BECKMAN COULTER

CE 2797

Ultra-Sensitive Estradiol RIA

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

REVISION HISTORY

Previous version: PI-DSL4800-06	**Current version:** IFU-DSL4800-01
—	IVDR requirements incorporated
Chapter INTENDED USE removed	Chapter INTENDED PURPOSE added
—	Chapter APPENDIX: Interference data added

REF DSL4800

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

Ultra-Sensitive Estradiol RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of estradiol in human serum and plasma. Measurement of estradiol is intended to be used for the assessment of fertility status and sexual development. In females, it is used in differential diagnosis of amenorrhea and other causes of female infertility and in monitoring of ovulation status. It is also used as an aid in diagnosis of precocious and delayed puberty in children. In males, it is used as an aid in diagnosis of feminizing syndromes, including gynecomastia. It is also used in monitoring patients on hormone replacement and antiestrogen therapy [1, 2, 3, 4, 5].

PRINCIPLE

The ultra-sensitive radioimmunoassay of estradiol (1,3,5(10)-Estratriene-3,17β-diol; 17β-estradiol, E2) is a competition assay. Samples and calibrators are first incubated in presence of polyclonal rabbit antiserum and then incubated again after addition of ^{125}I-labeled estradiol, as a tracer. 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 estradiol concentrations in the samples are obtained by interpolation from the standard curve. The concentration of estradiol 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

Tracer	WARNING	
		
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P337+P313	If eye irritation persists: Get medical advice/attention.
		Acetic Acid 1 - < 3%
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 at 2-8°C, if the assay is to be performed within 24 hours. For longer storage keep frozen (at < -20°C, 1 year 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 25 samples (serum values ranging from 8.90 to 441.6 pg/mL) were compared using the DSL4800 Ultra-Sensitive Estradiol RIA. Results are as follows:

[EDTA-plasma] = 0.96[serum] - 2.59

R = 0.9917

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 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-estradiol serum in a buffer with proteins (BSA), sodium azide (<0.1%) and a dye.

^{125}I-Tracer: one 11 mL vial (ready-to-use)

At the time of manufacture, the vial contains 185 kBq of ^{125}I-labeled estradiol in buffer with proteins and 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 750 pg/mL (0 to approximately 2.78 nmol/L) of estradiol in bovine serum with sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to an internal reference standard.

Zero calibrator may be ordered separately, too (REF. B64533, Diluent - US Estradiol + α subunit).

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

The vials contain estradiol in bovine serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to an internal reference standard.

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

The bottle contains goat anti-rabbit gamma globulin serum in buffer with polyethylene glycol as a precipitating aid, with sodium azide (<0.1%) and ProClin 300.

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:

- 12 x 75 mm plastic or glass test tubes.
- Test tube rack for 12 x 75 mm tubes.
- Precision micropipette (200 µL).
- Semi-automatic pipette (100 µL, 1 mL).
- Vortex type mixer.
- Aspiration system.
- Centrifuge (1500 x g, preferably refrigerated).
- A sponge rack or similar device for decantation.
- 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 < -20°C until expiration date of kit. Avoid repeated freezing and thawing of reagents.

Assay procedure

Step 1 Additions, 1st incubation	Step 2 2nd incubation & centrifugation	Step 3 Counting
To labeled test tubes add successively:	Add 100 µL of tracer to all tubes. Vortex gently 1-2 seconds. Cover and incubate 2 hours at 18 - 25°C without shaking.**	Aspirate or decant all tubes (except «total cpm» tubes) by simultaneous inversion with a sponge rack into a radioactive waste receptacle.
200 µL of calibrator, control or sample,*	Add 1.0 mL of well mixed Precipitating Reagent to all tubes except the two «total cpm» tubes and immediately vortex all tubes.	Drain on absorbent material for 15-30 seconds and gently blot the tubes.
100 µL of antiserum (except the 2 «total cpm» tubes and 2 tubes for NSB). Vortex gently 1-2 seconds. Cover and incubate 60 minutes at 18-25°C without shaking.	Incubate all tubes for 15-20 min at 18-25°C without shaking. Centrifuge (approx. 3000 rpm, preferably refrigerated) all tubes for 15-20 min at 1500x g (except the 2 tubes «total cpm»).	Count bound cpm (B) and total cpm (T) for 1 min.

To the NSB tubes add **300 µL of the zero calibrator.*

***Add 100 µL of tracer to 2 additional tubes to obtain «total cpm».*

RESULTS

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

Standard curve

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.

Total activity: 64,438 cpm					
NSB: 1,667 cpm					
Calibrators	**Estradiol (pg/mL)**	**cpm (n=3)**	**cpm - NSB**	**B/T (%)**	**B/B_0 (%)**
0	0	24,449	22,782	35.4	100.0
1	4.5	22,270	20,603	32.0	90.4
2	11	18,478	16,811	26.1	73.8
3	22	15,969	14,302	22.2	62.8
4	50	13,756	12,089	18.8	53.1
5	260	7,783	6,116	9.49	26.8
6	750	5,416	3,749	5.82	16.5

(Example of standard curve, do not use for calculation)

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.

