TheBone



MPI STANNOUS DIPHOSPHONATE (TECHNETIUM TC 99m ETIDRONATE KIT) CONSISTENTLY SEEKS BONE ... AND BONE LESIONS.

MPI Stannous Diphosphonate targets areas of diagnostic significance. Its reliability is magnified with:

Rapid Blood Clearance. The P-C-P bond of diphosphonate resists hydrolysis; clears the kidneys rapidly. Optimum imaging time is in two to four hours.

Increased Stability. Ascorbic acid within the reagent aids in maintaining tin in its reduced state. The ^{99m} Tc pertechnetate stays where it belongs...tagged to the reagent.

Optimum Tin Levels. The Sn(II) level provides high labeling efficiency, with minimum interference with subsequent brain scans.

Investigate the economy of MPI Stannous Diphosphonate

You can use up to 8 ml of 5 to 15 mCi ^{99m} Tc in each vial. The reagent is usable for six hours after labeling.

You also have no delivery charges when you order MPI Stannous Diphosphonate with any other MPI products.

Ask your Medi-Physics representative about our economical, reliable delivery proceduresor call toll free:

(800) 227-0483—Outside California (800) 772-2446—Inside California





MPI Stannous Diphosphonate

Technetium Tc 99m Etidronate Kit-Diagnostic

DESCRIPTION: Each ampul contains a total of 1.54 mg of the sodium salt of etidronate, 0.42 mg stannous chloride, and 3.87 mg ascorbic acid in a 2.2-ml sterile, pyrogen-free aqueous solution. Hydrochloric acid and/or sodium hydroxide may have been added to adjust the pH to 2.5-5.0. The solution is under a nitrogen atmosphere. A complex is formed with the addition to the reagent of sterile, pyrogen-free sodium pertechnetate Tc 99m in isotonic saline.

INDICATIONS: Technetium Tc 99m etidronate is used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS: None known.

WARNINGS: This radiopharmaceutical should not be administered to children, pregnant women, or nursing mothers unless the expected benefit outweighs the potential risk. Radiopharmaceutical examinations of women of childbearing capability should be performed during the first few days following the onset of menses.

PRECAUTIONS: To minimize radiation dose to the bladder, the patient should be encouraged to drink fluids and void when the examination is completed and as often thereafter as possible for the next 4-6 hours. Where feasible, brain scans

should precede bone imaging procedures. Technetium Tc 99m etidronate should be formulated, following aseptic procedures, within 6 hours prior to clinical use. ADVERSE REACTIONS: Seven suspected reactions to technetium Tc 99m etidronate were reported in more than 22,500 clinical reports. There were two instances each of headaches and allergic reactions and one each of vomiting, rheumatoid arthritis flare-up, and skin rash.

DOSAGE AND ADMINISTRATION: The suggested adult dose is 5-15 mCi administered by slow I.V. injection. Do not administer more than 2.0 ml of unlabeled reagent per patient. Measure the patient dose with a suitable radioactivity calibration system immediately prior to administration. Scanning post-injection is optimal at 2-4 hours.

Optiminal at 2-4 nours. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides and who have been approved by the appropriate government agency.

HOW SUPPLIED: Each kit package contains five sealed glass ampuls as described above, five sterile, pyrogen-free mixing vials, five each of mixing-vial and record labels and one package insert. Store at 5°-8°C; protect from light.

A remarkable advance in Nuclear Scintigraphy-Functional and Physiological Imaging



Here is a whole-body positron imaging system—now available from The Cyclotron Corporation—which fully exploits the unique capabilities of annihilation coincidence detection in conjunction with short-lived, positronemitting radionuclides such as ¹¹C, ¹³N, and ¹⁵O—isotopes which can replace their stable counterparts in compounds that enter directly into all life processes.

Designated the Model 4200, it is the one system with the flexibility, performance, and operational features required for studies ranging from basic medical research to clinical diagnoses, and treatment evaluation.

Exceptional utility and performance characterize this new system. It is capable of both multiplane lateral tomographic imaging and transverse axial tomography. The Model 4200 Positron Camera offers high sensitivity, resolution, and count rate capability in all modes. In the lateral imaging mode high-speed dynamic studies or detailed static studies may be displayed tomographically on selected focal planes. In the transverse CT. mode, a cylindrical volume 33 cm by 33 cm may be completely characterized in 3 dimensions in contiguous or overlapping slices in one scan. In addition, accurate, quantitative images may be obtained by means of a transmission scan using an accessory flood source which permits correction for attenuation effects in the subject.

