BECKMAN COULTER

CE 2797

ACTIVE® Aldosterone RIA

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

REVISION HISTORY

Previous version:	Current version:
IFU-DSL8600-01	IFU-DSL8600-02
—	Adding Slovenian to the IFU.

REF DSL8600

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

ACTIVE® Aldosterone RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of aldosterone in human serum, plasma or urine. Measurement of aldosterone is intended to be used as an aid in diagnosis and differential diagnosis of primary and secondary hyperaldosteronism and hypoaldosteronism in general population [1, 2].

PRINCIPLE

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

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%

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

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

Serum or EDTA plasma or urine are the recommended sample types.

Diuretics, antihypertensive drugs, cyclic progestogens, estrogens, and licorice should be terminated for at least two weeks, and preferably four weeks, prior to testing. Sample donors should be on a normal sodium diet for 2-4 weeks (approximately 135 mEq or 3 g of sodium per day).

Serum and plasma

- It is necessary to specify the patient's position during specimen collection. A supine sample should be drawn in the early morning before the subject arises, if feasible. If an upright sample is indicated, the subject should be upright for ≥2 hours prior to sampling.
- 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, 2 years 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 in zero calibrator.

Serum and EDTA plasma values for 56 samples (serum values ranging from 34.7 to 275 pg/mL) were compared using the DSL8600 Aldosterone RIA kit. Results are as follows:

[EDTA-plasma] = 1.0493 [serum] + 10.331

R = 0.9746

Urine

- The total volume of urine excreted during a 24-hour period should be collected and mixed in a single container. Add 1 g of boric acid per 100 mL of urine to serve as a preservative. The preserved urine may be stored at 2-8°C for seven days. Urine may be stored in aliquots at < -20°C for up to one month. Thawing of sample should be performed at room temperature.

  NOTE: Specimens should be stored at 2-8°C during collection period and total volume collected should be recorded.
- Aliquot a well-mixed sample to be used in the procedure.
- Add 1 mL of 0.2N HCl to 0.5 mL of the urine.
- Allow this solution to stand at room temperature (18-25°C), in the dark, for 14 to 24 hours.
- Dilute ten-fold by adding 450 µL of zero calibrator to 50 µL of the urine solution.
- Use 100 µL of this diluted urine solution in the normal assay procedure as outlined in the package insert.
- Correct results for volume and dilution as specified in the Results section.

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 or dilution are indicated in paragraph Procedure.

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

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

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

Calibrators: seven vials (lyophilized)

The calibrator vials contain from 0 to approximately 1,600 pg/mL (0 to approximately 4,448 pmol/L) of aldosterone in human serum and 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. A98160 – 12 mL).

Control samples: two vials (lyophilized)

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

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (50 µL and 100 µL).
- Semi-automatic pipette (500 µL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- 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.

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 at < -20°C until the expiry date of the kit.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 100 µL of calibrator, control or sample 500 µL of tracer. Mix rack gently by hand.	Incubate 3 hours at 18-25°C with shaking (≥180 rpm).	Aspirate or decant the content of tubes (except of the 2 tubes «total cpm»), by simultaneous inversion with a sponge rack into a radioactive waste receptacle. Strike tubes sharply and drain on absorbent material for >2 minutes and gently 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: 25,344 cpm				
Calibrators	**Aldosterone (pg/mL)**	**cpm (n=2)**	**B/T (%)**	**B/B$_0$ (%)**
0	0	9,465	37.3	100.0
1	25	8,627	34.0	91.2
2	50	7,357	29.0	77.6
3	100	5,899	23.3	62.3
4	250	4,125	16.3	43.6
5	800	2,300	9.08	24.3
6	1,600	1,324	5.22	14.0

· *(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.

For urine samples multiply result in pg/mL by 30 to obtain the aldosterone concentration in pg/mL of the original unextracted urine sample. Divide this figure by 1000, then multiply by the total volume in liters to report the 24-hour aldosterone output in µg/day.

To convert concentrations from pg/mL to pmol/L, multiply results by **2.78**.

