





A versatile, disposable system

Xenon 133-V.S.S. includes everything you need for a xenon Xe 133 ventilation study. The completely disposable system includes the xenon Xe 133 contained in a valve-shield, a CO_2 absorber and bag for rebreathing and collection of expired xenon Xe 133, and a mouthpiece.

One system can be used for single-breath, rebreathing and wash-out studies.

The valve-shield can deliver either a concentrated or a dispersed dose.

Safe, convenient assembly

Xenon 133-V.S.S. can be assembled in less than a minute. Radiation exposure is minimized because there is no need to dilute the xenon gas or transfer it to a delivery system. After assembly, the ventilation study may begin immediately.

For complete information consult the package insert, a summary of which follows:

Xenon Xe 133-V.S.S. (Ventilation Study System) Xenon Xe 133 Diagnostic

DESCRIPTION: The Xenon Xe 133-Ventilation Study System (V.S.S.) consists of a sealed plastic tube containing 10 millicuries $\pm 20\%$ of Xenon 133 gas at calibration time and date with less than 1% carrier Xenon in air.

INDICATIONS AND USAGE: Study of pulmonary ventilation.

CONTRAINDICATIONS: None known.

WARNINGS: Xenon Xe 133 should not be administered to children or to patients who are pregnant, or to nursing mothers unless the benefits to be gained outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

of menses. Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Xenon Xe 133 should be used in pregnant women only when clearly needed.

CONSIDER MPI's XENON 133-V.S.S. (VENTILATION STUDY SYSTEM) Xenon Xe 133 diagnostic





True, single-unit dose

The MPI Xenon 133-V.S.S. contains enough xenon Xe 133 for one ventilation study. You only use what you need and are not "locked into" an expensive delivery system that requires daily use to justify costs. Another advantage of singleunit dosage is that the risk of cross infection via reusable apparatus is significantly reduced.



Reduced radiation exposure

The xenon Xe 133 is supplied in a sealed plastic container. The valve-shield is designed to prevent radiation leaks during transport and use. Additionally, a shield to reduce radiation exposure to patient and attending personnel and a valve assembly to minimize the escape of exhaled xenon during washout studies are available as accessory components.

PRECAUTIONS: Xenon Xe 133 as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel and to the patients consistent with proper patient management.

the patients consistent with proper patient management. Exhaled Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leak-proof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems. Xenon Xe 133 adheres to some plastics and rubber and should

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

ADVERSE REACTIONS: Adverse reactions specifically attributable to Xenon Xe 133 have not been reported.

DOSAGE AND ADMINISTRATION: The recommended activity range for pulmonary ventilation studies in the average patient (70 kg) is 2 to 20 millicuries (0.03 to 0.3 millicuries/kg).

HOW SUPPLIED: Each Ventilation Study System (V.S.S.) contains Xenon 133 in a sealed plastic tube containing 10 millicuries $\pm 20\%$ at calibration time and date stated on the label.

The sealed plastic tube is enclosed in a metal valve-shield which is sealed with a plastic shrink band to prevent accidental loss of Xenon 133 during shipping. A key is provided to remove the end plugs of the valve-shield and to turn the valve fitting which breaks the sealed plastic tube. The V.S.S. also includes a disposable mouthpiece and a breathing-collection bag with an attached CO₂ absorber canister.

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Computer enhanced scintigram of left adrenal adenoma in Cushings Syndrome. Nuclear Enterprises Mk 3 γ-camera 2.6 day post injection of Scintadren (kidneys localized with 5mCi 99mTc DTPA) R Montz, Department of Nuclear Medicine, University Hospital, Hamburg, FDR.



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Scintadren* reliable adrenal scintigraphy Full information is available on request.