To convert concentrations from pg/mL to nmol/L, multiply results by 0.0037.

EXPECTED VALUES

Each laboratory should establish its own reference ranges. The serum estradiol concentrations shown in the table were obtained from 54 male and 47 female donors and are provided for reference only.

Group	n	Mean ± 1 SD	Absolute range	Median
		(pg/mL)		
Male	54	24.6 ± 9.1	5.6 - 50.1	24.2
Female				
Folicular phase	9	81.7 ± 58.5	37.4 - 201.6	54.4
Luteal phase	17	119.5 ± 82.6	34.9 - 374.0	89.9
Oral contraceptives	12	26.9 ± 32.3	5.4 - 122.1	16.1
Untreated postmenopausals	9	27.5 ± 28.4	5.7 - 102.8	18.3

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

The analytical sensitivity is 2.2 pg/mL.

Specificity

The antibody used in the immunoassay is highly specific for estradiol. Low cross reactivities were obtained with several related molecules (estrone, estrone-β-D-glucuronide, estrone-3-sulfate etc).

Precision

Intra-assay

Serum samples were assayed 12 times in the same series. The coefficients of variation were found below or equal to 8.9%.

Inter-assay

Serum samples were assayed in duplicate in 8 different series. The coefficients of variation were found below or equal to 12.2%.

Accuracy

Dilution test

High-concentration serum samples were serially diluted with zero calibrator. The recovery percentages obtained were between 87.6% to 112%.

Recovery test

Low-concentration serum samples were spiked with known quantities of estradiol. The recovery percentages obtained were between 81.7% to 107%.

Measurement range (from analytical sensitivity to the highest calibrator): 2.2 to approximately 750 pg/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 [6, 7, 8].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Summary and explanation of the test

Estradiol (1,3,5(10)-Estratriene-3,17β-diol; 17β-estradiol, E2), a C18 steroid, is the most potent naturally secreted estrogen and is the major estrogen produced by the ovary [4]. In the ovary, estradiol is produced by de-methylation and aromatization of testosterone [4,5]. Ovarian estradiol is also produced from estrone (3-Hydroxy-1,3,5(10)-estratrien-17-one; E1), a less potent estrogen derived from androstenedione. Estrone and estradiol are interconverted in many body tissues. In men, small amounts of estradiol are produced in the testes and from peripheral conversion of androgens. Circulating levels of estradiol increase during fetal life, are relatively high at term in both sexes, decrease rapidly postnatally, show a small increase in early infancy, and are low in prepubertal children [9].

Circulating estradiol levels increase gradually during puberty in both sexes, although the absolute levels are higher in females [10]. In adult premenopausal women, ovarian estradiol production is stimulated by the interactions of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) throughout the menstrual cycle. The increasing estradiol levels during the follicular phase of the menstrual cycle appear to enhance gonadotropin stimulation, leading to a midcycle gonadotropin surge and subsequent ovulation [11]. Increased estradiol (and progesterone) levels during the luteal phase inhibit gonadotropin secretion. In adult men and postmenopausal women, estradiol production is low and estrone is the major estrogen in the circulation. Most of the circulating estradiol is bound to either sex-hormone binding globulin (SHBG) or, with lower affinity, to albumin.

The small amounts of free and dissociable estradiol have diffuse biological actions mediated by binding to specific intracellular receptors. The biological actions of estradiol include stimulation of linear bone growth, acceleration of epiphyseal closure, stimulation of mammary development, and maturation of the vaginal mucosa and uterine endometrium [11]. Estradiol may also contribute to the development of the female (gynoid) body habitus, and may have metabolic and behavioral effects [11].

Interference

Serum samples containing estradiol concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Ultra-Sensitive Estradiol RIA. Values were calculated as described in CLSI EP07, 3rd ed. [12]. 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	1,713 ng/mL
Conjugated bilirubin	428.6 µg/mL
Hemoglobin	106.6 µg/mL
Triglycerides	3.39 mg/mL
Unconjugated bilirubin	386.9 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, as calculated by the interpolation of the mean minus two standard deviations of 16 replicates of the zero calibrator, is 2.2 pg/mL.

Specificity

The cross-reactivity has been measured against various compounds in this assay. The percent cross-reactivity is expressed as the ratio of the estradiol concentration to the concentration of the reacting compound at 50% binding of the estradiol zero calibrator.