The System is complete in all respects including a dedicated computer with required software.

All data acquisition, image processing and display, plus patient filekeeping are under the control of a digital computer system which is widely known and accepted in nuclear medical appliTo avoid obscuring camera details, patient couch furnished as part of the System, is not shown.

cations—Digital Equipment Corporation's Gamma 11.™

Any medical technologist can master the simple, interactive operating format: a computer specialist is not required. For the sophisticated user, the complete, stand-alone capability of the PDP 11/34 is available. Included with the computer without additional cost are software-support and program development tools available under the RT-11 operating system including Fortran, Basic, and Macro assembly languages.

The Cyclotron Corporation also offers a full line of compact cyclotron systems which are ideal for production of short-lived positron emitting radionuclides.

For more information on the Model 4200 Positron Camera System and compact cyclotron systems, complete and mail the coupon.





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THE CYCLOTRON CORPORATION

950 Gilman St., Berkeley, California 94710, U.S.A. Cable''Cyclotron Berkeley, Tel. (415) 524-8670, Telex 910-366-7116 You are entering a remarkable era of diagnostic advancement. Instead of being limited to a single imaging method, you will take advantage of many techniques, choosing them to meet your specific diagnostic criteria and the condition of your patient.

Searle is helping shape this era of advancement. Over the past decade, guided by your needs, we have developed sophisticated nuclear imaging instruments to a high degree of performance. Now, the knowledge gained during that time is being applied to the creation of instrumentation in the fields of ultrasound and CT scanning.

What Searle developed yesterday in nuclear imaging, the medical community relies on today. And *today* we are planning significant advances in ultrasonic, CT, and nuclear imaging. Tomorrow is in view.

MAGING: The Living Art



Searle Radiographics Inc. Subsidiary of G. D. Searle & Co.

Northwestern Memorial Hospital has put a new 91-tube image maker to work.



The Raytheon Cameray XL-91.

Northwestern Memorial Hospital is a major midwestern teaching hospital associated with Northwestern University. The busy nuclear medicine section is using the Raytheon Cameray XL-91 gamma camera.

Cameray XL-91 was specifically designed to give superior quality images. In fact, the Cameray XL-91 may be the ultimate medical gamma camera. It gives the widest undistorted field of view available from any gamma camera. 16¹/₂ inches.

Image uniformity also is no longer a problem with Cameray XL-91. Its exclusive Autocomp circuitry provides $\pm 2\%$ uniformity... automatically. Autocomp contains four memories... allowing users to calibrate to four different isotopes or collimators.

At Northwestern Memorial, Cameray XL-91 is being used each working day for a variety of clinical studies and is producing clinically useful images very rapidly. Hospital authorities are particularly pleased with the speed at which Cameray XL-91 was placed on-line after delivery as well as how quickly technicians were able to master its operation.

Get more details on Cameray XL-91 by phoning or writing today. Raytheon Company, Medical Electronics, 70 Ryan Street, Stamford, Conn. 06907. Telephone 800-243-9058.



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And for the changing needs of the new world of diagnostics, Kodak offers films for recording the information generated by these new technics. Films for nuclear medicine... for recording multiple, single, or dynamic images...with single and double emulsions...with spectral sensitivities compatible with cathode-ray tube displays. Films for CT scanning... for ultrasound... for thermography that can capture a wide range of gray tones.

For more information, contact your x-ray products dealer. Or write: Eastman Kodak Company, Dept. 740-B, Rochester, New York 14650.

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A New Generation Of Integrated Instrument Systems Used In Combination With A Swinghead Centrifuge — The Answer To Present And Future Radioassay **Requirements Of Clinical, Hospital And Research Laboratories**

PRIAS Sample Preparation Unit — automatically samples, dilutes, adds up to four cooled reagents and aspirates reaction tubes for counting of bound or free fractions . . . or both.

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For further information, request Bulletin 1226



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The New SPAC Digoxin Test. (Digoxin I-125 Radioimmunoassay Test)

The challenge of creating tube-to-tube antibody uniformity in an RIA solid phase system has now been answered.