EXPECTED VALUES

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

Serum

N	Normal adult	2.5th - 97.5th percentile	Mean	Min-Max
23	Early Morning, Supine	68.0-173 pg/mL	118 pg/mL	49.3-175 pg/mL
35	Upright, 2 Hours	48.3-270 pg/mL	143 pg/mL	34.7-275 pg/mL

24-hour urine

N	Normal adult	Mean volume	Mean	Expected range
30	Urine	2,175 mL	11.81 µg/day	2.84- 33.99 µg/day

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 APPENDIX)

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

Sensitivity

Analytical sensitivity: 7.64 pg/mL

Specificity

The antibody used in the immunoassay is highly specific for aldosterone. Low cross reactivities were obtained with several related molecules (corticosterone, 18-OH corticosterone, etc).

Precision

Intra-assay

Serum samples were assayed 12 times in the same run. The coefficients of variation were ≤ 4.5%. Urine samples were assayed 25 times in the same run. The coefficients of variation were ≤ 10.0%.

Inter-assay

Serum samples were assayed in duplicate in 6 different runs. The coefficients of variation were ≤ 9.8%. Urine samples were assayed in duplicate in 10 different runs. The coefficients of variation were ≤ 13.2%.

Accuracy

Dilution test

High-concentration serum or urine samples were serially diluted with zero calibrator and assayed. The recovery percentages ranged from 89% to 111% for serum and from 91.8% to 118% for urine.

Recovery test

Low-concentration serum and urine samples were spiked with known quantities of aldosterone and assayed. The recovery percentages ranged from 88% to 116% for serum and from 80.2% to 108% for urine.

Measurement range (from analytical sensitivity to the highest calibrator): 7.64 to approximately 1,600 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

Aldosterone (11β,21-Dihydroxy-3,20-dioxo-4-pregnen-18-al), produced in the adrenal cortex, is the most potent mineralocorticoid in humans. As with other steroid hormones, aldosterone is synthesized from cholesterol through a series of enzyme-mediated steps [6]. Aldosterone and cortisol differ only in that a hydroxyl modification occurs at the 18, rather than 17, position on the steroid molecule. The first and rate-limiting step in steroidogenesis, conversion of cholesterol to pregnenolone, is stimulated by adrenocorticotropic hormone (ACTH) [6]. However, ACTH has only a minimal effect on aldosterone production.

Aldosterone secretion appears to be stimulated primarily through the renin-angiotensin system: decreased plasma volume and renal perfusion (or decreased plasma sodium chloride concentration) leads to increased renin secretion and activation of angiotensin, with angiotensin II then stimulating aldosterone synthesis. Increased plasma potassium concentrations are also a strong independent stimulus for aldosterone production, although this effect is partially countered by potassium inhibition of renin release[7,8,9,10]. The major defined action of aldosterone is stimulation of renal tubular sodium and chloride reabsorption, primarily at the level of the collecting ducts [7,8,9,10].

Other important renal actions include enhancement of urinary potassium and hydrogen (acid) excretion. Similar effects on transmembrane sodium and hydrogen transport have been observed in other tissues, including lymphocytes, brain and arterial smooth muscle [11,12]. Plasma aldosterone levels normally vary with body position (upright>supine) and salt intake. Overall plasma aldosterone levels show a circadian rhythm which is similar to but less marked than cortisol, with peak levels in the early morning [13]. Age-related levels tend to decline from fetal through adult life [10,14]. Aldosterone concentrations in urine and saliva have also been characterized [10,15,16]. Abnormally high plasma aldosterone concentrations can occur as either primary (e.g. adenomas, glucocorticoid-responsive hyperaldosteronism, idiopathic) or secondary conditions. In primary hyperaldosteronism, renin levels are low, blood pressure is elevated and the potassium level is decreased [9].

