	0.58-6.36
Postmenopausal (no HRT)	28	1.06 (0.40)	0.97	0.50-1.91
Postmenopausal (+HRT)	15	4.39 (4.84)	1.62	0.53-15.77

QUALITY CONTROL

Good laboratory practices imply that control samples be used regularly to ensure the quality of the results obtained. These samples must be processed exactly in the same way as the assay samples, and it is recommended that their results be analyzed using appropriate statistical methods.

Failure to obtain the appropriate values for controls may indicate imprecise manipulations, improper sample handling or deterioration of reagents.

In case of packaging deterioration or if data obtained show some performance alteration, please contact your local distributor or use the following e-mail address: imunochem@beckman.com

In the US, contact the Beckman Coulter technical support at 1-800-854-3633; or by email at: immunoassay@beckman.com

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

PERFORMANCE CHARACTERISTICS

(For more details, see the data sheet "APPENDIX")

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Sensitivity

Analytical sensitivity: 0.01 ng/mL

Specificity

The antibody used in the immunoassay is highly specific for estrone sulfate. Low cross reactivities were obtained with following compounds (estrone and estrone glucuronide, 17β-estradiol 3-sulfate, etc.).

Precision

Intra-assay

Serum samples were assayed 14 times in the same series. The coefficients of variation were found below or equal to 9.2%.

Inter-assay

Serum samples were assayed in duplicate in 8 different series. The coefficients of variation were found below or equal to 8.8%.

Accuracy

Dilution test

High-concentration serum samples were serially diluted with zero calibrator. The recovery percentages obtained were between 80.2% to 119%.

Recovery test

Low-concentration serum samples were spiked with known quantities of estrone sulfate. The recovery percentages ranged from 83% to 111%.

Measurement range (from analytical sensitivity to the highest calibrator): 0.01 to approximately 80 ng/mL.

LIMITATIONS

Failure to follow these instructions for use (IFU) may significantly affect results.

Results should be interpreted in the light of the total clinical presentation of the patient, including clinical history, data from additional tests and other appropriate information.

Do not use hemolyzed, lipemic or icteric samples. For more details, see Appendix, § Interference.

In immunoassays, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Immunoassays may be also affected by presence of anti-avidin or anti-streptavidin antibodies, as well as by the presence of autoantibodies directed against the determined analyte. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [2, 3, 4].

APPENDIX

PERFORMANCE CHARACTERISTICS

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Summary and explanation of the test

Estrone sulfate [1,3,5(10)-estratrien-3-ol-17-one-3-sulfate] is the most abundant circulating estrogen in non-pregnant women as well as normal men [5,6]. It is found in peripheral circulation, due to sulfokinases, present in the peripheral tissues as well as gonad and adrenal cortex, as a major metabolite of estradiol and estrone, and also known to have a longer half-life in blood [6,7]. Circulating levels of estrone sulfate are high during fetal life in both sexes, decrease to very low levels within the first few days of life, remain relatively low during childhood and increase steadily during puberty [8].

Postnatal circulating levels in females are higher than males. In premenopausal women, estrone sulfate levels generally parallel those of estrone, rising gradually during follicular phase, peaking just prior to ovulation, with a secondary and smaller increase during the luteal phase [8,9]. In post-menopausal women, estrone sulfate could play a significant role, since the ovary secretes very little estrogen, and can be used as an important marker in monitoring post-menopausal women.

Interference

Serum samples containing estrone sulfate concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Estrone Sulfate RIA. Values were calculated as described in CLSI EP07, 3rd ed. [10]. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). No interference (defined as a shift in dose > 15 %) was found for addition of interferent up to concentration stated in the table below.

Interferent	Test concentration
Biotin	1,513 ng/mL
Conjugated bilirubin	425.8 µg/mL
Hemoglobin	539.7 µg/mL
Triglycerides	21.14 mg/mL
Unconjugated bilirubin	560.1 µg/mL

In spite of hemoglobin, bilirubin (conjugated, unconjugated) and triglyceride interference data in the table, we advise to avoid using hemolyzed, lipemic or icteric samples.

Sensitivity

The analytical sensitivity, or minimum detection limit, calculated by the interpolation of the mean minus two standard deviations of 16 replicates of the estrone sulfate zero calibrator, is 0.01 ng/mL.