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exposure

CintiChem HSA Technetium Tc 99m Human Serum Albumin Reagent Kit

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CintiChem[®]

HSA Multidose Kit TECHNETIUM Tc 99m HUMAN SERUM ALBUMIN MULTIDOSE REAGENT KIT DIAGNOSTIC – FOR INTRAVENOUS USE

description

The kit consists of 5 multidose reaction vials each containing a lyophilized mixture of 21 mg human serum albumin and 0.23 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment. All components are sterile and pyrogen-free. When a solution of sterile and pyrogen-free Sodium Pertechnetate Tc 99m in isotonic saline is mixed with these components, following the instructions provided with the kit, Technetium Tc 99m Human Serum Albumin is formed, with a labeling efficiency of 90% or greater. The product so derived has a pH of 2.5-3 and is intended for intravenous injection. The precise structure of Technetium Tc 99m Human Serum Albumin is not known at this time. The Normal Human Serum Albumin used in this preparation was nonreactive when tested for hepatitis B surface antigen (HBsAg) by radioimmunoassay.

physical characteristics

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.03 hours⁽¹⁾. Photons that are useful for detection and imaging studies are listed in Table I.

table I. principal radiation emission data radiation mean % / disintegration mean energy (keV) Gamma-2 87.9 140.5

⁽¹⁾Dillman, L.T. and Von der Lage, F.C., Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation, MIRD Pamphlet No. 10, p. 62, 1975.

external radiation

The specific gamma ray constant for Technetium Tc 99m is 0.8 R/millicurie-hour at 1 cm. The first halfvalue thickness of lead (Pb) for Technetium Tc 99m is 0.2 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table II. For example, the use of 2.7 mm of Pb will decrease the external radiation exposure by a factor of 1,000.

table II. radiation attenuation by lead shielding shield thickness (Pb) mm coefficient of attenuation

| nickness (Pb) mm | coefficient of attenuation |
|------------------|----------------------------|
| 0.2 | 0.5 |
| 0.95 | 10-' |
| 1.8 | 10-2 |
| 2.7 | 10-3 |
| 3.6 | 10-4 |
| 4.5 | 10-3 |

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals relative to the time of calibration are shown in Table III.

table III. physical decay chart:

Tc 99m, half-life 6.03 hours

| hours | fraction remaining | hours | fraction remaining |
|-------|-----------------------|-------|-----------------------|
| 0. | 1.000 | 7 | .447 |
| 1 | .891 | 8 | .399 |
| 2 | .795 | 9 | .355 |
| 3 | .708 | 10 | .317 |
| 4 | .631 | 11 | .282 |
| 5 | .563 | 12 | .252 |
| 6 | .502 | | |

*Calibration Time. (Time of Preparation)

clinical pharmacology

Normal Human Serum Albumin, being a normal component of blood, leaves the vascular space at a rate slow enough to permit imaging procedures utilizing radioactive tags. Technetium Tc 99m Human Serum Albumin does not rapidly leak from the vascular space, nor is there significant accumulation in organs other than those of excretion, the kidney and bladder. Therefore, the vascular system may be imaged with a minimum of background and organ interference. In humans, a two-component blood clearance rate is observed. the T 1/2 slow component ranging from 10 to 16 hours. Twenty-four hour urine clearance averaged 39%.

indications and usage

Technetium Tc 99m Human Serum Albumin is used as an agent for imaging the heart blood pool and to assist in the detection of pericardial effusion and ventricular aneurysm.

contraindications

The use of Technetium Tc 99m Human Serum Albumin is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

warnings

The contents of the kit are not radioactive. However, after the Sodium Pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

This radiopharmaceutical preparation should not be administered to children or to patients who are pregnant or to nursing mothers unless the expected benefits to be gained outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

precautions

The components of the kit are sterile and pyrogen-free. It is essential that the user follows the directions carefully and adheres to strict aseptic procedures during preparation of the radiodiagnostic.

Technetium Tc 99m Human Serum Albumin must not be used after three hours from the time of formulation. Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Human Serum Albumin should be used in pregnant women only when clearly needed. It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

are excreted in human milk. Safety and effectiveness in children have not been

established.

Technetium Tc 99m Human Serum Albumin, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients, consistent with proper patient management.

