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 CO₂ 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)

DESCRIPTION: The Xenon Xe 133-Ventilation Study System (V.S.S.) consists of a sealed plastic tube containing 10 millicuries ±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.

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 single-unit 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.
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 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.

DOSEAGE 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 ±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.
Packard proudly introduces PRIAS: a new generation of instruments designed to meet the present and future requirements of the clinical, hospital and research laboratory in radioassay sample preparation and counting.

While particularly well-suited for radioimmunoassay routines, the PRIAS instruments offer equally advantageous capabilities in other types of clinical and research procedures involving sample preparation, gamma counting or beta counting.

PRIAS consists of three independent benchtop instruments which can be used with a swinghead centrifuge to form a complete, integrated radioassay system:

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- The PRIAS Automatic Gamma Counter which offers exceptional simplicity and ease of operation; and
- The PRIAS Miniature Vial Liquid Scintillation Counter which offers high performance combined with low cost per sample.

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Abington Memorial chose a camera for maximum image quality and convenience.

The 520-bed Abington Memorial Hospital in Abington, PA, outside Philadelphia, has added a new Raytheon XL-91 gamma camera to its new wing. And right from start-up the XL-91 has been producing images of superior resolution, with much greater patient accessibility and operator convenience than other equipment.

The reasons for the XL-91’s success at Abington are clear. At 16½ inches the XL-91 provides the widest undistorted field of view of any gamma camera. The XL-91’s exclusive Autocomp circuitry achieves ±2% uniformity and — with as many as four memories — permits users to calibrate to four different isotopes or collimators.

Patient comfort, operator convenience, superior high resolution images. No wonder Abington Memorial had the XL-91 working a full patient schedule just days after delivery. And outstanding customer acceptance of the XL-91 — such as at Abington Memorial — is the reason Raytheon has had to expand its sales and service coverage greatly. From coast to coast, wherever you are, Raytheon is now near you.

If you'd like more information on the XL-91, write or phone Raytheon Company, Medical Electronics, 70 Ryan Street, Stamford, CT 06907. Telephone: 800-243-9058. We will put you in touch with your nearest Raytheon sales engineer.

The Raytheon XL-91...the 91-tube image maker.
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Radiopharmaceutical Division
Atomlight Place, North Billerica, Mass. 01862
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Los Angeles: 213-321-3311

EUROPE: NEN Chemicals GmbH, D-6072 Darmstadt, W. Germany, Daimlerstrasse 23. Postfach 401240. Telephone: (66103) 85034. Telex: 4-17993 NEN D
If you get an odd result when using one of our thyroid testing kits, there's something wrong with the patient.

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Thyroid function kits

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In the Americas: Amersham Searle Corp, Illinois 60005. Telephone: 312-593-6200

In W.Germany: Amersham Buchler GmbH & Co.KG, Braunschweig. Telephone: 05307-4693-97

*Trademark
Mallinckrodt research has now developed a formula that combines the quality features of our frozen TechneScan MAA product with the convenience of lyophilization. Our goal was to match—as closely as possible—particle-size range and consistency specifications that had been established with the frozen process. In our search we were determined not to compromise current product performance or specifications of our frozen product for the sake of convenience.

The introduction of Mallinckrodt’s TechneScan MAA—Lyophilized—represents the successful conclusion of our search for a specially designed freeze dry process. No need to freeze. Simply refrigerate for these same quality features.

**Safety . . .**
TechneScan MAA is very well tolerated. Effective lung excretion half-life is approximately 3.8 hours—virtually complete biological excretion occurs in about 24 to 48 hours. Although the possibility exists, there is, to date, no evidence of antibody formation.

**Increased Shelf Life . . .**
The expiration date of each TechneScan MAA lyophilized kit is now one year after date of manufacture. This extended shelf life permits the convenience of larger inventories plus the cost savings of buying in quantity.

**Reliable Consistency . . .**
Reconstitution does not affect either particle quality or size distribution. The particle size does not change after the addition of pertechnetate solution. There is no tendency for the particles to hydrate and increase in size after labeling. WE ENCOURAGE MICROSCOPIC EVALUATION AND COMPARISON!

**Controlled Particle-Size Range . . .**
Specifications require that not less than 90% of the particles be 10 to 90 microns in size, with not more than 10% below 10 microns, and none greater than 150 microns. Our investigations indicate that, typically, 90% of the TechneScan MAA particles are in the 10–40 microns range. This controlled particle size range, plus the fact that there is no tendency to agglomerate, results in good images of lung perfusion.

**High Tagging Efficiency . . .**
The tagging efficiency experienced with the TechneScan MAA kit is remarkably consistent, always at or near 100% conversion of pertechnetate to labeled MAA, with no loss of the label for up to 24 hours.

**Easy Preparation . . .**
Preparation of TechneScan MAA Tc 99m is easy.
1. Allow five minutes to reach room temperature.
2. Add Tc-99m.
3. Agitate gently.
4. Wait fifteen minutes for high tagging efficiency.
That’s all!

**Economy . . .**
The TechneScan MAA Kit doesn’t need expensive accessory equipment. Up to 15 adult patients can be scintigraphed from the preparation of a single vial of TechneScan MAA. This helps reduce the procedure cost per patient.

For those who were acquainted with the frozen product, we give our assurance of continued satisfaction; for those who were unable to use frozen TechneScan MAA because of storage considerations, we invite your evaluation of our lyophilized formula. For further information contact your Mallinckrodt representative.