Specificity

The cross-reactivity of the Estrone Sulfate antiserum has been measured against the following compounds:

Compound	% Cross-reactivity
Estrone sulfate	100
Estrone	4.9
Estrone glucuronide	3.4
17β-Estradiol 3-sulfate	1.0
17β-Estradiol	0.3
17β-Estradiol glucuronide	0.1
5-Androsten-3β-ol-17-one (DHA)	ND
Δ-Androsten-3,17-dione (androstenedione)	ND
5α-Androstane-3β,17β-diol 3-glucuronide	ND
5α-Androstan-3α-ol-17-one sodium sulfate	ND
5α-Androstan-3α-ol-17-one glucuronide (androsterone glucuronide)	ND
5α-Androstan-3β-ol-17-one glucuronide	ND
5β-Androstan-3α-ol-17-one sodium sulfate	ND
Hydrocortisone	ND
Progesterone	ND
4-Pregnen-21-ol-3,20-dione	ND
5-Androsten-3β-ol-17-one sulfate (dehydroisoandrosterone-3-sulfate)	ND
4-Estren-17β-ol-3-one	ND
1,4-Pregnadien-11β,17α, 21-triol-3,20-dione (prednisolone)	ND
5α-Androstan-3α-ol-17-one (androsterone)	ND
17α-Hydroxyprogesterone	ND
Corticosterone	ND
5β-Androstan-3β-ol-17-one	ND
Norethindrone	ND
Medroxyprogesterone acetate	ND

· *ND = Non-detectable (<0.1%)*

Precision

Intra-assay

Serum	S1	S2	S3
Number of determinations	14	14	14
Mean value, ng/mL	0.35	8.98	59.33
C.V., %	9.2	4.6	4.7

EDTA plasma	P1	P2	P3
Number of determinations	25	25	25
Mean value, ng/mL	0.58	3.16	13.3
C.V., %	11.72	5.47	3.53

Inter-assay

Serum	S1	S2	S3
Number of determinations	8	8	8
Mean value, ng/mL	0.08	0.49	11.30
C.V., %	8.8	5.1	5.5

EDTA plasma	P1	P2	P3
Number of determinations	10	10	10
Mean value, ng/mL	1.02	2.54	7.04
C.V., %	16.64	8.17	7.83

Accuracy

Dilution test

Samples were diluted in zero calibrator and assayed according to the assay procedure of the kit.

Serum	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(ng/mL)		
S1	-	13.17	-	-
	1:2	5.28	6.59	80.18
	1:4	2.82	3.29	85.65
	1:8	1.46	1.65	88.69
	1:16	0.89	0.82	108.1
S2	-	14.89	-	
	1:2	6.71	7.45	90.13
	1:4	3.61	3.72	96.98
	1:8	1.60	1.86	85.96
	1:16	0.91	0.93	97.78
S3	-	6.56	-	-
	1:2	3.54	3.28	107.9
	1:4	1.53	1.64	93.29
	1:8	0.82	0.82	100.0
	1:16	0.34	0.41	82.93
S4	-	9.00	-	-
	1:2	4.50	4.50	100.0
	1:4	2.65	2.25	117.8
	1:8	1.34	1.13	119.1
	1:16	0.50	0.56	88.89
S5	-	17.42	-	-
	1:2	8.60	8.71	98.74
	1:4	4.75	4.36	109.1
	1:8	2.47	2.18	113.4
	1:16	1.27	1.09	116.6

EDTA plasma	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(ng/mL)		
P1	-	10.97	-	-
	1:2	4.65	5.49	84.78
	1:4	2.86	2.74	104.3
	1:8	1.38	1.37	100.6
	1:16	0.67	0.69	97.72
P2	-	8.51	-	-
	1:2	3.47	4.26	81.55
	1:4	2.26	2.13	106.2
	1:8	1.21	1.06	113.7
	1:16	0.52	0.53	97.77
P3	-	9.16	-	-
	1:2	3.81	4.58	83.19
	1:4	2.20	2.29	96.07
	1:8	1.12	1.15	97.82
	1:16	0.58	0.57	101.3
P4	-	15.66	-	-
	1:2	6.63	7.83	84.67
	1:4	3.78	3.92	96.55
	1:8	2.16	1.96	110.3
	1:16	0.94	0.98	96.04
P5	-	15.65	-	-
	1:2	7.15	7.83	91.37
	1:4	3.36	3.91	85.88
	1:8	1.83	1.96	93.55
	1:16	0.87	0.98	88.95

Recovery test

Samples were spiked with known quantities of estrone sulfate and assayed according to the assay procedure of the kit.