Secondary hyperaldosteronism occurs as a result of elevated renin secretion, and is observed in renovascular hypertension, renin-secreting tumors, intravascular volume depletion (dehydration), hyponatremia, and in Bartter's syndrome [9,17]. High aldosterone and renin levels are also observed in pseudohypoaldosteronism, a condition caused by end-organ unresponsiveness to aldosterone leading to clinical features of aldosterone deficiency [18]. Abnormally low aldosterone secretion occurs in a number of conditions including salt-wasting forms of congenital adrenal hyperplasia, isolated 18-hydroxylase (carboxymethyl oxidase type II) deficiency, renin deficiency (e.g. nephropathy), and type 4 renal tubular acidosis [10,19,20].

Low aldosterone concentrations in the presence of clinical features of hyperaldosteronism can be observed in 11β-hydroxylase (P450c11) deficiency, 11-hydroxysteroid dehydrogenase deficiency, and after ingestion of materials containing mineralocorticoid-like substances (e.g. licorice, glycyrrhizic acid) [8,9,10]. This aldosterone radioimmunoassay uses a highly specific rabbit anti-aldosterone polyclonal antibody. Cross-reactivity to closely related naturally occurring steroids is negligible.

Interference

Serum samples containing aldosterone concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using ACTIVE® Aldosterone RIA. Values were calculated as described in CLSI EP07, 3rd ed. [21]. 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	1,806 ng/mL
Conjugated bilirubin	412.9 µg/mL
Hemoglobin	9,957 µg/mL
Triglycerides	15.29 mg/mL
Unconjugated bilirubin	451.5 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 12 replicates of the 0 pg/mL aldosterone calibrator, is 7.64 pg/mL.

Specificity

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

COMPOUND	% CROSS- REACTIVITY	COMPOUND	% CROSS- REACTIVITY
Aldosterone	100	Deoxycorticosterone	ND
Corticosterone	0.02	Dexamethasone	ND
18-OHcorticosterone	ND	Prednisolone	ND
Cortisol	ND	Pregnenolone	ND
Cortisone	ND	3α,5β-Tetrahydroaldosterone	0.69

· ND = Non-detectable

Precision

Intra-assay

	Serum			EDTA plasma			Urine		
Sample	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
N	12	12	12	25	25	25	25	25	25
Mean (pg/mL)	66.0	118.7	494.5	124.6	515.6	810.0	159.9	345.2	451.5
C.V. (%)	3.3	4.5	3.9	8.18	4.41	5.59	10.0	6.4	6.9

Inter assay

	Serum			EDTA plasma			Urine		
Sample	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
N	6	6	6	10	10	10	10	10	10
Mean (pg/mL)	59.0	112.8	526.8	53.38	256.8	809.5	97.19	274.5	452.7
C.V. (%)	9.0	9.8	5.9	12.24	8.59	8.46	13.2	9.1	6.6

Accuracy

Dilution test

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

Serum	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(pg/mL)		
S1	-	511.3	-	-
	1:2	242.5	255.6	94.76
	1:4	114.2	127.8	89.36
	1:8	58.4	63.9	91.39
S2	-	333.2	-	-
	1:2	163.6	166.6	98.20
	1:4	86.3	83.3	103.6
	1:8	46.2	41.7	110.8
S3	-	611.8	-	-
	1:2	309.9	305.9	101.3
	1:4	138.9	153.0	90.78
	1:8	69.7	76.5	91.11

EDTA plasma	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(pg/mL)		
P1	-	994.4	-	-
	1:2	532.3	497.2	107.1
	1:4	274.1	248.6	110.3
	1:8	116.9	124.3	94.08
	1:16	63.71	62.15	102.5
	1:32	25.49	31.07	82.03
P2	-	1,140	-	-
	1:2	652.5	570.1	114.5
	1:4	283.6	285.0	99.48
	1:8	141.8	142.5	99.50
	1:16	62.28	71.26	87.40
	1:32	32.34	35.63	90.77
P3	-	1,246	-	-
	1:2	612.6	623.0	98.33
	1:4	333.3	311.5	107.0
	1:8	138.7	155.8	89.07
	1:16	65.17	77.88	83.68
	1:32	32.70	38.94	93.98
P4	-	872.2	-	-
	1:2	485.0	436.1	111.2
	1:4	229.6	218.0	105.3
	1:8	106.4	109.0	97.58
	1:16	47.38	54.51	86.92
	1:32	22.60	27.25	82.92
P5	-	757.1	-	-
	1:2	445.5	378.6	117.7
	1:4	189.0	189.3	99.87
	1:8	98.82	94.64	104.4
	1:16	42.74	47.32	90.32
	1:32	19.58	23.66	82.76