---

**LYOPHILIZED**

**TechneScan MAA**

**AGGREGATED ALBUMIN (HUMAN)**

**LUNG SCAN KIT**

Consult package insert for complete prescribing information, a summary of which follows the next page.
TechneScan® MAA KIT

AGGREGATED ALBUMIN (HUMAN) KIT (Lyophilized)
Catalog No. 093
Store at 2°C – 8°C
Technetium Tc 99m is a suspension and as such the particles will settle with time. Failure to mix the vial contents adequately before use may result in a non-homogenous suspension with a resulting non-uniform distribution of radioactivity in the lung.

It is also recommended that, because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m aggregated albumin will not be used after eight hours from the time of reconstitution. Refrigerate at 2°C to 8°C after reconstitution. If blood is withdrawn into the syringe, unnecessary delay prior to injection may result in clot formation in situ.

The contents of the vial are under a nitrogen atmosphere and should be protected from air. On reconstitution with pertechnetate Tc 99m, the contents of the vial should be mixed by gentle swirling to avoid changes in particle size. Do not use if clumping or foaming of the contents is observed.

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 aggregated 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.

Safety and effectiveness in children have not been established.

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

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

ADVERSE REACTIONS

The literature contains reports of deaths occurring after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Tc 99m-labeled aggregated albumin have been reported.

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

DOSE AND ADMINISTRATION

The recommended intravenous dose range for the average patient (70 kg) is 1 to 4 milliliters. The volume of the dose may vary from 0.4 to 1.0 ml.

The recommended number of aggregated albumin particles to be administered per dose is 200,000-1,200,000 with the suggested number being approximately 600,000.

HOW SUPPLIED

Catalog Number 093

TechnetScan MAA Kit

(Lyophilized)

Kit Contains:

5—Aggregated Albumin (Human) Reaction Vials

(1 ml each)—for the preparation of Technetated (Tc-99m) Aggregated Albumin (Human)

Reaction Vial Contains (in lyophilized form):

2.0 mg Aggregated Albumin (Human) (8 ± 2 x 10^6 particles)

120 µg Stanom chloride Dihydrate

80 mg Lactose

24 mg Succinic Acid

1.4 mg Sodium Acetate

Hydrochloric Acid or Sodium Hydroxide is added for pH adjustment

Each vial contains 8 ± 2 x 10^6 aggregated albumin particles.

TechnetScan MAA contains no preservatives; after reconstitution, the shielded vial should be stored at 2°C to 8°C.

Included in each package is one (1) package insert, 5 radiation labels and 5 radioassay information string tags.

Mallinckrodt, Inc.
P.O. Box 5840
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GammaCoat
Hepatitis B
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Now Clinical Assays offers you a convenient, fast, economical and sensitive third generation radioimmunoassay for HBsAg . . . with “no need for a bead.” Years of applied research in antibody coated tube technology bring you this system that eliminates the bead-in-tube approach, for reliable and efficient results. The seamless tubes are uniquely coated with guinea pig anti-HBs, and each kit includes [125I] chimpanzee anti-HBs and negative and positive controls.

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EUROPE: Clinical Assays • Parc Industriel, Rue Du Progres No. 12. Nivelles 1400, Belgium • (067) 228911 • Telex: 57344
OSTEOLITE™ Technetium Tc 99m Medronate Sodium Kit.
(Formerly Known as MDP)
For Diagnostic Use.

INDICATIONS AND USAGE: Technetium Tc 99m OSTEOLITE may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINdications: None known.

WARNINGS: The contents of the OSTEOLITE vial are intended only for use in the preparation of Technetium Tc 99m medronate sodium and are NOT to be directly administered to the patient.

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

PRECAUTIONS: A thorough knowledge of the normal distribution of intravenously administered Technetium Tc 99m medronate sodium is essential in order to accurately interpret pathologic studies.

Technetium Tc 99m medronate sodium, as well as any radioactive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used 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.

The Technetium Tc 99m labeling reaction involved in preparing Technetium Tc 99m medronate sodium depends on the maintenance of tin in the divalent state. Any oxidant present in the sodium pertechnetate Tc 99m employed may adversely affect the quality of the prepared agent. Thus, Sodium pertechnetate Tc 99m containing oxidants should not be used without first demonstrating that it is without adverse effect on the properties of the resulting agent.

The use of bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc 99m may adversely affect the biologic distribution of the prepared agent, and its use is not recommended.

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 medronate sodium 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: None reported.

DOSAGE AND ADMINISTRATION: The recommended dose for the average 70kg adult patient is 15mCi with a range of 10-20mCi. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Optimal imaging results are obtained within one to four hours after administration.

OSTEOLITE should be used within six hours after aseptic reconstitution with sodium pertechnetate Tc 99m. For optimum results this time should be minimized.

The vial contains no bacteriostat.

Radiopharmaceuticals should be used by persons 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 governmental agencies authorized to license the use of radionuclides.