The technology of the SPAC system is based on sectional processing of the antibody coating. This ingeniously simple idea provides tube-to-tube antibody uniformity in the SPAC Digoxin Test.

Tens of thousands of the lower sections of SPAC tubes (the reactive sections) are immersed and coated at one time in a solution of antiserum. They are then sealed to the upper cylinders. As a result, all tubes in a lot are produced from one batch of antiserum and have equal coating on the same reactive surface area.

Covalent bonding eliminates desorption

Since the antiserum is chemically linked to the tube surface, there will be no antibody loss due to desorption. Also, a specially selected copolymer material is used in the tube for bonding optimal quantities of antibody.

The improvements go beyond uniformity

1. Mechanical separation is eliminated in the SPAC Digoxin Test. You merely pipette, incubate, decant and count. There's no centrifuging, second incubation, or rinsing; no vortexing, aspirating or rotating.

2. Enhanced reaction rate, short incubation and high counting rate are a result of a stippled surface area for bonding optimal quantities of antibody.

3. There's no preparation of reagents.

4. It is necessary to pipet only one micro-quantity. There's no pipetting of antiserum.

5. The test system lends itself readily to sophisticated automation.

6. The packaging adds convenience. Tube identification, pipetting, incubating and decanting can be done without removing the tubes from the holder shown below.

The test, available in 50 and 100test sizes, offers standards made from USP Reference Standard Digoxin. Once you try the test, you'll see how well accuracy, reproducibility, convenience and simplicity apply to the SPAC system.

For information or to arrange an evaluation, call Bob Sheppard at 314/895-0404 or contact your Mallinckrodt representative.





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SIMIS 3

The most advanced data processing system for nuclear medicine



Left ventricle sequence of images, constructed from a first pass study, showing the wall motion and valve action of the heart. Images courtesy of Harbor General Hospital-UCLA, Torrance, California.



Region of Interest and color coordinated solid line timeactivity curves for cerebral blood flow study. The upper right-hand curves are the anterior cerebral and two carotid curves, the lower right-hand curves are the two carotids, and the lower lefthand curves are the two middle cerebrals.



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Simultaneous acquisition and display.



Programmable color display (256 x 256 resolution) with up to 256 programmable levels of color.

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The most comprehensive software package available, including cardiac programs for both first pass and multiple-gated studies.



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CLINICAL DATA PROCESSING SYSTEMS

Sensor can detect Deep Venous Thrombosis when it starts and provide daily monitoring capability

SENSOR[®] RADIONUCLIDE-LABELED (1251) FIBRINOGEN (HUMAN) Only from Abbott Diagnostics

Goes to the trouble spot

SENSOR RADIONUCLIDE-LABELED (1251) FIBRINOGEN (HUMAN)

can detect *early* deep venous thrombosis...even in the absence of clinical signs and symptoms

SENSOR test results correlate (73%) with venographic findings.*

SENSOR injections of Radionuclidelabeled (1251) Fibrinogen (Human) every 7 to 10 days provide monitoring capability for as long as the physician deems advisable.

SENSOR in vivo technique presents little or no risk to the patient; minimal trauma or discomfort.

SENSOR procedure requires little patient movement and manipulation; suitable for use with the critically ill or comatose patient.

SENSOR is the only product of its kind licensed for use in the United States.

Assists prompt diagnosis

Deep vein thrombosis can be a serious complication of many medical problems including hip fracture, myocardial infarction, cerebrovascular accident and malignancy, as well as surgical and orthopedic procedures. The SENSOR test, therefore, may be useful for the detection of thrombus formation in:

- patients undergoing major orthopedic or surgical procedures;
- patients with medical conditions known to predispose to thromboembolism;
- patients presenting with signs and symptoms suggestive of deep vein thrombosis, with or without accompanying pulmonary embolism;
- patients presenting with pulmonary embolism, with or without peripheral deep vein thrombosis.

*Data on file at Abbott Laboratories

10 day monitoring capability

Injected intravenously at the patient's bedside, SENSOR circulates in the bloodstream and is incorporated into forming thrombi along with endogenous fibrinogen. These sites of fibrin deposit can be detected as "hot spots" one or more hours after injection, by scanning each leg with a portable gamma scintillation counter.

Repeat scanning every one to three days lets you monitor the patient's clinical course for up to 10 days following a single injection. This distinguishes the technique as a valuable research tool in assessing both preventive and therapeutic methods of dealing with thromboembolic disease.