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
S1	0.30	13.05	13.35	13.07	97.90
	0.30	36.63	32.93	27.35	83.05
	0.30	65.25	65.55	66.99	102.2
S2	0.45	13.05	13.50	11.26	83.41
	0.45	36.63	33.07	28.43	85.97
	0.45	65.25	65.70	63.71	96.97
S3	1.95	13.05	15.00	16.58	110.5
	1.95	36.63	34.57	36.39	105.3
	1.95	65.25	67.20	70.45	104.8

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	2.13	0.41	2.54	2.75	108.1
	2.10	0.81	2.91	3.14	108.0
	2.07	1.19	3.26	3.75	115.1
P2	1.75	0.41	2.16	2.30	106.4
	1.72	0.81	2.53	2.91	115.1
	1.70	1.19	2.89	3.44	119.2
P3	0.74	0.41	1.15	1.14	99.34
	0.73	0.81	1.53	1.76	114.9
	0.71	1.19	1.90	2.27	119.2
P4	1.62	0.41	2.03	2.06	101.3
	1.60	0.81	2.40	2.52	104.9
	1.57	1.19	2.76	3.00	108.6
P5	2.00	0.41	2.41	2.67	110.9
	1.96	0.81	2.77	3.15	113.7
	1.93	1.19	3.12	3.58	114.6

^{125}I Characteristics

$T_{1/2}$ (^{125}I) = 1443 h = 60.14 d

^{125}I	E (MeV)	%
γ	0.035	6.5
K_α X-ray	0.027	112.5
K_β X-ray	0.031	25.4

Symbols Key

DANGER — Danger / Danger / Gefahr / Pericolo / Peligro / Perigo / Fara / Κίνδυνος / 危険 / Pavojus / Veszély! / Niebezpieczeństwo / Nebezpečí / Nebezpečenstvo / 위험 / Tehlike / Опасно! / Опасност / 危險

REF — Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κωδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Ürün Referansı / Ссылка на продукт / Референца за производ / 產品參考

IVD — In Vitro Diagnostic / Diagnostic in vitro / In-vitro-Diagnostikum / Diagnostica in vitro / Para diagnóstico in vitro / Diagnóstico in vitro / InVitro-diagnostik / Για διάγνωση in vitro / 体外诊断 / In vitro diagnostika / In vitro diagnosztikai felhasználásra / Diagnostyka in vitro / Diagnostika in vitro / 체외 진단 / İn Vitro Diagnostik / Диагностика in vitro / За ин витро диагностика / 體外診斷

CONTENTS — Contents / Contenu / Inhalt / Contenuto / Contenido / Conteúdo / Περιεχόμενο / 组成 / Rinkinio sudėtis / Tartalom / Zawartość / Obsah / Obsah / 내용물 / İçindekiler / Содержание / Съдържание / 目錄

Manufactured by / Fabriqué par / Hergestellt von / Prodotto da / Fabricado por / Tillverkas av / Κατασκευαστής / 制造商 / Gamintojas / Gyártó: / Producent / Výrobce / Výrobca / 제조 / Üretici / Изготовлено / Произведено от / 製造商

Contains sufficient for <n> tests / Contenu suffisant pour "n" tests / Inhalt ausreichend für <n> Prüfungen / Contenuto sufficiente per "n" saggi / Contenido suficiente para <n> ensayos / Conteúdo suficiente para "n" ensaios / Räcker till "n" antal tester / Περιεχόμενο επαρκές για "v" εξετάσεις / 含量足够 <n> 次测试 / Turinio pakanka < n > tyrim / <n> teszthez elegendő mennyiséget tartalmaz / Zawartość wystarcza na <n> testów / Lze použít pro <n> testů / Obsah vystačí na < n > testov / <n> 테스트에 대해 충분한 양 포함 / <n> sayıda test için yeterlidir / Содержит достаточно для количества тестов: <n> / Съдържа достатъчно за <n> теста / 內容物足夠執行 <n> 次測試

CE Mark / Marquage CE / CE-Kennzeichnung / Marchio CE / Marcado CE / Marcação CE / CE-märkning / Σήμανση CE / CE 标志 / CE ženklas / CE jelzés / Znak CE / Značka CE / Označenie CE / CE 표시 / CE İşareti / Маркировка CE / CE маркировка / CE 標識

SDS — Safety Data Sheet / Fiche technique santé-sécurité / Sicherheitsdatenblatt / Scheda dati di sicurezza / Hoja de datos de seguridad / Ficha de Dados de Segurança / Säkerhetsdatablad / Φύλλο Δεδομένων Ασφάλειας / 安全数据单 / Saugos duomenų lapas / Biztonsági adatlap / Karta Charakterystyki Bezpieczeństwa / Bezpečnostní list / Bezpečnostný list / 안전보건자료 / Güvenlik Bilgi Formu / Паспорт безопасности / Информационен Лист За Безопасност / 安全性資料表

Consult Instructions for Use / Consultez le mode d'emploi / Siehe Gebrauchsanweisung / Consultare le istruzioni per l'uso / Consulte las Instrucciones de uso / Instruções de utilização / Konsultera bruksanvisning / Συμβουλευτείτε τις οδηγίες χρήσης / 请参阅使用说明 / Skaitykite naudojimo instrukciją / Olvassa el a használati utasítást / Zapoznać się z instrukcją użycia / Postupujte podle návodu k použití / Prečítajte si návod na použitie / 사용 안내 문의 / Kullanma Talimatına Başvurun / Обратитесь к инструкциям / Вижте Инструкциите за употреба / 請參閱使用說明