HOW SUPPLIED: NEN's OSTEOLITE™ Technetium Tc 99m Medronate Sodium Kit is supplied as a set of five or thirty vials, sterile and non-pyrogenic. Each nitrogen-flushed vial contains in lyophilized form:

Medronate Disodium - 10mg
Stannous Chloride Dihydrate - 0.85mg

The pH is adjusted to between 7.0-7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial were lyophilized under nitrogen. Store at room temperature (15°C-30°C). Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.
OSTEOLITE™
Technetium Tc 99m Medronate Sodium Kit (MDP)

- Superior target to background ratio*
- Faster urinary excretion and blood clearance than pyrophosphate or EHDP**
- Earlier imaging — within one to four hours after administration

*Denis A. and Jones, A.G. Seminars in Nuclear Medicine, Vol 6, No 1 (Jan 1976)
**Subramaniam, G et al., Journal of Nuclear Medicine, Vol 16, No 8 (Aug 1975)
NUCLEAR DVT DIAGNOSIS
Certain, Safe, Simple: Read between the lines

Inject

Inspect
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 (‘‘I) 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 100 mcCi 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 rechargeable 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.
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 \(^{131}I\) 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 radioactive fibrin deposition occurs in a sufficient quantity to allow detection. Its use is not contraindicated in patients on anticoagulants.

B. The IBRIN (Radionuclide-Labeled \(^{131}I\) Fibrinogen (Human)) test is indicated for the detection of thrombus formation in patients undergoing major orthopedic or other surgical procedures, myocardial infarction, pulmonary disease, 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 \(^{131}I\) 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 5) days following the onset of menses. Nursing mothers should substitute formula feeding after the administration of Fibrinogen \(^{131}I\).

Extraordinary precautions have been taken in the preparation of IBRIN (Radionuclide-Labeled \(^{131}I\) Fibrinogen (Human)) to eliminate the possible transmission of hepatitis. Nevertheless, the remote risk of hepatitis associated with the administration of Radionuclide-Labeled \(^{131}I\) Fibrinogen (Human) cannot 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 product contains radioactive material 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.

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 immunoassay) of the recipients.

There are a number of clinical circumstances requiring consideration in the interpretation of the test results. (See complete Package insert.)

Fibrinogen \(^{131}I\) 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 determine whether this drug affects fertility in males or females, has any teratogenic potential, or has other adverse effects on the fetus. Radionuclide-Labeled \(^{131}I\) 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.

Amersham
AMERICAN CORPORATION:
A SUBSIDIARY OF THE RADIOCHEMICAL CENTRE
2636 S. Clearbrook Dr., Arlington Heights, IL 60005
312/593-6300 or 800/323-0668 (Toll free)

In Canada
505 Iroquois Shore Rd., Oakville, ONT L6H 2R3
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After one million doses, TechneColl keeps boiling along.

A time-tested formula. An outstanding performance record. Have your Mallinckrodt Representative demonstrate the difference!

TechneColl®
Sulfur Colloid Kit
for the preparation of Technetium Tc99m
Sulfur Colloid
*Based on an estimated average of two patients dosed per vial.

See next page for brief summary.

Mallinckrodt NUCLEAR
Mallinckrodt, Inc.
P.O. Box 5840
St. Louis, MO 63134
Kit for the Preparation of Technetium Tc-99m Sulfur Colloid

DESCRIPTION
The kit contains all of the non-radioactive reagents required to prepare a sterile, non-pyrogenic preparation of Technetium Tc 99m Sulfur Colloid suitable for direct intravenous injection. When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the reaction vial, Technetium Tc 99m Sulfur Colloid is formed with the non-radioactive reagents.

ACTIONS
Following intravenous administration, Technetium Tc 99m Sulfur Colloid is rapidly cleared by the reticuloendothelial system from the blood with a median clearance half-time of approximately 0.5 minutes. Uptake of the radioactive colloid by organs of the reticuloendothelial system is dependent upon both their relative blood flow rates and the functional capacity of the phagocytic cells. In the average normal patient 80 to 90% of the injected colloidal particles are phagocytized by the Kupffer cells of the liver and 5 to 10% by the spleen and the balance by the bone marrow.

INDICATIONS
Technetium Tc 99m Sulfur Colloid is used as an agent for imaging areas of functioning reticuloendothelial cells in the liver, spleen, and bone marrow.

CONTRAINDICATIONS
None.

WARNINGS
The contents of the double-compartment dose syringes are intended only for use in the preparation of Technetium Tc 99m Sulfur Colloid and are not to be directly administered to the patient.

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.

Radiopharmaceuticals should be used only by physicists, 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.

This radiopharmaceutical preparation should not be administered to patients who are pregnant or during lactation 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.

PRECAUTIONS
The components of the kit are sterile and non-pyrogenic. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during the preparation of the colloid.

The stability of the colloidal preparation may be decreased in the presence of polyvalent cations, thus resulting in the agglomeration of the individual colloidal particles. The larger particles are likely to be trapped by the pulmonary capillary bed following intravenous injection.

It is recommended that pertechnetate solutions containing more than 10 micrograms/ml of aluminum be not be used for formation of the Technetium Tc 99m Sulfur Colloid.

Technetium Tc 99m Sulfur Colloid is physically unstable and as such the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactivity.

It is also recommended that, because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m Sulfur Colloid not be used after six hours from the time of formulation.

As in the use of any other radioactive material care should be taken to ensure minimal radiation exposure to the patient, consistent with proper patient management, and to ensure minimum radiation exposure to other hospital personnel.

ADVERSE REACTIONS
Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparation. Although rare, pyrogen reactions have been reported following the administration of the drug stabilized with gelatin. Arm pain following injection has been reported.

DIRECTIONS FOR PREPARATION
Note: Read complete directions thoroughly before starting preparation procedure.