Yours for the asking...

A variety of additional material is available from Abbott Diagnostics Division for your use and review, including a slide/tape presentation which describes the ¹²⁵I-fibrinogen test rationale and the SENSOR step-by-step procedure. For more information, please contact your Abbott Diagnostics representative or call toll-free: (800) 323-9100



Abbott Laboratories Diagnostics Division North Chicago, IL 60064 800/323-9100

SENSOR[®] RADIONUCLIDE-LABELED (1251) FIBRINOGEN (HUMAN)

Goes to the trouble spot to detect Deep Venous Thrombosis when it starts

Indications and Usage

SENSOR [radionuclide-labeled (1251) fibrinogen (human)] is indicated as an aid in the diagnosis of deep-vein thrombosis of the legs.

- A. The SENSOR [radionuclide-labeled (1251) fibrinogen (human)] test may be useful for the detection of thrombi formation in patients undergoing major orthopedic or other surgical procedures, and in patients with myocardial infarction, pulmonary disease, malignant disease and other medical conditions known to predispose to thromboembolism.
- B. The SENSOR [radionuclide-labeled (¹²⁵I) 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 may not be positive if radionuclide-labeled fibrin deposition does not occur in sufficient quantity to allow detection. Its use is not contraindicated in a patient on an anticoagulant regimen.

Contraindications

The iodides given to block the uptake of ¹²⁵I by the thyroid gland are contraindicated in patients with a known sensitivity to iodides.

Warnings

This radiopharmaceutical drug product should not be administered to children, to patients who are pregnant or to nursing mothers unless the expected benefits to be gained outweigh the potential risk.

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.

Extraordinary precautions have been taken in the preparation of SENSOR [radionuclide-labeled (1251) fibrinogen (human)] to eliminate the possible transmission of hepatitis. Nevertheless, the remote risk of hepatitis associated with the administration of radionuclide-labeled (1251) fibrinogen (human) cannot be entirely eliminated. The finding of viral hepatitis in any patient up to six months after the administration of SENSOR should be reported to Abbott Laboratories.

Precautions

Care should be taken to insure minimum radiation exposure by using the recommended dose. With blockade of thyroidal uptake of the radioactive iodine, however, repeat injections may be performed in patients remaining at high risk of venous thrombosis.

There are a number of clinical circumstances requiring care in the interpretation of the test results (see Interpretation of the Results).

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. ¹²⁵I-fibrinogen (human) 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.

¹²⁵I-fibrinogen (human), 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.

Adverse Reactions

Side effects have not been reported following the administration of SENSOR.

Dosage and Administration

If material is received thawed, DO NOT USE.

Allow vial and contents to come to room temperature without agitation. This process takes approximately 20 minutes.

Thawed material should be a clear, colorless solution; if material appears clotted or precipitated, DO NOT USE.

Recommended Dose: Approximately 100 microcuries should be administered intravenously for an average adult (70 kg) patient.

The expiration of radionuclide-labeled (1251) fibrinogen is 45 days after iodination is completed.

The patient 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 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.

Interpretation of the Results

Conditions of the legs such as active arthritis, inflammation, hematoma, phlebitis, surgical or other trauma, may cause incorporation of radionuclide-labeled fibrinogen and result in a positive test. These conditions do not preclude the use of the fibrinogen test to detect thrombi in areas not affected by such local lesions or trauma, or in the opposite unaffected leg and to give additional diagnostic information over the involved area.

Other Methods Used in the Detection of Thrombi

It is generally agreed that, of all the tests for deep-vein thrombosis, venography yields the most definitive results. Accordingly, when confirmation of the diagnosis of thrombosis is sought, venography is most commonly used.

It is emphasized that venography is reliable in detecting thrombi in the veins of the upper thigh (at the inguinal ligament). The high levels of background radiation emanating from the great vessels of the thigh and lower abdomen, and from the urinary bladder may obscure SENSOR test results.

How Supplied

No. 6104, SENSOR [radionuclide-labeled (125]) fibrinogen (human)] is supplied in a single dose vial. Each dose (1 ml) contains radionuclide-labeled human fibrinogen at a concentration not to exceed 2.0 mg of clottable protein.



