

Iodinated I 125 Albumin Injection (IHSA I 125)

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Iodinated I 125 Albumin Injection (IHSA I 125)	350,352,353,355
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A35010

Diagnostic--For Intravenous Use

Revised 3/96

DESCRIPTION

Iodinated I 125 Albumin Injection (IHSA I 125) is supplied in an isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. The amount of free (unbound) iodine at the time of production is 3% or less.

IHSA I 125 is available in

ISOJEX™ Syringe single dose units containing 370 kilobecquerels (10 microcuries) Iodinated I 125 Albumin Injection at a specific activity of 314.5 kilobecquerels (8.5 microcuries) iodine-I 125 per milligram of albumin on the calibration date. Each milliliter contains 246.8 kilobecquerels (6.67 microcuries) (0.8 milligram) Iodinated I 125 Albumin, 9 milligrams sodium chloride, 122 micrograms dibasic sodium phosphate anhydrous and 64 micrograms monobasic potassium phosphate, and 0.5 microgram of guanidine hydrochloride, with 0.9% (v/v) benzyl alcohol added as a preservative. Sodium hydroxide or hydrochloric acid may be present for pH adjustment.

Multiple dose vials containing approximately 3.7 megabecquerels (100 microcuries) Iodinated I 125 Albumin Injection at a specific activity of 37 kilobecquerels (1.0 microcurie) iodine I 125 per milligram of albumin on the calibration date. Each milliliter contains 370 kilobecquerels (10 microcuries) (10 milligrams) Iodinated I 125 Albumin, 9 milligrams sodium chloride, 29 micrograms dibasic sodium phosphate anhydrous and 15 micrograms monobasic potassium phosphate, and 0.7 micrograms of guanidine hydrochloride, with 0.9% (v/v) benzyl alcohol added as a preservative. Sodium hydroxide or hydrochloric acid may be present for pH adjustment.

ACTIONS

The dilution principle is used to determine an unknown volume by introducing a known quantity of radioactive material into that volume and measuring the concentration after adequate mixing.

INDICATIONS AND USAGE

IHSA I 125 (Iodinated I 125 Albumin Injection) is indicated for blood and plasma volume determinations, measurement of circulation time and cardiac output.

CONTRAINDICATIONS

Radiopharmaceuticals are contraindicated in pregnancy and during lactation, and in persons less than 18 years of age, unless in the judgment of the physician the situation requires their use.

Iodinated I 125 Albumin Injection is not to be used intramuscularly.

PRECAUTIONS

To block the possible accumulation of Iodine I 125 in the thyroid gland resulting from the catabolism of Iodinated I 125 Albumin, prior administration of Lugol's Solution is recommended. This precaution is particularly important when dosages of more than 1.85 megabecquerels (50 microcuries) are given.

ADVERSE REACTIONS

The possibility of allergic reaction in patients receiving subsequent doses several weeks after the initial one should be borne in mind.

DOSAGE AND ADMINISTRATION

Blood and Plasma Volume Determinations

The dosage required is in the range of 0.185 to 1.85 megabecquerels (5 to 50 microcuries), depending on the sensitivity of the detection instrumentation. Doses of less than 740 kilobecquerels (20 microcuries) will suffice with well-type scintillation counters. With such doses, determinations can be safely repeated as often as clinically indicated.

Procedure and Calculations for ISOJEX™

The following procedure provides a direct measurement of the plasma volume. The whole blood and red cell volumes are a function of the venous hematocrit which is not representative of the whole body hematocrit in certain conditions.

1. Inject the entire contents of the IHSA I 125 ISOJEX™ syringe intravenously. Rinse the syringe at least twice with the patient's blood while the needle remains in the vein.
2. After 5 to 10 minutes, withdraw 20 mL of blood using an appropriate anticoagulant.
3. Remove a sample for a microhematocrit determination.
4. Pipette* 4 mL of whole blood into a counting vial or test tube.
5. Centrifuge the remaining blood and pipette* 4 mL of plasma into another counting vial or test tube.
6. Count the standard, whole blood, and plasma sample for 1 minute each or a minimum of 10.0 counts.
7. Count background for an equivalent time as in step 6, and subtract from the plasma, whole blood and standard counts.

*Volumetric pipettes are recommended.