The labeling reactions involved in preparing the agent depend on maintaining the tin in the reduced state. Any oxidant present in the Sodium Pertechnetate Tc 99m supply may thus adversely,affect the quality of the prepared agent. Hence, Sodium Pertechnetate Tc 99m containing oxidants, or other additives, should not be employed without first demonstrating that it is without adverse effect on the properties of the resulting agent.

adverse reactions

Hypersensitivity reactions are possible whenever protein-containing materials such as Technetium Tc 99m labeled human serum albumin are used in man. Epinephrine, antihistamines and corticosteroid agents should be available for use.

dosage and administration

The suggested intravenous dose used in the average patient (70 kg) is 3-5 millicuries of Technetium Tc 99m Human Serum Albumin.

Each dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

radiation dosimetry

The estimated absorbed radiation doses⁽²⁾ to an average patient (70 kg) from an intravenous injection of a maximum dose of 5 millicuries of Technetium Tc 99m Human Serum Albumin are shown in Table IV.

table IV. estimated absorbed dose

| tissue | absorbed radiation dose (rads / 5 mCi) |
|------------|---|
| Brain | 0.047 |
| Marrow | 0.076 |
| Kidneys | 0.063 |
| Bladder | 0.166 |
| Ovaries | 0.082 |
| Testes | 0.079 |
| Total Body | 0.073 |

⁽²⁾Method of Calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides. Supplement No. 1, MIRD Pamphlet No. 1, J. Nucl. Med., p. 7, 1968.

how supplied

kit contents

- 5 STERILE MULTIDOSE REACTION VIALS (10 cc, silver aluminum overseal), each containing 21 mg human serum albumin and 0.23 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment.
- 1 RADIATION SHIELD for preparation and storage of a Technetium Tc 99m Human Serum Albumin preparation.
- 10 PRESSURE-SENSITIVE LABELS for final Technetium Tc 99m Human Serum Albumin preparation. 1 PACKAGE INSERT.

storage

Store kit contents in refrigerator (2-8°C). Do not freeze.

disposal

The residual materials may be discarded in ordinary trash provided the vials and syringes read background with an appropriate low range survey meter. It is suggested that all identifying labels be destroyed before discarding.

directions

The following directions must be carefully followed for optimum preparation of the Technetium Tc 99m Human Serum Albumin.

- 1. Aseptically swab rubber septum of sterile vial containing the sterile, lyophilized human serum albumin.
- 2. Aseptically inject 1.0 ml of Sterile Water for Injection; withdraw an equal volume of air.
- 3. Mix contents by swirling.
- 4. Place vial in radiation shield provided.
- 5. Aseptically swab rubber septum of shielded vial.
- Aseptically inject up to 100 millicuries Sodium Pertechnetate Tc 99m in a maximum of 3 ml into the vial; withdraw an equal volume of air.
- 7. Mix contents of vial by gentle shaking for 10 seconds.
- 8. Affix pressure-sensitive label to shielded vial.
- Allow to stand for 20 minutes after mixing to allow maximum tagging.
- 10. The TECHNETIUM 99m HSA is ready for use.
- 11. Mix contents of vial (step 7) prior to withdrawing patient dose.
- Mix contents of syringe by repeated inversion immediately prior to injection.
- 13. Maintain adequate shielding of the radioactive preparation.
- 14. Do not use the preparation after 3 hours from the time of formulation.

The radioactivity concentration of the final Technetium Tc 99m Human Serum Albumin preparation may be calculated by using the following formula:

- C = A/V where C equals radioactivity concentration of the preparation (millicuries/ml).
- A = Tc 99m activity added to the reaction mixture vessel (millicuries).
- V = Total volume in the final mixture (ml).

This kit is approved for use by persons licensed by the U. S. Nuclear Regulatory Commission pursuant to Sec. 35.14 and Sec. 35.100 Group III of 10 CFR Part 35 or under equivalent license of Agreement States.