Abbott Laboratories Diagnostics Division North Chicago, IL 60064 800/323-9100

Varian Clinical Computation Systems

New Dimensions in Advanced Computer Applications

The fast and flexible Varian V-70 series minicomputers and supporting software have, through application in the Varian CT scanner and other medical equipment, proven to be ideal for clinical use. Varian's real-time, multi-task operating systems VORTEX and BETA give wide flexibility and ease of use for busy, patient-oriented environments. Combined with Varian special application software, Varian systems put the most advanced digital data-processing tools at the medical staff's fingertips.

The first standardized clinical system introduced by Varian was VARICAM, a comprehensive nuclear medicine data processing system, now in use in many hospitals around the world. Gamma camera raw-data are directly input to VARICAM and submitted to data processing procedures according to simple operator instructions. VARICAM gives the user unique options for developing his own processing protocols and manipulating data output format. VARICAM processed data are displayed in video black and white, color, or as life-sized hardcopy by the remarkable Varian STATOS[®] electrostatic printer/plotter.

Varian computers are used for many other clinical applications including radiotherapy planning, ultrasound image processing, electro-cardiology diagnosis, and intensive care monitoring.

Write Varian Radiation Division, 611 Hansen Way, Palo Alto, CA 94303



1 Contour map of embolized lung in left lateral view.

2 Dynamic liver examination showing Regions of Interest as defined by operator.

3 Isometric view of summed matrix of dynamic liver examination.

4 Curves formed from each Region of Interest shown in 2.



3 NOT: 2







Smart gamma cameras: a tiny electronic brain means greater clinical confidence.

Three scintillation cameras from Ohio-Nuclear are redefining the standard of excellence in image quality. A miniature computerlike brain and precise electronic balance give diagnostic teams a unique benefit: Guaranteed uniformity with high resolution.

A Sigma camera from Ohio-Nuclear does what no other gamma camera can do.

Prior to the start of a day's activities, a flood is loaded into the Dynamic Uniform Flood Correction (DUFC) memory. The Microprocessor Control (MPC) then analyzes the flood and determines the correction parameters necessary to assure $\pm 5\%$ uniformity.

These correction parameters are then applied to every study performed, assuring the physician that any abnormalities observed are anatomical rather than machine induced.

Advanced solid-state circuitry.

The microprocessor control, a feature of all Sigma cameras, incorporates arithmetic, logic and memory functions in one unit. Image uniformity and resolution are both optimized—with no trade-off. Result: Increased diagnostic confidence, faster patient throughput, and higher camera utilization.

Current owners of Ohio-Nuclear cameras can also realize Sigma benefits. All Series 100, 110 and 120 models can be retrofitted with MPC.

Sigma means smart.

A camera in the Sigma Series is not only smart electronically. It is an intelligent instrument for many other reasons.

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Fast analog, nonlinear circuitry provides consistently superior image quality and high count



Three Sigma cameras, each with microprocessor control.

• Fast, competent service worldwide. • Full range of collimators available.

rate data collection. MPC data analysis permits better results from all peripheral equipment and photo options.

Smart for technologists:

A Sigma camera is pre-eminently stable. Because DUFC is continuously monitoring the flood, retuning is minimized.

Auto Peak Track (APT) automatically centers the primary photopeak in the desired window. It also makes the use of precalibrated pushbuttons for isotope selection practical.

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The confident alternative.

Ohio-Nuclear recognizes that you constantly strive to perfect imaging techniques. Now you can enhance your efforts with the first intelligent camera system.

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Harshaw's partnership with nuclear medicine spans 25 years. Our

commitment to excellence in service, innovative design, and materials research is more important today than ever before.

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Dependable bone



R. L.

Posterior L. R.

lesion detection





Excellent in vitro stability

Greater than 98% labeling efficiency 8 hours after preparation. Osteoscan contains sodium ascorbate, an antioxidant that inhibits action of radiolysis by-products and oxidants capable of causing complex break-down and resultant soft tissue visualization.

Compatible with all types of technetium

Delivers consistently high-quality scans, using either instant or generator technetium.

Plus these other Osteoscan benefits

- very low tin level to minimize potential for liver visualization and for interference with subsequent brain scans
- rapid blood clearance
- high target-to-nontarget ratio
- diphosphonate's P-C-P bond for excellent in vivo stability

For further information about Osteoscan, please contact: Arnold Austin, Technical Manager, Professional Services Division, Procter & Gamble (513) 977-8547.

