BECKMAN COULTER

CE 2797

ACTIVE® Dihydrotestosterone RIA

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

REVISION HISTORY

Previous version: IFU-DSL9600I-01	**Current version:** IFU-DSL9600I-02
—	Adding Slovenian to the IFU.
Radioactivity table in the chapter APPENDIX.	Better specification of Iodine 125 characteristics table at the end of the chapter Appendix.

REF DSL9600I

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

ACTIVE® Dihydrotestosterone RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of dihydrotestosterone (DHT) in human serum and plasma. Measurement of DHT is intended to be used as an aid in diagnosis of androgen-related endocrine disorders, including 5α- reductase deficiency, in general population [1, 2].

PRINCIPLE

The radioimmunoassay of dihydrotestosterone (5α-Dihydrotestosterone; DHT; 17β-Hydroxy-5α-androstan-3-one) is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled dihydrotestosterone, 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 dihydrotestosterone concentrations in the samples are obtained by interpolation from the standard curve. The concentration of dihydrotestosterone 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

Oxidation solution	WARNING	
		
		
	H361	Suspected of damaging fertility or the unborn child.
	H411	Toxic to aquatic life with long lasting effects.
	P201	Obtain special instructions before use.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P391	Collect spillage.
		Potassium Permanganate 1 - 5%
Sample buffer	DANGER	
		
		
	H226	Flammable liquid and vapour.
	H314	Causes severe skin burns and eye damage.
	P210	Keep away from heat, hot surfaces, and sparks. No smoking.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER or doctor/physician.
		Ethyl Alcohol 10 - 20%
		Sodium Hydroxide 20 - 30%

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.
- Samples MUST be extracted prior to assay. See Procedure.
- If samples have concentrations greater than the highest calibrator, they must be diluted into the zero calibrator.

Serum and EDTA plasma values for 19 samples (serum values ranging from 53.75 to 341.5 pg/mL) were compared using the ACTIVE® Dihydrotestosterone RIA, DSL9600i. Results are as follows:

[EDTA-plasma] = 0.9592[serum] + 31.583 R = 0.9783

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 reconstitution are indicated in paragraph Procedure.

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

^{125}I-Tracer: 1 vial (lyophilized)

The vial contains 185 kBq, at the date of manufacture, of ^{125}I-labeled DHT in buffer with proteins (BSA) and sodium azide (<0.1%).

Calibrators: one 50 mL of «zero» calibrator vial (ready to use) **and seven vials** (lyophilized)

The calibrator vials contain from 0 to approximately 2,500 pg/mL of dihydrotestosterone in buffer with proteins (BSA) and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to a certified reference material (Cerilliant). Do NOT extract calibrators prior to assay.

Control samples: two vials (lyophilized)

The vials contain dihydrotestosterone in human serum and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to a certified reference material (Cerilliant). Controls MUST be extracted prior to assay (see Procedure).

Control samples may be ordered separately, too (REF. B75485).

Oxidation solution: two 25 mL bottles (ready-to-use)

Bottles contain potassium permanganate solution (<5%) in a buffer with sodium azide (<0.1%).

Sample buffer: one 5.5 mL vial (ready-to-use)

The vial contains buffer with Ethyl Alcohol (<23%) and Sodium Hydroxide (<29%).

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- 12 x 75 mm or 13 x 100 mm or 16 x 150 mm **GLASS** tubes and safety caps.
- Precision micropipette (100 µL, 250 µL and 400 µL).
- Semi-automatic pipette (500 µL, 3 mL).
- Vortex type mixer.
- 5 mL graduated glass pipettes - **USED IN EXTRACTION.**
- Organic solvents: n-hexane and ethanol (HPLC grade).
- Centrifuge (1500 x g, preferably refrigerated).
- Nitrogen gas or a speed-vac assembly with heating (for extractions).
- Horizontal or orbital shaker.
- A sponge rack or similar device for decantation.
- Aspiration system.
- Absorbent material for blotting tubes.
- Gamma counter set for ^{125}I.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of tracer

The content of the vial is reconstituted with the volume of distilled water indicated on the label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solution at 2-8°C for up to 14 days.

Reconstitution of calibrators and control samples

The content of the vials is reconstituted with the volume of distilled water indicated on the label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solutions aliquoted at < -20°C for a longer time, until the expiry date of the kit.

Extraction of samples

Note: Extractions must be done using clean, preferably disposable, GLASS tubes and pipettes. Allow the Oxidation solution and other extraction reagents to reach room temperature (18-25°C) before use.

Samples and controls require extraction. Do NOT extract calibrators.

- Number one tube for each sample or control.
- Add 400 µL of sample or control to a numbered glass tube and add 500 µL of Oxidation solution. Thoroughly vortex and incubate at room temperature (18-25°C) for 15 minutes.
- Prepare the extraction mixture: 98% n-hexane and 2% ethanol.
- Using a glass pipette, extract the oxidized sample by adding 4.0 mL n-hexane-ethanol mixture (98% hexane: 2% ethanol). Vortex each sample immediately for 1 minute.
- Add 50 µL of Sample buffer, cap tubes and mix gently by inverting tubes 3-4 times.