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*Davis, A. and Jones, A.G., Seminars in Nuclear Medicine, Vol. 6, No. 1 (Jan. 1976) **Subramanian, G. et. al., Journal of Nuclear Medicine, Vol. 16, No. 8 (Aug. 1975)





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Complete directions for use are provided with each product. These directions should be read and understood before use. Particular attention should be paid to all warnings and precautions. Additional performance data are available. Should you have any questions, contact your Clinical Assays representative.

The Clinical Cyclotron[®] A new dimension in nuclear medicine

Designed by The Cyclotron Corporation specifically for installation in a hospital's nuclear medical department, the Model CP-16 Clinical Cyclotron™ produces the short-lived, positron emitting ¹⁵O, ¹³N, ¹¹C and ¹⁸F plus other medically useful isotopes. Multicurie quantities of the positron emitters are produced, making possible labelling of organic compounds in addition to online applications.

Among the many new innovative design features incorporated in the Clinical Cyclotron[™] is the ability to ex-tract the beam from the machine at more than one location. Furthermore. two radioisotopes can be made simultaneously. It is now possible to make full use of the beam at multiple target locations without the requirement for an external beam transport system.

As the name suggests, the Clinical Cyclotron[™] is remarkably easy to operate. In a few weeks a senior hospital technician can be trained in all phases of its use. Production of radioisotopes with the Model CP-16 can be simplified further by selection of the computer control option. In this configuration, start up, operation and shut down of the Clinical Cyclotron[™] are handled automatically after the operator has entered the required data.

Another potentially valuable option is complete self-shielding. This can be of particular advantage when it is necessary to make use of existing facilities because of budgetary or other constraints on new construction. As the artist's illustration reveals, this feature permits locating the controls and the Model CP-16 Cyclotron in the same room under "controlled area" conditions.

The standard Clinical Cyclotron™ produces the desired radioisotopes utilizing selected (p,n), (p,xn), and (p, α) reactions shown in the accompanying table. Should a user prefer to employ some or all of the listed (d,n) or (d, α) reactions, this capability is available as an option. Likewise, the ability to vary the energy of the particles accelerated by the Model CP-16 Cyclotron is an optional feature. The energy range applicable to protons is 4-16 MeV: for deuterons, 3-8 MeV.

Drawing on the extensive experience gained in building over 20 cyclotron systems and the advice and counsel of users of these systems. The Cyclotron Corporation also has developed the Model CP-30 Cyclotron. This machine is designed for those users who want to have the ability to produce the full range of medically useful isotopes in the hospital. With the Model CP-30, virtually all of the longer halflife isotopes can be produced in commercial quantities. This cyclotron

also can be used as a major component of a neutron therapy system. Computer control and variable energy are standard features of the Model CP-30 Cyclotron. Like the Clinical Cyclotron™ this machine produces protons but the energy range is 8-30 MeV; for optional deuterons, 4-15 MeV.

The Cyclotron Corporation also can provide target and beam transport systems plus complete laboratories including hot cells. Experienced personnel are available to assist the users' architects and engineers in designing a new or remodeled facility.

| PRODUCTION OF ISOTOPES IN CURRENT USE* | | | | | | | | | | |
|--|-----------------------|---|--------------------------------------|--|-------------------------------------|-----------------------------|---------------------------------------|---|------------------------|--------------------------------------|
| Isotope | 11 C | ¹³ N | ¹⁵ 0 | ¹⁸ F | ⁸¹ Kr ← ⁸¹ Rb | 123 | ⁶⁷ Ga | ¹¹¹ In | ⁶⁸ Ge | ²⁰¹ TI← ²⁰¹ Pb |
| Reaction CP-16** | ¹⁴ N(p,α) | ¹⁶ O(p, α) ¹² C(d,n) | 15 N(p,n) 14 N(d,n) | 18 O(p,n) ²⁰ Ne(d, α) | | 123 Te(p,n) | Zn(p,xn) 66 Zn(d,n) | Cd(p,xn) III Cd(p,n) | | |
| CP-30** | ¹⁴ N(p, α) | ¹⁶ O(p, α) ¹² C(d,n) | 15 N(p,n) 14 N(d,n) 16 O(p,pn) | ¹⁸ O(p,n) ²⁰ Ne(d, a) | ⁸² Kr(p,2n) | 123 Te(p,n) 124 Te(p,2n) | Zn(p,xn) 66 Zn(d,n) 68 Zn(p,2n) | Cd(p,xn) 111 Cd(p,n) 112 Cd(p,2n) | ⁶⁹ Ga(p,2n) | 203 TI(p,3n) |