PROCEDURAL PRECAUTIONS
1. All transfer and vial stopper entries must be done using aseptic technique.
2. The Technecoll Kit should be stored at room temperature (approximately 25°C).
3. The Technecoll Kit reagents must be at room temperature before use. At lower temperatures, there may be evidence of undissolved gelatin in the double-compartment syringes. The syringes should be allowed to stand at room temperature (approximately 25°C) until the gelatin returns to solution. Do not warm the syringes in water bath or incubator.
4. The water bath used for heating the contents of the Reaction Vial must be at a continuous rolling boil during the two heating steps of the preparation procedure. The Reaction Vial should be in direct contact with the rolling boil water bath, and the level of the bath should be at least even with the level of the contents of the Reaction Vial.
5. If the Reaction Vial is incubated in a lead safe, the temperature of the safe should be allowed to reach the temperature of the water bath before being used, and before incubating the Reaction Vial.
6. As a result of heating the contents of the closed Reaction Vial, internal pressure will be created causing some resistance when injecting the contents of Syringe II into the Reaction Vial. The resistance may be minimized either by employing a syringe to evacuate approximately 30 ml of air from the Reaction Vial before the addition of the generator eluate (Step 3) or by venting the Reaction Vial with a sterile needle prior to injecting the contents of Syringe II into the Reaction Vial (Step 7). If venting is used, remove vent needle before returning Reaction Vial to water bath.
7. When attaching the disposable needles to the double-compartment syringes, care must be taken to insure that the needles are firmly attached to the syringes.

PROCEDURE: For preparing Technetium Tc 99m Sulfur Colloid

Note: The radioactive material should be shielded at all times during preparation.
1. Prepare a rolling boil water bath.
2. Fill in the necessary information on the "Caution: Radioactive Material" label and place directly over the yellow area provided on the Reaction Vial label. Attach the string tag to the neck of the Reaction Vial. Place the Reaction Vial in a lead Dispensing Shield fitted with a lid and with a minimum wall thickness of ½ inch.
3. After swabbing the rubber stopper of the Reaction Vial with an appropriate antiseptic, aseptically inject a calculated volume of technetium-99m generator eluate or prepackaged sodium pertechnetate Tc-99m into the Reaction Vial. The volume of pertechnetate solution used must be between 0.1 and 5.0 mV (Withdraw a 5 ml or greater volume of air to relieve pressure). 
4. Aseptically assemble Syringe II and aseptically inject the contents into the Reaction Vial.
5. Invert the Reaction Vial several times to obtain complete mixing.
6. Immediately transfer the Reaction Vial to a lead (minimum wall thickness of ½ inch) Boiling Shield which has been equilibrated to the temperature of the rolling boil water bath. This may be accomplished by placing the shield in the rolling boil bath a few minutes prior to transferring the Reaction Vial. The level of the water bath must be even with或 above the contents of the Reaction Vial. Allow the Reaction Vial to incubate for 8 minutes.
7. Aseptically assemble Syringe II. Immediately after the incubation period (Step 6) remove the Reaction Vial from the Boiling Shield and place in the Dispensing Shield. Swab the vial stopper with an appropriate antiseptic and aseptically inject the contents of the Syringe II into the Reaction Vial.
8. Immediately return the Reaction Vial to the Boiling Shield and incubate for 5 minutes.
9. Remove the Reaction Vial from the Boiling Shield and place in the Dispensing Shield. Allow the contents of the Reaction Vial to cool for approximtely 15 minutes to reach body temperature. The final Technetium Tc 99m Sulfur Colloid preparation should be clear to slightly hazy in appearance, but there should be no flocculent present. If a precipitate is visible, the preparation should not be used.
10. Calculate the radioactivity concentration of the Technetium Tc 99m Sulfur Colloid and fill in the appropriate information on the string tag. Do not use this material after 6 hours from time of preparation.

Calculation of Radioactivity Concentration

\[ \text{mCi/ml of colloid} = \frac{\text{mCi of Tc99m added}}{\text{ml of Tc99m added} + 5 \text{mCi}} \]

**The total delivered non-radioactive reagent volume employed in the preparation is 5 ml.

DOSEAGE AND ADMINISTRATION
The suggested intravenous dose range used in the average patient (70 kg) is 1 to 8 millicuries of Technetium Tc 99m Sulfur Colloid.

When orally administered, the Technetium Tc 99m Sulfur Colloid is not absorbed from the G.I. tract. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

HOW SUPPLIED
Catalog Number: TechneColl Kit
090 Package contains 5 Preparation Units for the preparation of Technetium Tc 99m Sulfur Colloid.

Each Preparation Unit Contains:
1—Reaction Vial. Contents 2.0 ml; each ml contains 50 mg phosphoric acid.
1—Syringe I (2-compartment disposable syringe)—Component A, 1.1 ml. Each ml contains 12 mg gelatin and 9 mg sodium chloride. Component B, 0.55 ml. Each ml contains 12 mg sodium thiosulfate.
1—Syringe II (6-compartment disposable syringe)—Component A, 0.6 ml. Each ml contains 36 mg gelatin and 9 mg sodium chloride. Component B, 1.0 ml. Each ml contains 544 mg sodium acetate and 4 mg disodium edetate.
2—Disposable needles.
1—Pressure-sensitive "Caution: Radioactive Material" label.
1—Radioactivity information string tag.