Calculations

$$\text{Plasma Volume (mL)} = \frac{\text{Net Standard Count} \times 4000}{\text{Net Plasma Count}}$$

$$\text{Whole Blood Volume (mL)} = \frac{\text{Net Standard Count} \times 4000}{\text{Net Whole Blood Count}}$$

$$\text{Red Cell Volume (mL)} = \text{Whole Blood Volume} - \text{Plasma Volume}$$

$$\text{Radioactive Hematocrit} = \frac{\text{Red Cell Volume}}{\text{Whole Blood Volume}}$$

PROCEDURE AND CALCULATIONS FOR MULTIDOSE VIAL

1. A measured quantity of IHSA I 125 is withdrawn from the product vial and administered intravenously to the subject, using sterile technique. The quantity (CPM) administered may be determined by counting the syringe before and after intravenous injection of its contents and calculating the amount injected from the difference in the two counts.
2. A volume of blood is drawn at five and fifteen minutes after injection of albumin, using an appropriate anticoagulant. The net CPM/mL of the two whole blood samples should then be plotted on semilog paper and extrapolated to zero circulation time to obtain the net CPM/mL of whole blood used in the equation in Step 3. This technique will yield optimal accuracy, since removal of albumin starts immediately after injection.
3. For whole blood volume, an exact volume of the blood is counted. Four milliliters is suggested, in order to attain improved counting statistics, and to provide counting geometry comparable to that of the standard.

Whole Blood Volume (mL): $V_{WB} = \frac{\text{Net CPM Injected}}{\text{Net CPM per 1 mL of Whole Blood}}$

4. Plasma volume can be determined by centrifuging part of the same blood sample, and measuring the radioactivity of an exact volume of plasma. The net CPM/mL of the two plasma samples should then be plotted on semilog paper and extrapolated to zero circulation time to obtain the net CPM/mL of plasma used in the equation included in this step. This technique will yield optimal accuracy, since removal of albumin starts immediately after injection.

Plasma Volume (mL): $V_P = \frac{\text{Net CPM Injected}}{\text{Net CPM per 1 mL of Plasma}}$

5. Red cell volume can be calculated by subtracting the plasma volume from the wholeblood volume.

Red Cell Volume (mL): $V_{RC} = V_{WB} - V_P$

NOTE

A comparison of the radioactive hematocrit with the microhematocrit will give an indication of the accuracy of the procedure and calculations.

The standard, blood, and plasma counts must be taken under identical sample volume and geometric conditions relative to the detector crystal or the difference accounted for in the computations by an appropriate correction factor.

Blood Circulation and Cardiac Output

A dose of 370 to 925 kilobecquerels (10 to 25 microcuries) may be used. For the measurement of circulation time, the time is measured for the albumin to move from the site of injection to the point in question. When the first albumin arrives at the site, a very marked increase in counting rate over the site is observed. A directionally shielded detector is needed.

Correction for Radioactive Decay

Each package of I¹²⁵ is carefully assayed and marked with the radioactive strength as of a specified date. In the event that the drug is to be used at a later date, the radioactive strength may be calculated from the following chart. The strength on the indicated date must be multiplied by the factor corresponding to the number of days after the indicated date.

Iodine I 125 Half Life 60.1 Days

Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining
-14	1.175	1	0.989	18	0.813
-12	1.148	2	0.977	20	0.794
-10	1.122	3	0.966	22	0.776
-8	1.096	4	0.955	25	0.750
-7	1.084	5	0.944	30	0.708
-6	1.072	6	0.933	35	0.668
-5	1.059	7	0.922	40	0.631
-4	1.047	8	0.912	45	0.595
-3	1.035	10	0.891	50	0.562
-2	1.023	12	0.871	55	0.531
-1	1.012	14	0.851	60	0.501
0*	1.000	16	0.832	75	0.421

*Calibration day.

HOW SUPPLIED

Catalog Number

350 IHSA I 125 Injection available in 3.7 megabecquerels (100 microcuries) multiple dose vials with a concentration of approximately 10 microcuries/milliliter.

352 IHSA I 125 ISOJEX™ Syringe available in 370 kilobecquerels(10 microcuries) disposable 1.5 milliliter syringes in packages of 3, 5 and 10.

353 I 125 Plasma Volume Kit (3 Test Kit) containing 3 IHSA I 125 ISOJEX Syringes 370 kilobecquerels (10 microcuries), 1 IHSA I 125 Reference Standard, 6 Counting Vials and 3 Disposable Needles (21 g x 1").

355 IHSA I 125 Reference Standard available in screw-cap vials containing 1/1,000 of the 370 kilobecquerels (10 microcuries) ISOJEX dosage (Catalog No. 352) in 4 milliliters.

STORAGE

IHSA I 125 should be stored at 2⁰C to 8⁰C.

The U.S. Nuclear Regulatory Commission has approved distribution of this radiopharmaceutical to persons licensed to use byproduct material listed in Section 35.100, and to persons who hold an equivalent license issued by an Agreement State.

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St. Louis, MO 63134

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