NOTE: *Where current use data indicates reaction is possible only with Model CP-30 or significantly higher yields are obtained using CP-30, the reaction is printed in blue.

**Acceleration of deuterons is available as an option.

Denotes enriched isotope.

For years the Profession has been considering the potential value of the short-lived positron emitting nuclides in the diagnostic process, particularly ¹⁵O, ¹³N and ¹¹C. Until recently, the interest had to be relatively academic in the absence of effective positron imaging devices. With the development of The Cyclotron Corporation's versatile Model 4200 Positron Camera System (pictured) and EG&G Ortec's Ecat™ this void has been filled. Since the early sixties compact cyclotrons have been used to produce the short-lived radioisotopes in medical research centers. However, in the opinion of some, such machines are considered too complicated or for other



reasons somewhat less than ideal for installation in the typical nuclear medical department. The advent of the Clinical Cyclotron[™] removes the last obstacle blocking full exploitation of this exciting new field.



CORPORATION

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Dr. Willard Smullen, right, and John LaFond, RT(R), FASRT, with the KODAK X-OMAT Processor, Model M3, which served St. Mary's Hospital in Decatur, Illinois, for 14 years with a total of 2 days out for service. It processed 1.3 million sheets of film and 61 miles of 70-mm and 16-mm film.

When you buy a processor, it may be years before you know the true cost. It all depends on how many hours of trouble-free service the processor gives you. That may be one reason KODAK *RP* X-OMAT Processors are virtually unmatched in performance. When you're considering processors, you'll discover there's a dependable KODAK Up-time Processor to fit your needs.

90-second processing: You're familiar with the Model M6A-N, which provides consistent highquality, 90-second processing. Now you can get the *same* dependability in a new 90-second processor that uses an *ambient water wash* (40-90°F). Called the Model M6AW, it occupies only 5 square feet of floor space and can save you money on initial plumbing and subsequent water-heating costs.

150-second processing: The Model M7A also provides for an ambient water wash (40 to 87°F). In addition, it features an automatic standby control to decrease wear and power consumption when the processor must be left on but no films are being processed. For an even greater saving, you can order the KODAK *RP* X-OMAT Water Saving Kit, Model M7. This accessory turns off the water flow *completely* when the processor is not in use.

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If you've been using Kodak processors, you probably have a reliability example of your own. If you'd like to know more about Kodak processors, just ask your Kodak representative. Or contact your dealer in Kodak x-ray products. Either will be glad to show you why we call them the Up-time Processors.



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Inject



Inspect



The **IBRIN®** Radionuclide-Labeled (1²⁸1) Fibrinogen (Human) **IBRINITOR** Portable Radioisotope Monitor

CERTAIN The diagnostic accuracy of IBRIN for the detection of deep-vein thrombosis (DVT) has been confirmed in over 100 studies which show a 92% correlation with venography. IBRIN actively participates in thrombus physiology; its consistent clottability insures bioactivity and allows accurate detection of both forming and established thrombi.

SAFE DVT monitoring with the IBRIN System can be performed on medical, surgical and orthopedic patients. There is no need to move the patient to a special procedure area. The IBRIN System of DVT detection reduces the need to subject the patient to radiopaque venography.