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Volume 19, Number 2
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![Elscint MOBILE 1 Gamma Camera](image)

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Volume 19, Number 2 31A
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Indications and use:

Technetium Tc 99m Sulphur Colloid injection is used as an agent for imaging areas of functioning reticuloendothelial cells in the liver, spleen, and bone marrow.

Contraindications:

None known.

Warnings:

The contents of the two syringes, one syringe containing the injection solution and the second syringe containing the appropriate buffer solution, are intended only for use in the preparation of the Technetium Tc 99m Sulphur Colloid Injection and are not to be administered to the patient. The contents of the kit are radioactive. However, the Sodium Pertechnetate Tc 99m is added, adequately diluted and thoroughly mixed prior to injection. The radiopharmaceutical preparation should not be administered to children or to patients who are pregnant or during lactation unless the expected benefits to the patient outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those effective in nature of a 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 colloid. The stability of the colloidal preparation may be decreased by the addition of particulate matter, thus resulting in the agglomeration of the individual colloidal particles. These larger particles are likely to be trapped in the pulmonary capillary bed following intravenous injection. It is recommended that Sodium Pertechnetate Tc 99m solutions containing more than 10 micrograms/ml of aluminium be not used for formation of the Technetium Tc 99m Sulphur Colloid Injection. The Sodium Pertechnetate Tc 99m solution must also be free of any traces of oxidizing agents such as peroxides or hypochlorites.

Technetium Tc 99m Sulphur Colloid Injection is physically unstable and such as the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radionuclide. It is also recommended that because of the increasing probability of aggregation with aging, a batch of Technetium Tc 99m Sulphur Colloid Injection not be used after six hours from the time of formation. Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic or other adverse effects on the fetus. Technetium Tc 99m Sulphur Colloid Injection 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 breast milk. Safety and effectiveness in children have not been established. Technetium Tc 99m Sulphur Colloid Injection, 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 any radiation exposure to patients, consistent with proper patient management.

Adverse reactions:

Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparations.

Dosage and administration:

The suggested intravenous dose range used in the average patient (70 kg) is 1 to 8 millicuries of Technetium Tc 99m Sulphur Colloid Injection. When orally administered, the sodium pertechnetate Tc 99m Sulphur Colloid Injection is not absorbed from the G.I. tract.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Radiopharmaceuticals should be used only by physicists who have been trained in the proper 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 to license the use of radionuclides.

Storage:

The kit contents should be stored at room temperature (18-25°C). The following directions must be carefully followed for vials containing 25 millicuries or more of Technetium Tc 99m Sulphur Colloid Injection:

1. Refrigerate the radioactive symbol label to reaction vial.
2. Rapidly inject a dose of 0.1-0.5 ml of sterile Sodium Pertechnetate Tc 99m, up to 75 millicuries which must contain at least 10 micrograms of aluminum in the reaction vial. Relieve the excess pressure in the vial by withdrawing an equal volume of air. Mix the solution.
3. Assemble the thiosulphate syringe (labeled "A") and inject the total contents into the reaction vial with gentle agitation. Relieve the excess pressure by withdrawing an equal volume of air. Mix the solution.
4. Immediately immerse the reaction vial in a vigorously boiling water bath, deep enough to cover the entire liquid contents of the vial. Keep the vial in the water bath for five minutes plus or minus 30 seconds.
5. During heating step, assemble buffer syringe cartridge (labeled "B").
6. Remove vial from water bath, place in lead shield, and vent using 20 gauge, disposable needle.
7. Immediately inject contents of syringe B into reaction vial.
8. Remove vent and shake gently for a few seconds.
9. Rapidly cool to room temperature (note rapid cooling rate) before use and then affix the descriptive label to the dose vial shield. Maintain adequate shielding of the radioactive colloid preparation. Do not use the preparation after six hours from the time of formulation.

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Technetium Tc 99m-Pyrophosphate-Tin Kit

DESCRIPTION: Phosphotec provides all the nonradioactive components required to prepare sterile, pyrogen-free technetium Tc 99m-pyrophosphate-tin complex. Each reaction vial contains 40 mg. sodium pyrophosphate (equivalent to 223 mg. anhydrorous sodium pyrophosphate) and 1 mg. stannous fluoride. When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the reaction vial, a technetium Tc 99m-pyrophosphate-tin complex is formed.

INDICATIONS AND USAGE: Technetium Tc 99m-Pyrophosphate-Tin complex may be used as a bone imaging agent to delineate areas of osseous osteogenetic.

CONTRAINDICATIONS: None known.

WARNINGS: This product should not be administered 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 (approx. 10) days following the onset of menopause.

It has been reported that false-positive or false-negative brain scans may result when brain scans using sodium pertechnetate Tc 99m are performed after a bone scan has been done using an agent containing stannous ions, e.g., a pyrophosphate bone agent. This is thought to be due to the interaction of Tc 99m with stannous ions inside red blood cells. Therefore, in those cases where both bone and brain scans are indicated, the brain scan should be performed first, if feasible. Alternatively, another bone imaging agent, such as Tc 99m DTPA, may be employed.