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 ^{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 99mTc-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 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 goverrment agency authorized to license the use of radionuclides.

The ^{99m}Tc-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 ^{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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BASIC STEPS IN PREPARING FOUR TECHNETIUM

6

1. Add 1-3 ml. of 99mTc** Maintain shielding at all times.	 2. Shake vigorously for 10-15 seconds. 2. Add 99mTc^{**} Maintain shielding at all times. 	
1. Remove reaction vial from freezer and wait approxi- mately 5 minutes for con- tents to come to room temperature.		
1. Add 4-10 ml. of 99mTc **	2. Shield completely and vigorously shake for 5-15 seconds.	
1. Shake <i>ampul</i> vigorously to suspend particles.	2. Open ampul.	
	 Add 1-3 ml. of 99mTc** Maintain shielding at all times. Remove reaction vial from <i>treezer</i> and <i>wait approxi-</i> <i>mately 5 minutes</i> for con- tents to come to room temperature. Add 4-10 ml. of 99mTc** Shake <i>ampul</i> vigorously to suspend particles. 	 Add 1-3 ml. of 99mTc** Maintain shielding at all times. Shake vigorously for 10-15 seconds. Remove reaction vial from <i>freezer</i> and <i>wait approxi- mately 5 minutes</i> for con- tents to come to room temperature. Add 99mTc** Maintain shielding at all times. Add 99mTc ** Maintain shielding at all times. Add 4-10 ml. of 99mTc** Shield completely and vigorously shake for 5-15 seconds. Shake <i>ampul</i> vigorously to suspend particles. Open ampul.

MACROTEC[®] (Aggregated Albumin [Human])

Macrotec (Aggregated Albumin [Human]) is a sterile, non-pyrogenic, lyophilized preparation of aggregated albumin. Each vial of the preparation contains 0.08 mg, tin as chloride, 1.5 mg, denatured human serum albumin, and 10 mg. Normal Serum Albumin (Human).

INDICATIONS: For use in perfusion lung imaging as an adjunct to other diagnostic procedures.

CONTRAINDICATIONS: At present there are no known contraindications to the use of this product.

WARNINGS: Radiopharmaceuticals 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.

Since ^{sem}Tc is excreted in milk during lactation, formulafeedings should be substituted for breast-feedings. Radiopharmaceuticals should be used only by physi-

cians who are qualified by specific training in the safe use and handling of radionuclides pro-

duced 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.

Note: Macrotec (Aggregated Albumin [Human]) is not radioactive. However, after ^{son}Tc is added, adequate shielding of the resultant preparation should be maintained.

PRECAUTIONS: In the use of any 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. Aseptic technique is essential in the preparation of Technetated (Tc-99m) Aggregated Albumin (Human).

ADVERSE REACTIONS: At present, adverse reactions have not been reported following the administration of this product.

For full prescribing information, consult package insert.

HOW SUPPLIED: In boxes of 5 vials.

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* Recommended maximum activity: 50 mCi.

3. Gently agitate vial for few seconds.

4. Allow to stand for 15 minutes at room temperature.

99m-LABELED LUNG IMAGING AGENTS

5. Visually inspect vial for presence of large aggregates. If present, do not use.

6. Agitate to effect homogenous suspension of the aggregated albumin.

**Recommended maximum activity: 60 mCi.

**Recommended maximum activity: 30 mCi.

3. Remove vial from shield (with forceps) and place in center of operating *ultrasonic bath* containing 3/4" of water. Bath should be protected by *lead glass or bricks. Ultrasound for 5 minutes.*

3. Withdraw (very slowly) 1.5-2.0 ml. of aggregate from ampul with syringe. Inject (very slowly) syringe contents into mixing vial.
 Wrap mixing vial in absorben paper disc and place in lead shield.

 Wrap mixing vial in absorbent paper disc and place in lead shield.
 Add 0.5-2.0 ml. of 99mTc** in saline into shielded mixing vial. Shake vigorously for at least 30 seconds. *Incubate* at

7. Shake contents vigorously just before removing aliquot intended for patient use.

**Recommended maximum activity: 25 mCi/ml.

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A BRIEF SUMMARY OF PRODUCT INFORMATION ALBUMIN MICROSPHERES (HUMAN) (10-35½, DRIED) INSTANT MICROSPHERES FOR LABELING WITH TECHNETIUM 99m.