SIMPLE IBRIN has a long *in-vivo* half-life, permitting monitoring for up to seven days without additional injections. Serial monitoring allows constant updating of the patient's status. IBRIN emits low energy radiation enabling the use of a lightweight isotope monitor such as the IBRINITOR for rapid testing of a large number of patients. Monitoring can begin within three hours after injection and results can be confirmed within twenty-four hours.

INJECT IBRIN, a Radionuclide-Labeled (¹²⁵I) Fibrinogen (Human), is supplied freeze-dried for convenient storage and extended stability. It is reconstituted immediately prior to injection. The patient is intravenously injected with 100μ Ci of IBRIN prior to testing.

INSPECT Initial monitoring can be performed three hours after the IBRIN injection. The IBRINITOR is specifically designed and built for detecting DVT. Sophisticated electronic design assures reliable accumulation of statistically valid data and eliminates most operator error. The IBRINITOR has a continuous stage design that requires all the correct data in the correct order before giving results. A digital data display and built-in printout insure ease and accuracy of data collection. Push button controls on the detector probe are provided for quick, accurate testing. The probe design includes an angled detector head to facilitate positioning for maximum operator convenience and patient comfort. The IBRINITOR is powered by rechargable Ni-Cd batteries. A source is provided for calibration convenience and the complete unit weighs less than eight pounds.

DETECT The IBRIN System includes a patient data sheet which provides a convenient display of printout tape and graphical representation of data for the physician's interpretation and diagnosis.

We will be glad to help you explain the benefits of the IBRIN System to your surgical staff. Write or phone Amersham for complete details.

See following page for brief summary of package insert.



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In Canada

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Detect

eros



IRR IN R **BRINITOR** System

INDICATIONS IBRIN is indicated for use in prospective studies for the early detection and subsequent monitoring of developing deep-vein thrombosis and in diagnostic studies for the detection of established thrombosis in the legs.

- A. The IBRIN (Radionuclide-Labeled (1281) Fibrinogen (Human)) test is indicated In patients with signs and/or symptoms suggestive of deep-vein thrombosis with or without associated pulmonary embolism or in patients with pulmonary embolism, with or without evidence of peripheral deep-vein thrombosis. In patients with established, old or "inactive" thrombi, the test will be positive only if radionuclide-labeled fibrin deposition occurs in a sufficient quantity to allow detection. Its use is not contraindicated in patients on anticoagulants.
- B. The IBRIN [Radionuclide-Labeled (1281) Fibrinogen (Human)] test is indicated for the detection of thrombus formation in patients undergoing major or thopedic or other surgical procedures, myocardial infarction, pulmonary dis-ease, malignant disease and other medical conditions known to predispose to thromboembolism.

CONTRAINDICATIONS

There are no known contraindications to the use of IBRIN. However, it should be noted that the iodides given to block the uptake of ¹³⁸I by the thyroid gland are contraindicated in patients with a known sensitivity to the iodides.

WARNINGS

This radiopharmaceutical should not be administered to patients under 18 years of age, to patients who are pregnant, or to patients who are lactating, unless the information to be gained outweighs the potential risk.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of child bearing capability should be performed during the first few (approximately 10) days following the onset of menses. Nursing mothers should substitute formula feeding after the administration of Fibrinogen ¹⁵⁸I.

Extraordinary precautions have been taken in the preparation of IBRIN (Radionuclide-Labeled (¹⁴¹) Fibrinogen (Human)) to eliminate the possible transmission of hepatitis. Nevertheless, the remote risk of hepatitis associated with the administration of Radionuclide-Labeled (¹⁴¹) Fibrinogen (Human) can-not be entirely eliminated. The finding of viral hepatitis in any patient up to six months after the administration of IBRIN should be reported to Amersham for further evaluation, since there are numerous possible sources of hepatitis infection.

PRECAUTIONS

Care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.