The contents of the Phosphotec reaction vial are intended only for use in the preparation of Technetium Tc 99m-Pyrophosphate-Tin solution and are not to be directly administered to the patient. Any sodium pertechnetate Tc 99m solution which contains an oxidizing agent is not suitable for use with Technetium Tc 99m-Pyrophosphate-Tin Kit. The contents of the kit are not radioactive. However, after sodium pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

PRECAUTIONS: Technetium Tc 99m-Pyrophosphate-Tin solution, 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. Also, care should be taken to minimize radiation exposure to the patients consistent with patient management.

Both prior to and following administration of Technetium Tc 99m-Pyrophosphate-Tin solution, the patient should be encouraged to drink fluids and to void as often as possible thereafter to minimize radiation exposure to the bladder and background interference during imaging. Technetium Tc 99m-Pyrophosphate-Tin solution must be used within 12 hours of reconstitution.

Adequate reproductive 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. This drug 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 the drug since many drugs are excreted in human milk. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: No adverse reactions specifically attributable to the use of Technetium Tc 99m-Pyrophosphate-Tin have been reported.

For full prescribing information see package insert.

HOW SUPPLIED: In a kit containing five reaction vials (5 ml size).

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Princeton, N.J. 08540


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The latest addition to our range is the unique Technetium (tin colloid) Agent. Its preparation is much simpler than sulphur colloid agents and requires no heating stage. It will visualize liver and spleen and unlike agents based on phytate, the colloid is formed in the vial, allowing quality control checks prior to injection.

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Amersham

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Five sterile multidose reaction vials each containing 21 mg human serum albumin and 0.23 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment.

REAGENT KIT FOR CARDIAC BLOOD POOL IMAGING

Maximum vial activity 100 mCi/3 ml

Easy to prepare (see directions): Just add sterile preservative-free water, Technetium 99m pertechnetate, then shake. Requires no electrolytic equipment or time-consuming procedures.

High blood concentrations: Approximately 60% remains in the circulation after 2 hours, approximately 45% after 4 hours (in normal patients).

Consistently high binding efficiency: Technetium binding range of 90-99% immediately after tagging.

Stable formulation: Uses stannous tartrate, which is more stable to air oxidation than stannous chloride.

Free from extraneous constituents: Following aseptic preparation, final product contains HSA, water, stannous tartrate, and sodium chloride.

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? Lymphoma
? Hodgkin's disease
? Bronchogenic carcinoma

Gallium Ga 67:
Now available for routine use as a non-invasive adjunct in diagnosis.
HSA  Multi-dose
Technetium Tc 99m
Human Serum Albumin Reagent Kit

Five sterile multidose reaction vials each containing 21 mg human serum albumin and 0.23 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment.

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For ordering, customer service, and technical information on HSA (Product Number UC-HA-80)
Call toll-free: (800) 431-1146.
In New York State call: (914) 351-2131.

Union Carbide Corporation
Clinical Diagnostics
Nuclear Medicine Products
Tuxedo, New York 10987

(REVERSE SIDE: PRODUCT INFORMATION)
CintiChem

TECHNETIUM 99m

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, the following instructions provided with the Kit, the 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>
<thead>
<tr>
<th>Table I. Principal emission data</th>
<th>radiation mean % disintegration mean energy (keV)</th>
<th>Gamma-2</th>
<th>87.9</th>
<th>140.5</th>
</tr>
</thead>
</table>

external radiation

The specific gamma ray constant for Technetium Tc 99m is 0.8 R/racal-hour at 1 cm. The first half-value thickness of lead (Pb) for Technetium Tc 99m is 0.2 mm. After 27 mm of Pb for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table I. For example, the use of 2.7 mm of Pb will decrease the external radiation exposure by a factor of 1.000.

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>
<thead>
<tr>
<th>Table III. Physical decay chart: Tc 99m, half-life 6.03 hours</th>
<th>hours remaining</th>
<th>fraction remaining</th>
<th>hours remaining</th>
<th>fraction remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>0*</td>
<td>1.000</td>
<td>7</td>
<td>447</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>891</td>
<td>8</td>
<td>399</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>795</td>
<td>9</td>
<td>355</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>708</td>
<td>10</td>
<td>317</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>631</td>
<td>11</td>
<td>282</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>563</td>
<td>12</td>
<td>252</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>502</td>
<td>13</td>
<td>223</td>
<td></td>
</tr>
</tbody>
</table>

*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 contain any foreign material 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 mini

<table>
<thead>
<tr>
<th>Table IV. Estimated absorbed dose</th>
<th>absorbed radiation dose (rad/s/5 mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
<td>0.047</td>
</tr>
<tr>
<td>Marrow</td>
<td>0.076</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.063</td>
</tr>
<tr>
<td>Bladder</td>
<td>0.166</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.062</td>
</tr>
<tr>
<td>Testes</td>
<td>0.079</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.273</td>
</tr>
</tbody>
</table>


how supplied

kit contents

5 STERILE MULTIDOSE REACTION VIALS (10 cc, silver albumin oversaturated with sterile vial containing the sterile, lyophilized human serum albumin.

2. Aseptically inject 1.0 ml of containing 21 mg human serum albumin in a 0.23 mg stannous tartrate, hydrolyzed. 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 radioactivity of a low level on a 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 containing 21 mg human serum albumin in a 0.23 mg stannous tartrate, hydrolyzed. Hydrochloric acid was added prior to lyophilization for pH adjustment.

3. Mix contents by swirling.

4. Place vial in radiation shield provided.

5. Aseptically swab rubber septum of shielded vial.

6. 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 shield vial.

9. 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.