- Centrifuge at 1500 X g for 15 minutes at 2-8°C to separate the organic layer from the aqueous layer.
- Transfer 2.5 mL of the upper organic layer into appropriately labeled clean glass tubes and evaporate to dryness, using either nitrogen gas or a speed-vac assembly with heating.
- Reconstitute the dried material with 250 µL of the DHT zero calibrator. Thoroughly vortex and keep at room temperature (18-25°C) at least 1 hour.

NOTE:

- DO NOT EXTRACT KIT CALIBRATORS
- Use 12 x 75 mm or 13 x 100 mm glass tubes with safety caps. If safety caps are not available, 16 x 150 mm tubes can be used. After extraction, cover the 16 x 150 mm tubes with aluminum foil to avoid evaporation of organic solvent.
- Avoid using lipemic samples.

Assay procedure

Step 1 Additions	Step 2 Incubation	Step 3 Counting
Extract samples and controls as directed in section Procedure. To coated tubes add successively: 100 µL of calibrator, control or sample and immediately add 500 µL of tracer.* Vortex gently 1-2 seconds.	Cover and incubate 2 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.	Add 3.0 mL deionized water to all tubes, except «total cpm» tubes. 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. Drain for >2 minutes. Blot the tubes. Count bound cpm (B) and total cpm (T) for 1 minute.

*. Add 500 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 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: 57,936 cpm				
Calibrators	**DHT (pg/mL)**	**cpm (n=2)**	**B/T (%)**	**B/B_0 (%)**
0	0	37,670	65.0	100.0
1	24.0	31,164	53.8	82.7
2	48.0	26,403	45.6	70.1
3	96.0	19,356	33.4	51.4
4	192	12,449	21.5	33.0
5	480	6,948	12.0	18.4
6	960	4,570	7.88	12.1
7	2,400	2,514	4.33	6.67

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

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 3.44.

EXPECTED VALUES

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

	Age (years)	n	(pg/mL)			
			Median	**2.5th percentile**	**97.5th percentile**	**Range**
Male	20 - 60	119	274.7	109.2	583.1	33.69 - 756.0
Female	20 - 60	122	82.81	33.28	196.5	17.67 - 245.8

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

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: 9.14 pg/mL

Functional sensitivity: 19.63 pg/mL

Specificity

The antibody used in the immunoassay is highly specific for DHT. Extremely low cross reactivities were obtained with several related molecules (androstenedione, estradiol, testosterone etc).

Precision

Intra-assay

Samples were assayed 25 times in the same run. The coefficients of variation were ≤ 7.9%.

Inter-assay

Samples were assayed in duplicate in 10 different series. The coefficients of variation were found below or equal to 7.1%.

Accuracy

Dilution test

High-concentration samples were serially diluted with zero calibrator. The recovery percentages obtained were between 80.5% to 114%.

Recovery test

Low-concentration samples were spiked with known quantities of DHT. The recovery percentages obtained were between 88.0% to 107%.

Measurement range (from analytical sensitivity to the highest calibrator): 9.14 to approximately 2,500 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 [3, 4, 5].

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

5α-Dihydrotestosterone (DHT; 17β-Hydroxy-5α-androstan-3-one), the most potent naturally-occurring androgen, is produced from testosterone through the action of cholestenone 5α-reductase [6]. The concentrations of 5α-reductase are highest in certain peripheral tissues, including genital skin and hair follicles, and is localized intracellularly in apparent association with the nuclear membrane. DHT exerts its biological action by intracellular binding to the androgen receptor; this complex is then transferred to the nucleus where DNA-binding occurs with resultant effects on DNA transcription [7]. Most of the residual DHT undergoes intracellular metabolism to 3α-androstanediol and 3α-androstanediol glucuronide. Only a small proportion of DHT escapes into the peripheral circulation, where it is present primarily complexed to sex-hormone binding globulin [8].

Testosterone causes virilization of the Wolffian ducts during fetal life, while DHT is responsible for the development of the male external genitalia and prostate, and is primarily responsible for the physical changes which occur during male sexual maturation. An autosomal-recessive genetic deficiency of 5α-reductase, sometimes called male pseudohermaphroditism or pseudovaginal perineoscrotal hypospadias, leads to inadequate differentiation of DHT-dependent peripheral tissues. Male infants with this disorder have ambiguous genitalia and are often raised as females, although significant virilization may occur later in life presumably due to the natural increase in testosterone levels [7]. Measurement of DHT concentrations can be complicated by antibody cross-reactivity to testosterone. This DHT Radioimmunoassay utilizes a sample oxidation/extraction procedure to remove most of the testosterone, coupled with a relatively specific immunoassay for DHT.

Interference

Serum samples containing DHT concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using ACTIVE® Dihydrotestosterone RIA. Values were calculated as described in CLSI EP07, 3rd ed. [9]. 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	1,651 ng/mL
Conjugated bilirubin	433.3 µg/mL
Hemoglobin	10,173 µg/mL
Triglycerides	9.08 mg/mL
Unconjugated bilirubin	241.6 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.