Temperature range(s) / Plage(s) de température / Temperaturbereich(e) / Intervallo/i di temperatura / Intervalo(s) de temperatura / Intervalo(s) de temperatura / Temperaturintervall / Εύρος(-η) θερμοκρασίας / 温度范围 / Temperatūros diapazonas (-ai) / Hőmérséklet-tartomány(ok) / Zakres(y) temperatury / Rozsahy teplot / Rozsah(y) teploty / 온도 범위 / Sıcaklık aralıkları / Диапазон(-ы) температуры / Температурен(ни) диапазон(и) / 溫度範圍 請參閱使用說明

Caution / Précaution / Achtung / Attenzione / Precaución / Atenção / Försiktighet / Προσοχή / 注意事项 / Įspėjimas / Figyelem / Uwaga / Upozornění / Upozornenie / 주의 / Dikkat / Внимание / 注意

Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum exspirace / Dátum exspirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日

LOT — Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號

Date of Manufacture / Date de Fabrication / Herstellungsdatum / Data di Fabbricazione / Fecha de Fabricación / Data de Fabrico / Produktionsdatum / Ημερομηνία Παραγωγής / 生产日期 / Pagaminimo Data / Gyártás Dátuma / Data Produkcji / Datum Výroby / Dátum Výroby / 제조 일자 / Üretim Tarihi / Дата Производства / Дата на Производство / 製造日期

Biohazard / Risque biologique / Biogefährdung / Rischio biologico / Riesgo biológico / Risco biológico / Biologisk fara / Βιολογικός κίνδυνος / 生物危害 / Biologisk fara / Veszélyes biológiai anyag / Zagrożenie biologiczne / Biologické riziko / Biologické riziko / 생물학적 위험 / Biyolojik tehlike / Биологическая опасность / Биологична опасност / 生物危害

Radioactive / Radioactif / Radioaktiv / Radioattivo / Radiactivo / Radioactivo / Radioaktivt / Ραδιενεργό / 放射性 / Radioaktyvioji medžiaga / Radioaktív / Radioaktywny / Radioaktivní / Rádioaktívny / 방사성 / Radyoaktif / Радиоактивный / Радиоактивен / 具放射性

Ag 125I / Ab 125I — Tracer / Traceur / Tracer / Marcato / Trazador / Marcador / Tracer / Ανιχνευτής / 追踪剂 / Atsekamoji medžiaga / Nyomjelző / Znacznik / Radioindikátor / Indikátor (tracer) / 트레이서 / Tracer´lar / метка / Индикатор / 追蹤劑

CAL / CAL 0 — Calibrator / Calibrateur / Kalibrator / Calibratore / Calibrador / Calibrador / Kalibrator / Βαθμονομητής / 校准品 / Kalibravimo medžiaga / Kalibrátor / Kalibrator / kalibrátor / Kalibrátor / 보정 물질 / Kalibratör / Калибратор / Калибратор / 校正液

CTRL — Control / Contrôle / Kontrolle / Controllo / Control / Controlo / Kontrolle / Μάρτυρας / 质控品 / Kontrolinė / Kontroll / Kontrola / Kontrola / Kontrola / 정도관리 / Kontrol / Контроль / Контролна / 質控品

Ab — Antiserum / Antisérum / Antisiero / Antisuero / Anti-soro / Αντιορός / 抗血清 / Antiserumas / Antiszérum / Antysurowica / Antisérum / 항혈청 / Антисыворотка / Антисерум / 免疫血清

IFU — Instruction for Use / Mode d'emploi / Gebrauchsanweisung / Istruzioni per l'uso / Instrucciones de uso / Instruções de utilização / Bruksanvisning / Οδηγίες χρήσης / 使用说明 / Naudojimo instrukcija / Használati utasítás / Instrukcja użycia / Návod k použití / Návod na použitie / 사용 안내 / Kullanma Talimatı / Инструкции / Инструкции за употреба / 使用說明

REAG PREC — Precipitating Reagent / Réactif précipitant / Präzipitationsreagens / Reagente precipitante / Reactivo Precipitante / Reagente de Precipitação / Fällningsreagens / Αντιδραστήριο Κατακρήμνισης / 沉淀试剂 / Nusodinamasis reagentas / Precipitáló reagens / Odczynnik wytrącający / Srážecí činidlo / Zrážacie činidlo / 침전 시약 / Çökelme Reaktifi / Преципитирующий реагент / Реактив за утаяване / 沉澱試劑

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