12. Mix contents of syringe by repeated inversion immediately prior to injection.


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 CFR Part 35 or under equivalent license of Agreement State.

Clinical Diagnostics

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Lymphoma
Hodgkin’s disease
Bronchogenic carcinoma

Gallium Ga 67:
Now available for routine use as a non-invasive adjunct in diagnosis.
Indications and Usage: Gallium Citrate Ga 67 may be useful to demonstrate the presence and extent of certain malignancies such as Hodgkin’s disease, lymphomas, and bronchogenic carcinoma. Positive Ga 67 uptake in the absence of prior symptoms warrants follow-up as an indication of a potential disease state.

Contraindications: None known.

Warnings: Gallium Citrate Ga 67 should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards, ideally, examinations using radiopharmaceutical drug products, especially those elective in nature of a woman of childbearing capability should be performed during the first few (approximately ten) days following the onset of menses.

Precautions:

General
A thorough knowledge of the normal distribution of intravenously administered Gallium Citrate Ga 67 is essential in order to accurately interpret pathologic studies.

The finding of an abnormal gallium concentration usually implies the existence of underlying pathology, but further diagnostic studies should be done to distinguish benign from malignant lesions. Gallium Citrate Ga 67 is intended for use as an adjunct in the diagnosis of certain neoplasms. Certain pathologic conditions may yield up to 40% false negative gallium studies. Therefore a negative study cannot be definitively interpreted as ruling out the presence of disease.

Lymphocytic lymphoma frequently does not accumulate Gallium Ga 67 sufficiently for unequivocal imaging; and the use of gallium with this histologic type of lymphoma is not recommended at this time.

Gallium Citrate Ga 67, 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.

Carcinogenesis
No long term animal studies have been performed to evaluate carcinogenic potential.

Pregnancy Category C
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. Gallium Citrate Ga 67 should be used in pregnant women only when clearly needed.

Nursing Mothers
Gallium Citrate Ga 67 has been found to accumulate in breast milk and should not be used in nursing mothers.

Pediatric Use
Safety and effectiveness in children have not been established.

Adverse Reactions: Severe itching, erythema and rash were observed in one patient of 300 studied.

Dosage and Administration: The recommended adult (70kg) dose of Gallium Citrate Ga 67 is 2-5mCi. Gallium Citrate Ga 67 is intended for intravenous administration only.

Approximately 10% of the administered dose is excreted in the feces during the first week after injection. Daily laxatives and/or enemas are recommended from the day of injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

Studies indicate the optimal tumor to background concentration of ratios are often obtained about 48 hours post-injection. However, considerable biological variability may occur in individuals, and acceptable images may be obtained as early as 6 hours and as late as 120 hours after injection.

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

Radiopharmaceuticals should be used by persons 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 agencies authorized to license the use of radionuclides.

New Supplied: Gallium Citrate Ga 67 is supplied sterile and non-pyrogenic for intravenous use. Each ml contains 2mCi of Gallium Ga 67 on the calibration date, as a complex formed from 9ng gallium chloride Ga 67, 2mg of sodium citrate, 8.8mg sodium chloride, and 0.9% benzyl alcohol w/v as preservative. The pH is adjusted to between 4.5-7.5 with hydrochloric acid and/or sodium hydroxide solution.

Vials are available from 3mCi to 18mCi in increments of 3mCi on calibration date.

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

CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription.
OSTEOSCAN®

(59MG DISODIUM ETIDRONATE, 016MG STANNOUS CHLORIDE)

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 99mTc-pertechnetate, these ingredients combine with 99mTc to form a stable soluble complex.

ACTIONS (CLINICAL PHARMACOLOGY)

When injected intravenously, 99mTc-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 99mTc-labeled OSTEOSCAN.

Three hours after intravenous injection of 1 ml 99mTc-labeled OSTEOSCAN, 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 stomach. The level of 99mTc-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.

The 99mTc-generator should be tested routinely for molybdenum breakthrough and aluminum. If either is detected, the eluate should not be used.

PRECAUTIONS

Both prior to and following 99mTc-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the 99mTc-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 ensure minimum radiation exposure to the patient, consistent with proper patient management, and to ensure minimum radiation exposure to occupational workers.

ADVERSE REACTIONS

None.

DOSEAGE 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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- Greater than 6 hour stability
- 10 vials per kit

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Of course the proof is in the using. We invite you to try our product at no obligation. Just write to us at the address below, and we'll send you a sample of any of our diagnostic kits for your use and evaluation.

Diagnostic Kits (10 vials per kit)
Tc 99m DTPA (Sn) Chelate
Tc 99m Polyphosphate-Tin
Tc 99m Diphosphonate-Tin

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Selenomethionine Se-75
Xenon - 133 Gas
Xenon - 133 Saline

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diagnostic isotopes incorporated
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201-429-7590  Telex 133393

THE JOURNAL OF NUCLEAR MEDICINE

56A
**Indications and Usage:** Gallium Citrate Ga 67 may be useful to demonstrate the presence and extent of certain malignancies such as Hodgkin's disease, lymphomas, and bronchogenic carcinoma. Positive Ga 67 uptake in the absence of prior symptoms warrants follow-up as an indication of a potential disease state.

**Contraindications:** None known.

**Warnings:** Gallium Citrate Ga 67 should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards. Ideally, examinations using radiopharmaceutical drug products, especially those elective in nature of a woman of childbearing capability should be performed during the first few (approximately) ten days following the onset of menses.