This drug contains radiacetive materials which must be handled only by qualified personnel in conformity with Nuclear Regulatory Commission, agreement state, or other appropriate government regulations. Care must be taken to avoid excessive exposure to its radiation. Shielding or equivalent radiation protective measures must be used.

measures must be used. This product is prepared from units of human plasma which have been tested using RIA methods and found non-reactive for Hepatitis B surface antigen. Approved detection methods are not sensitive enough to detect all infectious units of blood or all possible cases of hepatitis. However, IBRIN has been prepared from single donor plasma and has been injected into recipients without incidence of fibrinogen related Hepatitis B as evidenced by periodic physical examination and laboratory testing (liver profile, CBC, and Hepatitis B surface antigen and antibody by radioimmunoassay) of the recipients.

There are a number of clinical circumstances requiring consideration in the interpretation of the test results. (See complete Package Insert.) Fibrinogen ¹³⁴ scanning should preferably be performed prior to venography if both procedures are contemplated, since venography may cause increases in count rate making interpretation of post-venography monitoring data difficult.

Adequate reproduction studies on animals have not been performed to deter-mine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Radionuclide-Labeled (***) Fibrinogen (Human) should be used in pregnant women only when clearly needed.

ADVERSE REACTIONS

There has been no reported incidence of allergic or anaphylactic reactions following the intravenous administration of IBRIN.



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NUTRITION INFORMATION

| | _ | | |
|--|---|---|----------------------|
| 3 Servings (3.53 | oz Po | wder in 18 fl oz Water) | |
| protein | 9 9 9 9 | biotin | g g |
| vitamin A | IU IU IU mg | iron | mg mg mg mg |
| Tolic acid 0.44 thiamin 1.80 riboflavin 2.04 niacin 2.4 vitamin B ₆ 2.4 vitamin B ₁₂ 7.2 | 5 mg 0 mg 4 mg mg mg mcg | choline 20 potassium 0.4 sodium 0.4 chloride 0.54 manganese 3.0 | mg g g mg |

COMPOSITION: Sugar, pasteurized egg white solids, maltodextrin, calcium glycerophosphate, citric acid, natural and artificial flavors, mono and diglycerides, magnesium oxide, ammonium phosphate, vegetable oil, ascorbic acid, ferrous sulfate, choline bitartrate, artificial color, niacin, zinc sulfate, alpha tocopheryl acetate, calcium pantothenate, manganese sulfate, copper gluconate, pyridoxine hydrochloride, thiamin hydrochloride, vitamin A palmitate, riboflavin, folic acid, d-biotin, potassium iodide, cyanocobalamin, vitamin D₂.





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| NUTRIT | 'ION | INFORMATION | |
|---|--------------------|--|--------------------|
| 6 Servings (12.) | 36 oz | Powder in 48 fl oz Water) | |
| protein | 50 50 50 | biotin0.30 pantothenic acid10 calcium10 phosphorus1.0 | mg mg g g |
| vitamin A | | iodine | mg mg mg |
| folic acid |) mg i mg mg | vitamin K100 choline100 potassium1.5 sodium | mcg mg g |
| vitamin B ₆ 3.0 vitamin B ₁₂ 6.0 | mg mcg | chloride1.6 manganese4.0 | g mg |

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Volume 19, Number 4

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Thallous Chloride Tl 201 For Diagnostic Use

Indications and Usage: Thallous Chloride Tl 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction.

It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

Contraindications: None known.

Warnings: In studying patients in whom myocardial infarction or ischemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

Ideally, examinations using radiopharmaceutical drug products -especially those elective in nature-of women of childbearing capability should be performed during the first ten days following the onset of menses.

Precautions: Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of thallium Tl 201 scans. Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

Thallous Chloride Tl 201, as all radioactive materials, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management. No long-term animal studies have been performed to evaluate carcinogenic potential.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Thallous Chloride Tl 201 should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

Adverse Reactions: Adverse reactions related to use of this agent have not been reported to date.

Dosage and Administration: The recommended adult (70kg) dose of Thallous Chloride Tl 201 is 1-1.5mCi. Thallous Chloride T1201 is intended for intravenous administration only.

