BECKMAN COULTER

CE 2797

ACTIVE® Free Testosterone RIA

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

REVISION HISTORY

Previous version: IFU-DSL4900-04	**Current version:** IFU-DSL4900-05
MATERIALS PROVIDED **Calibrators: seven 0.5 mL vials and one 1 mL vial of «zero» calibrator** (ready-to-use) The calibrator vials contain from 0 to approximately 100 pg/mL (0 to approximately 346.7 pmol/L) of free testosterone in human serum with 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 0.5 mL vials** (ready-to-use) The vials contain free testosterone in human serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to an internal reference standard.	**Calibrators: seven 0.5 mL vials and one 1 mL vial of «zero» calibrator** (ready-to-use) The calibrator vials contain from 0 to approximately 100 pg/mL (0 to approximately 346.7 pmol/L) of free testosterone in human serum with 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 0.5 mL vials** (ready-to-use) The vials contain free testosterone in human serum with 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. Use the concentration of calibrators indicated on each vial label. The concentrations are lot specific, check carefully.)*	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 DSL4900

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

ACTIVE® Free Testosterone RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of free testosterone in human serum. Measurement of free testosterone is intended to be used for the assessment of fertility status and sexual development. It is used in diagnosis and monitoring of androgen excess states in females and androgen insufficiency states in males. It aids in diagnosis of precocious and delayed puberty in boys [1, 2, 3, 4].

PRINCIPLE

The radioimmunoassay of free testosterone is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled free testosterone, as a tracer, in polyclonal antibody-coated tubes. After incubation, the contents of the tubes are rinsed so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The free testosterone concentrations in the samples are obtained by interpolation from the standard curve. The concentration of free testosterone 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.
- Each tube must be used only once.

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

The materials of human origin, contained in this kit, were found negative for the presence of antibodies to HIV 1 and HIV 2, antibodies to HCV, as well as of Hepatitis B surface antigen (HBsAg). However, they should be handled as if capable of transmitting disease. No known test method can offer total assurance that no virus is present. Handle this kit with all necessary precautions.

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

GHS HAZARD CLASSIFICATION

Not classified as hazardous

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

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum is the recommended sample type.
- Allow serum samples to clot completely before centrifugation.
- Serum samples may be stored at 2-8°C, if the assay is to be performed within 24 hours. For longer storage keep frozen (at < -18°C up to 7 months), after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- Dilution of samples with concentration greater than the highest calibrator is not recommended. Dilution will change the proportion of free to bound testosterone.

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.

Tubes: 2 x 50 (ready-to-use)

^{125}I-Tracer: one 22 mL vial (ready-to-use)

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

Calibrators: seven 0.5 mL vials and one 1 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 100 pg/mL (0 to approximately 346.7 pmol/L) of free testosterone in human serum with 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 0.5 mL vials (ready-to-use)

The vials contain free testosterone in human serum with 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).

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (50 µL).
- Semi-automatic pipette (200 µL, 3 mL).
- Vortex type mixer.
- Temperature-controlled water bath, 37°C ± 2°C.
- A sponge rack or similar device for decantation.
- Absorbent material for blotting tubes.

- Aspiration system.
- 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	Step 3 Counting
To coated tubes add successively:	Cover and incubate 60 min in a water bath at 37 ± 2°C.	Aspirate or decant all tubes (except «total cpm» tubes) by simultaneous inversion with a sponge rack into a radioactive waste receptacle.
50 µL of calibrator, control or sample, immediately add 200 µL of tracer.*	Aspirate or decant all tubes (except «total cpm» tubes) by simultaneous inversion with a sponge rack into a radioactive waste receptacle.	Strike the tubes sharply on absorbent material to facilitate complete drainage.
Vortex gently 1-2 seconds.	Strike the tubes sharply on absorbent material to facilitate complete drainage.	Drain on absorbent material for a minimum of 2 minutes. Blot droplets from the rims of tubes.
	Add 3.0 mL of deionized water to all tubes, except «total cpm» tubes.	Count bound cpm (B) and total cpm (T) for 1 minute.