Urine	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(pg/mL)		
U1	-	1,315	-	-
	1:2	650.6	657.6	98.92
	1:4	311.6	328.8	94.75
	1:8	167.1	164.4	101.6
U2	-	1,282	-	-
	1:2	613.0	641.2	95.59
	1:4	294.4	320.6	91.84
	1:8	153.1	160.3	95.50
	1:16	80.10	80.15	99.94
U3	-	1,119	-	-
	1:2	542.2	559.6	96.89
	1:4	277.2	279.8	99.06
	1:8	159.9	139.9	114.3
	1:16	82.39	69.95	117.8
U4	-	1,332	-	-
	1:2	652.5	665.8	98.00
	1:4	346.3	332.9	104.0
	1:8	171.2	166.4	102.8
	1:16	86.61	83.22	104.1
U5	-	1,297	-	-
	1:2	677.8	648.3	104.5
	1:4	325.5	324.2	100.4
	1:8	189.4	162.1	116.8
	1:16	89.50	81.04	110.4

Recovery test

Samples were spiked with known quantities of aldosterone 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	79.2	25	104.2	104.7	100.5
		80	159.2	165.3	103.8
		160	239.2	277.5	116.0
S2	168.2	25	193.2	181.5	93.94
		80	248.2	223.3	89.97
		100	328.2	344.3	104.9
S3	229.7	25	254.7	224.3	88.06
		80	309.7	280.2	90.47
		100	389.7	421.6	108.2

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
P1	38.95	19.51	58.46	61.96	106.0
	38.95	36.59	75.54	89.93	119.0
	37.87	77.08	115.0	133.5	116.2
P2	62.76	32.00	94.76	105.7	111.5
	60.11	64.37	124.5	146.0	117.2
	59.43	136.4	195.8	208.4	106.4
P3	220.8	60.00	280.8	240.3	85.60
	215.6	93.75	309.3	298.2	96.40
	209.1	136.4	316.5	286.6	90.56
P4	189.5	65.74	255.2	237.7	93.13
	184.3	104.7	289.0	261.1	90.35
	180.1	136.4	316.5	286.6	90.56
P5	105.0	47.06	152.1	151.4	99.52
	104.6	93.75	198.4	196.6	99.08
	101.5	136.4	237.8	218.0	91.66

Urine	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
U1	46.28	23.78	70.06	73.30	104.6
	45.87	47.14	93.01	81.66	87.80
	45.06	92.63	137.7	123.5	89.70
U2	62.57	23.78	86.35	73.47	85.08
	61.46	70.09	131.6	120.1	91.31
	59.87	136.6	196.4	166.3	84.67
U3	75.13	23.78	98.91	93.58	94.61
	73.80	70.09	143.9	143.0	99.37
	71.89	136.6	208.4	173.7	83.31
U4	75.63	23.78	99.42	107.7	108.4
	73.64	92.63	166.3	170.6	102.6
	71.15	179.0	250.1	211.2	84.45
U5	103.8	47.14	151.0	142.7	94.54
	100.3	136.6	236.8	189.9	80.19
	96.12	240.0	336.1	286.6	85.27

Method Comparison

The DSL8600 ACTIVE® Aldosterone RIA (Method A) was compared to a commercially available RIA kit (Method B). The DSL8600 was proven to be substantially equivalent to Method B. The results are as follows:

Comparison

The DSL8600 sample range = 33-489 pg/mL

n = 72

Method A Mean = 121 pg/mL

Method B Mean = 134 pg/mL

Y-intercept = 10 pg/mL

Slope = 0.82

Correlation coefficient = 0.94

^{125}I Characteristics

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

^{125}I	E (MeV)	%
γ	7.645	
X	0.027	114
	7.642	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
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 "ν" 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
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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 ^{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

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