For patients undergoing resting thallium studies, imaging is optimally begun within 10-20 minutes after injection. Several investigators have reported improved myocardial-to-background ratios when patients are injected in the fasting state, in an upright posture, or after briefly ambulating.

Best results with thallium imaging performed in conjunction with exercise stress testing appear to be obtained if the thallium is administered when the patient reaches maximum stress and when the stress is continued for 30 seconds to one minute after injection. Imaging should begin within ten minutes post-injection since target-to-background ratio is optimum by that time. Several investigators have reported significant decreases in the target-to-background ratios of lesions attributable to transient ischemia by two hours after the completion of stress testing.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Radiopharmaceuticals should be used by persons with specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agencies authorized to license the use of radionuclides.

How Supplied: Thallous Chloride Tl 201 for intravenous administration is supplied as a sterile, non-pyrogenic solution containing at calibration time, 1mCi/ml of Thallous Tl 201, 9mg/ml sodium chloride, and 9mg/ml of benzyl alcohol. The pH is adjusted to between 4.5-6.5 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 1.5, 3.0, 4.5, 6.0, and 9.0 millicuries of Thallous Tl 201.

The contents of the vial are radioactive. Adequate shielding and handling precautions must be maintained.

Catalog Number NRP-427

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See following page for a brief summary of package insert.



PROCTER & GAMBLE OSTEOSCAN (59MG DISODUM ETUPONATE, 016MG STANNOUS CHLORDE)

SKELETAL IMAGING AGENT



Brief summary of Package Insert. Before using, please consult the full Package Insert included in each kit.

DESCRIPTION

Each vial of OSTEOSCAN contains 5.9 mg disodium etidronate and 0.16 mg stannous chloride as active ingredients. Upon addition of ADDITIVE-FREE ^{99m}Tc-pertechnetate, these ingredients combine with ^{99m}Tc to form a stable soluble complex.

ACTIONS (CLINICAL PHARMACOLOGY)

When injected intravenously, ^{99m}Tc-labeled OSTEOSCAN has a specific affinity for areas of altered osteogenesis. Areas of bone which are undergoing neoplastic invasion often have an unusually high turnover rate which may be imaged with ^{99m}Tc-labeled OSTEOSCAN.

Three hours after intravenous injection of 1 ml ^{99m}Tc-labeled OSTEO-SCAN, an estimated 40-50% of the injected dose has been taken up by the skeleton. At this time approximately 50% has been excreted in the urine and 6% remains in the blood. A small amount is retained by the soft tissue. The level of ^{99m}Tc-labeled OSTEOSCAN excreted in the feces is below the level detectable by routine laboratory techniques.

INDICATIONS

OSTEOSCAN is a skeletal imaging agent used to demonstrate areas of altered osteogenesis.

CONTRAINDICATIONS

None.

WARNINGS

This radiopharmaceutical should not be administered to patients who are pregnant or lactating unless the information to be gained outweighs the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

The $^{99m}\text{Tc}\xspace$ -generator should be tested routinely for molybdenum break-through and aluminum. If either is detected, the eluate should not be used.

PRECAUTIONS

Both prior to and following ^{99m}Tc-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the ^{99m}Tc-labeled OSTEOSCAN injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

As in the use of any other radioactive material, care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.

ADVERSE REACTIONS

None.

DOSAGE AND ADMINISTRATION

The recommended adult dose of 99mTc-labeled OSTEOSCAN is 1 ml with a total activity range of 10-15 mCi. 99mTc-labeled OSTEOSCAN should be given intravenously by slow injection over a period of 30 seconds within eight (8) hours after its preparation. Optimum scanning time is 3-4 hours postinjection.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

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*Walter D. Obrist, et al. STROKE, Vol. 6, May-June, 1975, pp. 245-256.

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Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

IMPORTANT: Since material obtained from the generator may be intended for intravenous administration, aseptic technique must be strictly observed in all handling. Only the eluent provided should be used to elute the generator. Do not administer material eluted from the generator if there is any evidence of foreign matter.

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