* Add 200 µL of tracer to 2 additional tubes to obtain «total cpm».

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 lin of *B/T or* B/B_0 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 on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

To convert concentrations from pg/mL to pmol/L, multiply results by **3.47**.

EXPECTED VALUES

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

Men (Age in years)	n	Median	Min.	Max.	2.5th percentile	97.5th percentile
		pg/mL				
20 - 29	30	15.40	7.54	27.79	8.68	25.09
30 - 39	30	14.94	6.77	22.36	8.85	21.40
40 - 49	30	11.48	7.37	20.47	7.56	18.64
50 and above	30	9.05	4.52	15.05	5.72	14.21
All	120	12.35	4.52	27.79	6.76	22.76

Women	n	Median	Min.	Max.	2.5th percentile	97.5th percentile
		pg/mL				
Follicular Phase	32	1.48	0.59	4.28	0.64	3.41
Luteal Phase	32	1.44	0.59	3.31	0.60	2.95
Preovulatory Peak	21	1.51	0.81	3.79	0.90	3.79
Postmenopausal	13	1.17	0.33	1.97	0.36	1.85
Contraceptives	19	1.45	0.49	2.81	0.57	2.70

Random women	n	Median	Min.	Max.	2.5th percentile	97.5th percentile
		pg/mL				
All	120	1.29	0.33	4.28	0.49	2.87

Detail information about expected values for children (sorted according to age and sex) can be found in the data sheet "APPENDIX".

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

Limit of detection (LoD): 0.13 pg/mL

The LoD of the assay is 0.13 pg/mL, determined consistent with guidelines in CLSI document EP17-A2 [5] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 120 blank and 120 low level samples; and Limit of Blank (LoB) of 0.05 pg/mL.

Limit of quantitation (LoQ): 0.37 pg/mL

The LoQ for Free Testosterone is 0.37 pg/mL, determined consistent with guidelines in CLSI document EP17-A2 [4] as the lowest concentration where criterion for maximum total error was achieved.

Specificity

The antibody used in the immunoassay is highly specific for free testosterone. Low cross reactivities were obtained against several related molecules.

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [6]. For repeatability the coefficients of variation were found below or equal to 13.2% for serum samples. For within laboratory precision the coefficients of variation were found below or equal to 19.3% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 0.30 to 114.11 pg/mL using serum samples (determined consistent with guidelines in CLSI document EP6-A [7]).

Measurement range (from LoQ to the highest calibrator): 0.37 to approximately 100 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 [8, 9, 10].

APPENDIX

PERFORMANCE CHARACTERISTICS

ACTIVE is a trademark of BECKMAN COULTER Inc. and its subsidiaries.

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

Summary and explanation of the test

Indications for use: Radioimmunoassay for the quantitative measurement of free testosterone in human serum. This assay is intended for in vitro diagnostic use. Free testosterone test is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in female's hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes [11].

Testosterone (17α-Hydroxy-4-androsten-3-one), a C_{19} steroid, is a potent circulating naturally-secreted androgen [12]. In normal postpubertal males, testosterone is secreted primarily by the testes with only a small amount derived from peripheral conversion of 4-Androstene-3,17-dione (ASD) [12]. In adult women, it has been estimated that more than 50% of serum testosterone is derived from peripheral conversion of ASD secreted by the adrenal glands and ovaries, with the remainder derived from direct secretion of testosterone by these glands [13,14]. Testosterone production rates in blood have been estimated at 0.34 mg/day in adult females and more than 20 times this amount in adult males [13,14,15]. Approximately 60% of blood testosterone is normally bound with high affinity to sex hormone-binding globulin (SHBG) [16]; of the remainder, all but 1-2% is loosely bound to albumin.