Specificity

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

COMPOUND	% CROSS-REACTIVITY
Dihydrotestosterone	100
Androstenedione	1.90
Estradiol	1.41
Testosterone	0.02*
Androstanediol	0.25
Androstanediol Glucuronide	0.19
Androsterone Glucuronide	ND
Dehydroepiandrosterone	ND
Cortisol	ND
11-Deoxycortisol	ND
17a-OH-Progesterone	ND
Progesterone	ND

*. after extraction, ND - Not detectable (<0.01%)

Precision

Intra-assay

The intra-assay precision (after extraction) was determined from the mean of 25 determinations.

Serum	S1	S2	S3
Number of determinations	25	25	25
Mean value, pg/mL	71.47	332.4	843.4
C.V., %	7.89	6.52	4.45

Inter-assay

The inter-assay precision (after extraction) was determined from the mean of average duplicates for 10 separate runs.

Serum	S1	S2	S3
Number of determinations	10	10	10
Mean value, pg/mL	54.65	315.7	813.4
C.V., %	5.17	7.08	2.47

Accuracy

Dilution test

Samples were extracted, 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	-	301.2	-	-
	1:2	148.9	150.6	98.87
	1:4	75.46	75.30	100.2
	1:8	42.93	37.65	114.0
S2	-	620.9	-	-
	1:2	268.4	310.5	86.45
	1:4	132.1	155.2	85.12
	1:8	64.20	77.61	82.72
	1:16	31.61	38.81	81.46
S3	-	409.9	-	-
	1:2	173.2	205.0	84.50
	1:4	86.97	102.5	84.87
	1:8	53.73	51.24	104.9
S4	-	481.9	-	-
	1:2	194.0	240.9	80.50
	1:4	107.8	120.5	89.48
	1:8	49.21	60.23	81.70
S5	-	1,126	-	-
	1:2	561.6	563.0	99.75
	1:4	239.1	281.5	84.94
	1:8	127.0	140.8	90.24
	1:16	64.92	70.38	92.25
	1:32	33.44	35.19	95.03

Recovery test

Samples were extracted, spiked with known quantities of DHT 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	270.7	119.0	389.8	370.3	95.01
	279.6	409.8	689.4	636.2	92.28
	275.1	806.5	1,082	1,049	97.03
S2	284.8	119.0	403.9	388.8	96.28
	294.2	409.8	704.0	684.1	97.18
	289.4	806.5	1,096	1,153	105.2
S3	371.7	156.3	528.0	501.6	95.00
	390.0	409.8	799.9	854.3	106.8
	383.7	806.5	1,190	1,201	100.9
S4	154.7	80.65	235.3	230.3	97.85
	147.5	192.3	339.8	299.1	88.02
	157.2	409.8	567.0	545.8	96.25
S5	316.8	156.3	473.1	439.1	92.81
	332.4	409.8	742.2	756.2	101.9
	327.0	806.5	1,134	1,158	102.1

Expected values

Male					
Age (years)	n	Median	2.5th percentile	97.5th percentile	Range
		(pg/mL)			
20 - 30	26	343.0	168.6	691.7	150.7 - 756.0
31 - 40	32	283.2	162.8	596.5	155.0 - 655.0
41 - 50	29	255.6	76.86	440.3	70.62 - 454.4
51 - 60	32	228.1	93.45	412.9	33.69 - 515.2
20 - 60	119	274.7	109.2	583.1	33.69 - 756.0

Female					
Age (years)	n	Median	2.5th percentile	97.5th percentile	Range
		(pg/mL)			
20 - 30	30	103.4	46.39	217.0	33.16 - 245.8
31 - 40	31	95.80	46.02	201.1	45.24 - 244.5
41 - 50	32	76.40	37.27	122.3	21.24 - 127.3
51 - 60	29	54.70	18.52	78.55	17.67 - 84.36
20 - 60	122	82.81	33.28	196.5	17.67 - 245.8

^{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

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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 ^{125}I
Ab ^{125}I

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

BUF

Buffer / Tampon / Puffer / Tampone / Tampón / Tampão / Buffert / Ρυθμιστικό Διάλυμα / 缓冲液 / Buferinis tirpalas/ Puffer / Bufor / Pufr / Tlmivý roztok / 완충액 / Tampon / Буфер / Буфер / 緩衝劑

SOLN OX

Oxidation Solution / Solution oxydante / Oxidationslösung / Soluzione di ossidazione / Solución de oxidación / Solução de oxidação / Oxidationslösning / Διάλυμα οξείδωσης / 氧化溶液 / Oksidacijos tirpalas / Oxidáló oldat / Roztwór do utleniania / Oxidační činidlo / Oxidačný roztok / 산화 용액 / Oksidasyon Çözeltisi / Окисляющий раствор / Разтвор за оксидация / 氧化溶液

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