**Precautions:**

**General**
A thorough knowledge of the normal distribution of intravenously administered Gallium Citrate Ga 67 is essential in order to accurately interpret pathologic studies.

The finding of an abnormal gallium concentration usually implies the existence of underlying pathology, but further diagnostic studies should be done to distinguish benign from malignant lesions. Gallium Citrate Ga 67 is intended for use as an adjunct in the diagnosis of certain neoplasms. Certain pathologic conditions may yield up to 40% false negative gallium studies. Therefore a negative study cannot be definitively interpreted as ruling out the presence of disease.

Lymphocytic lymphoma frequently does not accumulate Gallium Ga 67 sufficiently for unequivocal imaging; and the use of gallium with this histologic type of lymphoma is not recommended at this time.

Gallium Citrate Ga 67, 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.

**Carcinogenesis**
No long term animal studies have been performed to evaluate carcinogenic potential.

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**Pediatric Use**
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**Adverse Reactions:** Severe itching, erythema and rash were observed in one patient of 300 studied.

**Dosage and Administration:** The recommended adult (70kg) dose of Gallium Citrate Ga 67 is 2-5mCi. Gallium Citrate Ga 67 is intended for intravenous administration only.

Approximately 10% of the administered dose is excreted in the feces during the first week after injection. Daily laxatives and/or enemas are recommended from the day of injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

Studies indicate the optimal tumor to background concentration of ratios are often obtained about 48 hours post-injection. However, considerable biological variability may occur in individuals, and acceptable images may be obtained as early as 6 hours and as late as 120 hours after injection.

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

Radiopharmaceuticals should be used by persons 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 agencies authorized to license the use of radionuclides.

**How Supplied:** Gallium Citrate Ga 67 is supplied sterile and non-pyrogenic for intravenous use. Each ml contains 2mCi of Gallium Ga 67 on the calibration date, as a complex formed from 9mg gallium chloride Ga 67, 2mg of sodium citrate, 6.8mg sodium chloride, and 0.9% benzyl alcohol w/v as preservative. The pH is adjusted to between 4.5-7.5 with hydrochloric acid and/or sodium hydroxide solution.

Vials are available from 3mCi to 18mCi in increments of 3mCi on calibration date.

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

**CAUTION:** Federal (U.S.A.) law prohibits dispensing without prescription.
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For further information about Osteoscan, please contact: Arnold Austin, Technical Manager, Professional Services Division, Procter & Gamble (513) 977-5547.

In Europe, contact: Philips-Duphar B.V., Cyclotron and Isotope Laboratories, Petten, Holland.
See following page for a brief summary of package insert.
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 99mTc-pertechnetate, these ingredients combine with 99mTc to form a stable soluble complex.

ACTIONS (CLINICAL PHARMACOLOGY)
When injected intravenously, 99mTc-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 99mTc-labeled OSTEOSCAN.

Three hours after intravenous injection of 1 ml 99mTc-labeled OSTEOSCAN, 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 99mTc-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 a nuclear reactor or particle accelerator and who have experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

The 99mTc-generator should be tested routinely for molybdenum breakthrough and aluminum. If either is detected, the eluate should not be used.

PRECAUTIONS
Both prior to and following 99mTc-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the 99mTc-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 ensure minimum radiation exposure to the patient, consistent with proper patient management, and to minimize 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.

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NUCLEAR MEDICINE RESIDENCY. Two year residency in Nuclear Medicine at The New York Hospital-Cornell Medical Center, Position available July 1, 1978. Contact Jerome G. Jacobstein, M.D., Division of Nuclear Medicine, The New York Hospital-Cornell Medical Center, 525 East 68th Street, New York, N.Y. 10021.

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POSITIONS WANTED

BOARD CERTIFIED IN GENERAL radiology, presently second year resident in Nuclear Medicine at the University Medical center. Desires full time position in Nuclear Medicine or Radiology and Nuclear Medicine starting July 1, 1978. Please reply: F.O. Box 202, Society of Nuclear Medicine, 475 Park Ave. South, New York, N.Y. 10016.

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CONTRAINDICATIONS: None known.

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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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For further information, contact:
Rex B. Shafer, M.D., Chief, Nuclear Medicine Service (115), Veterans Administration Hospital, 54th St. & 48th Ave. So., Minneapolis, MN 55417

OR
Marle K. Loken, M.D., Ph.D., Director, Division of Nuclear Medicine, University of Minnesota Hospitals, Box 382, Mayo Memorial Building, Minneapolis, MN 55455

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The Division of Nuclear Medicine at the Massachusetts General Hospital is offering a 1-year Residency/Fellowship in Nuclear Radiology for individuals with a minimum of 2-years previous Radiology training who wish to qualify for special competence in Nuclear Medicine. The Program includes basic sciences, clinical applications and an opportunity to perform research. Interested individuals should contact either Juan M. Taveras, M.D., Radiologist-in-Chief, Department of Radiology or H. William Strauss, M.D., Director, Nuclear Medicine Division, at the Massachusetts General Hospital, Boston, MA 02114.

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Requests for further information should be directed to John A. Burdine, M.D., Chief, Nuclear Medicine Section, or Paul H. Murphy, Ph.D., Residency and Fellowship Coordinator, Department of Radiology, Bay- lor College of Medicine, Houston, Texas 77030.
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