The percentage bound to SHBG is somewhat lower in males as compared to females [17]. Both the albumin-bound and free fractions may be biologically active, while SHBG effectively inhibits testosterone action. Approximately half of the blood testosterone is metabolized in the liver to androsterone, etiocholanolone and epiandrosterone; all relatively weak androgens [12,14]. Testosterone is also converted to the potent androgen, dihydrotestosterone (DHT), in certain target tissues. Measurement of the free or unbound fraction of serum testosterone has been proposed as a means of estimating the physiologically bioactive hormone. Free testosterone levels are elevated in women with hyperandrogenism associated with hirsutism in the presence or absence of polycystic ovarian disease [16,17,18].

Traditional methods for measurement of free testosterone involve the addition of [^{3}H]-testosterone to serum or plasma, followed by various procedures, e.g. dialysis, filtration and precipitation, to separate the free and bound fractions. The partitioning of the tritiated testosterone is then used to calculate the endogenous bound and free fractions. These indirect methods are time-consuming and labor-intensive and are not practical for routine applications. The DSL4900 ACTIVE® Free Testosterone RIA utilizes an [^{125}I]-labeled testosterone analog which has low affinity for SHBG and albumin. The analog competes with the unbound testosterone in the test sample for binding to specific anti-testosterone polyclonal antibodies, which have been immobilized on the assay tube. This competitive binding format allows direct estimation of unlabeled free testosterone levels in unextracted samples.

Interference

Serum samples containing free testosterone concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using ACTIVE® Free Testosterone RIA. Values were calculated as described in CLSI EP07, 3rd ed. [19]. 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 > 10 %) was found for addition of interferent up to concentration stated in the table below.

Interferent	Test concentration
Hemoglobin	641 µg/mL
Bilirubin (conjugated)	199 µg/mL
Bilirubin (unconjugated)	92.7 µg/mL
Biotin	1,020 ng/mL
Ascorbic acid	40.5 µg/mL
Ibuprofen	122 µg/mL
Cholesterol	0.75 mg/mL
Heparin	7,248 ng/mL
Prednisone	384 ng/mL
Prednisolone	1,294 ng/mL
Protein (gamma globulin)	49.5 mg/mL
Rheumatoid factor	3.45 IU/mL
Acetylsalicylic acid	24.2 µg/mL
Triglycerides	3.35 mg/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.

Specificity

The cross-reactivity of the free testosterone antiserum has been measured against the following compounds according to CLSI recommendations (EP07, 3rd ed.) [19]. The percent cross-reactivity is expressed as the ratio of measured minus true free testosterone concentration and concentration of added cross-reactant.

COMPOUND	Pooled normal serum	
	Crossreactant Conc. (ng/mL)	Cross Reactivity (%)
19-Nortestosterone	8.62	0.068
11-Ketotestosterone	102	0.020
11β-Hydroxytestosterone	14.1	0.029
Androstenediol	14.8	0.010
Methyltestosterone	96.5	0.017
Androstenedione	92.4	0.006
Norethindrone	1,056	0.001
5α-Androstane-3α,17β-diol	1,076	0.002
5β-Androstane-3,17-dione	1,011	ND
5α-Androstane-3,17-dione	846	0.001
Danazol	921	0.001
Estradiol	946	0.001
Progesterone	956	0.001
Deoxycorticosterone	911	ND
Androsterone	1,002	ND
Epiandrosterone	943	ND
DHEA	896	ND
Estriol	882	ND
Estrone	913	ND
Corticosterone	951	ND
Cortisol	857	ND
Pregnenolone	944	ND
DHT	168	0.020
Androstanediol Glucuronide	1,031	ND
DHEA-S	922	ND
5α-Androstan-3β,17β diol	98.0	0.005
rhSHBG	10,407	ND