COMPOUND	% CROSS-REACTIVITY
Estrone	2.40
Estrone-β-D-Glucuronide	0.20
Estrone-3-Sulfate	0.01
Equilin	0.34
D-Equilenin	3.40
17α Estradiol	0.21
16 Keto Estradiol	0.21
17β-Estradiol-3-Glucuronide	2.56
Estradiol-3-Sulfate	0.17
Estriol	0.64
Testosterone	ND
DHEA	ND
Diethyl Stibesterol	ND
Mifepristone	ND
17βE2-17-Glucuronide	ND

ND = Non-Detectable = <0.01%

Precision

Intra-assay

Serum	S1	S2	S3
Number of determinations	23	12	12
Mean value, pg/mL	5.28	40.44	92.56
C.V., %	8.88	7.61	6.93

EDTA plasma	P1	P2	P3
Number of determinations	25	25	25
Mean value, pg/mL	23.09	36.30	66.02
C.V., %	9.71	7.11	8.97

Inter-assay

Serum	S1	S2	S3	S4
Number of determinations	8	8	8	8
Mean value, pg/mL	5.25	28.03	42.28	108.7
C.V., %	7.55	9.71	8.02	12.18

EDTA plasma	P1	P2	P3	P4
Number of determinations	10	10	10	10
Mean value, pg/mL	11.63	38.8	50.3	273
C.V., %	5.71	7.87	6.64	5.57

Accuracy

Dilution test

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

Serum	Dilution factor	Measured (pg/mL)	Expected (pg/mL)	Ratio (%) Measured/ Expected
S1	-	16.98	-	-
	1:2	8.09	8.49	95.29
	1:4	4.01	4.25	94.46
	1:8	1.96	2.12	92.34
S2	-	21.73	-	-
	1:2	10.58	10.87	97.38
	1:4	5.32	5.43	97.93
	1:8	2.39	2.72	87.99
S3	-	19.81	-	-
	1:2	8.73	9.91	88.14
	1:4	5.11	4.95	103.2
	1:8	2.17	2.48	87.63
S4	-	27.12	-	-
	1:2	14.58	13.56	107.5
	1:4	7.37	6.78	108.7
	1:8	3.54	3.39	104.4
S5	-	26.03	-	-
	1:2	13.07	13.02	100.4
	1:4	6.37	6.51	97.89
	1:8	3.63	3.25	111.6

EDTA plasma	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(pg/mL)		
P1	-	41.16	-	-
	1:2	17.57	20.58	85.37
	1:4	8.39	10.29	81.54
	1:8	5.75	5.15	111.8
P2	-	31.00	-	-
	1:2	15.59	15.50	100.6
	1:4	6.39	7.75	82.45
	1:8	3.51	3.88	90.58
P3	-	26.73	-	-
	1:2	13.74	13.37	102.8
	1:4	6.13	6.68	91.73
	1:8	3.99	3.34	119.4
P4	-	28.14	-	-
	1:2	12.93	14.07	91.90
	1:4	6.31	7.04	89.69
	1:8	3.45	3.52	98.08
P5	-	21.28	-	-
	1:2	10.45	10.64	98.21
	1:4	4.74	5.32	89.10
	1:8	2.22	2.66	83.46

Recovery test

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

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
S1	15.60	13.73	29.33	26.88	91.65
	15.45	20.39	35.84	29.74	82.98
	14.73	51.85	66.58	60.90	91.47
S2	17.91	13.75	31.66	26.01	82.15
	17.74	20.39	38.13	31.56	82.77
	16.92	51.85	68.77	60.88	88.53
S3	19.04	13.73	32.77	31.11	94.93
	18.85	20.39	39.24	35.29	89.93
	17.98	51.85	69.83	74.84	107.2
S4	28.65	11.02	39.67	36.09	90.98
	28.43	16.41	44.84	39.65	88.43
	27.46	39.62	67.08	54.78	81.66
S5	15.83	11.02	26.85	23.22	86.48
	15.70	16.41	32.11	26.23	81.69
	15.17	39.62	54.79	47.96	87.53

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
P1	17.67	13.73	31.40	27.71	88.25
	17.50	20.39	37.89	30.35	80.10
	16.69	51.85	68.54	56.84	82.93
P2	19.60	13.75	33.35	28.52	85.52
	19.41	20.39	39.80	32.21	80.93
	18.51	51.85	70.36	57.29	81.42
P3	17.48	13.73	31.21	26.51	84.94
	17.31	20.39	37.70	32.35	85.81
	16.51	51.85	68.36	57.21	83.69
P4	66.57	11.02	77.59	80.34	103.5
	66.05	16.41	82.46	87.67	106.3
	63.81	39.62	103.4	103.4	99.99
P5	43.35	11.02	54.37	51.13	94.04
	43.01	16.41	59.42	56.49	95.07
	41.55	39.62	81.17	80.95	99.73

^{125}I Characteristics

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

^{125}I	E (MeV)	%
γ	0.035	
X	0.027	114
	0.032	25

Symbols Key

WARNING — WARNING / AVERTISSEMENT / WARNUNG / AVVERTENZA / ADVERTENCIA / AVISO / VARNING / ΠΡΟΕΙΔΟΠΟΙΗΣΗ / 警告 / ĮSPĖJIMAS / VIGYÁZAT! / OSTRZEŻENIE / VAROVÁNÍ / VÝSTRAHA / 경고 / UYARI / ОСТОРОЖНО / ПРЕДУПРЕЖДЕНИЕ / 警告

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

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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 — 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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