* *ND = Non-Detectable (< 0.001%)*

COMPOUND	Pooled depleted serum	
	Crossreactant Conc. (ng/mL)	Cross Reactivity (%)
19-Nortestosterone	43.6	0.116
11-Ketotestosterone	6.59	0.026
11β-Hydroxytestosterone	2.62	0.029
Androstenediol	91.6	0.024
Methyltestosterone	11.1	0.005
Androstenedione	10.5	0.004
Norethindrone	40.0	0.002
5α-Androstane-3α,17β-diol	749	ND
5β-Androstane-3,17-dione	746	ND
5α-Androstane-3,17-dione	747	ND
Danazol	79.1	0.001
Estradiol	820	ND
Progesterone	8,330	ND
Deoxycorticosterone	7,681	ND
Androsterone	8,280	ND
Epiandrosterone	7,634	ND
DHEA	8,362	ND
Estriol	8,981	ND
Estrone	8,442	ND
Corticosterone	7,197	ND
Cortisol	79,944	ND
Pregnenolone	83,919	ND
DHT	96.1	0.013
Androstanediol Glucuronide	8,111	ND
DHEA-S	89,418	ND
5α-Androstan-3β,17β diol	43.1	0.001
rhSHBG	55,556	ND

* *ND = Non-Detectable (< 0.001%)*

Precision

Repeatability and within-laboratory precision

Samples were assayed for 20 days, 2 runs per day, triplicates per run. Assays were performed by two lab technicians, by two reagent lots. There were 120 individual measurements per sample with no invalid results.

Serum	Mean (pg/mL)	Repeatability		Within-laboratory precision	
		SD (pg/mL)	C.V. (%)	SD (pg/mL)	C.V. (%)
S1	0.65	0.09	13.23	0.12	19.32
S2	7.89	0.71	8.95	0.90	11.43
S3	13.65	1.44	10.54	1.67	12.20
S4	40.19	2.58	6.42	3.49	8.68
S5	74.29	4.80	6.47	5.78	7.78

Expected data for children

Results are sorted according to the age and sex.

Subgroups "Infant, Child and Adolescent" were defined according to Premarket Assessment of Pediatric Medical Devices, Guidance for Industry and Food and Drug Administration Staff [20].

The second tables provide more detailed age discrimination at the onset of puberty.

Free Testosterone (pg/mL)						
Boys	N	Median	Min.	Max.	2.5th percentile	97.5th percentile
Infant	18	< 0.13	< 0.13	0.31	< 0.13	0.28
Child	48	0.56	0.13	12.79	0.16	12.65
Adolescent	30	15.10	1.71	32.09	1.88	28.55

Free Testosterone (pg/mL)						
Boys	**N**	**Median**	**Min.**	**Max.**	**2.5th percentile**	**97.5th percentile**
6 months - 9 years	36	0.20	< 0.13	0.62	< 0.13	0.54
10 - 11 years	20	0.67	0.41	5.11	0.42	5.00
12 - 13 years	20	6.21	0.60	27.21	0.63	23.27
14 - 15 years	20	18.71	5.50	32.09	8.03	28.77

Free Testosterone (pg/mL)						
Girls	**N**	**Median**	**Min.**	**Max.**	**2.5th percentile**	**97.5th percentile**
Infant	34	< 0.13	< 0.13	0.42	< 0.13	0.33
Child	55	0.46	< 0.13	2.53	< 0.13	1.90
Adolescent	30	1.37	0.57	3.27	0.64	3.23

Free Testosterone (pg/mL)						
Girls	**N**	**Median**	**Min.**	**Max.**	**2.5th percentile**	**97.5th percentile**
6 months - 9 years	69	0.24	< 0.13	0.86	< 0.13	0.57
10 - 12 years	20	0.88	0.37	2.53	0.41	2.25
13 - 16 years	20	1.42	0.57	3.27	0.65	3.24

Method Comparison:

The current version of ACTIVE® Free Testosterone RIA (Method A) was compared to previous version of ACTIVE® Free Testosterone RIA (Method B):

n	Range (pg/mL)	Slope	Intercept	r
278	0.26 - 101.21	1.0078	0.0759	0.9956

^{125}I Characteristics

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

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

Symbols Key

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

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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

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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

TUBE — Tubes / tubes / Röhrchen / provette / tubos / Tubos de amostra / Provrör / σωληνάρια / 试管 / Mėgintuvėliai / Csövek / Probówki / Zkumavky / Skúmavky / 튜브 / Tüpler / пробирки / Епруветки / 試管

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

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