INDICATIONS Scintillation imaging of the lungs with ^{99m}Tc labeled Albumin Microspheres is indicated as an adjunct to other diagnostic procedures whenever information about pulmonary circulation is desired.^{4,5} The most useful clinical applications of lung imaging are in the diagnosis of 1) pulmonary embolism, 2) chronic obstructive pulmonary diseases such as emphysema and chronic bronchitis, 3) pathological conditions which impede pulmonary abscess, and 4) other pulmonary diseases such as pneumonia and tuberculosis. CONTRAINDICATIONS The safety of Albumin Microspheres in patients with a known right-to-left cardiac shunt has not been established and its use in such patients is contraindicated. WARNINGS The possibility that hypersensitivity reactions may occur should be considered whenever protein-containing materials such as 3M Brand Instant Albumin Microspheres are administered. Administration of epinephrine, antihistamines and corticosteroid drugs should be cons^{99m}Tc is excreted in milk during lactation, formula-feedings should

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be substituted for breast-feedings. 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. **PRECAUTIONS** 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** The most frequently reported adverse reactions associated with the use of Albumin Microspheres are transient facial flushing and dyspnea. Less frequent adverse reactions are transient nausea, perspiration and cyanosis. An adverse reaction, which occurs rarely, is severe respiratory distress. The literature contains one report of an alleged anaphylactoid reaction to

Albumin Microspheres. Administration of ephinephrine, antihistamines and corticosteroid drugs should be considered whenever a hypersensitivity reaction occurs.



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¹Urokinasc Pulmonary Embolism Trial. A National Cooperative Study. Circulation (Suppl 11) 47:11-61. 1973 (April)

²Wagner, Henry N. Jr., Strauss, H. William. *Radioactive Tracers In The Differential Diagnosis of Pulmonary Embolism*. Progress in Cardiovascular Diseases, Vol. XVII, No. 4 (January/February), 1975.

PULMOLITE[™]—Technetium Tc 99m **Aggregated Albumin Kit Diagnostic**—For Intravenous Use

Indications and Usage: Technetium Tc 99m aggregated albumin is indicated as a lung imaging agent to be used as an adjunct in the evaluation of pulmonary perfusion.

Contraindications: Technetium Tc 99m aggregated albumin should not be administered to patients with severe pulmonary hypertension.

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

Warnings: The possibility of allergic reactions should be considered in patients who receive multiple doses

Theoretically, the intravenous administration of particulate material such as aggregated albumin imposes a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients the administration of aggregated albumin is possibly hazardous in acute cor pulmonale and other states of severely impaired pulmonary blood flow.

This radiopharmaceutical preparation should not be administered to children or to pregnant or lactating women unless the expected benefits to be gained outweigh the potential risks.

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: In cases of right-to-left cardiac shunt, additional risk may exist due to the rapid entry of aggregated albumin into the systemic circulation.

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.

The labeling reactions involved in preparing the agent depend on maintaining tin in the reduced state. Any oxidant present in the sodium per-technetate Tc 99m supply may thus adversely affect the quality of the pre-pared 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. The contents of the vial are sterile and non-pyrogenic. It is essential that the user follow the directions carefully and adhere to strict aseptic

procedures during preparation of the radio diagnostic. Technetium Tc 99m aggregated albumin is physically unstable and as such the particles will settle with time. Failure to mix the vial contents adequately before use may result in non-uniform distribution of radioactivity.

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

The contents of the vial are under a nitrogen atmosphere and should be protected from air. 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 the occupational worker.

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 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.

Dosage and Administration: The recommended intravenous dose range for the average patient (70kg) is 1 to 4 millicuries. The volume of the dose may vary from 0.2 to 1.3ml.

The recommended number of aggregated albumin particles to be administered per dose is 200,000-700,000 with the suggested number being approximately 350,000.

For ease and accuracy in dispensing the prepared agent, it is recommended that prior to reconstitution, concentrated sodium pertechnetate Tc 99m be further diluted to a volume of 8ml with fresh, preservative-free sodium chloride injection (U.S.P.).

How Supplied: PULMOLITE[™] Technetium Tc 99m Aggregated Albumin Kit is supplied in kits of five (5) or thirty (30) vials, sterile and non-pyrogenic, each vial containing in lyophilized form:

Aggregated albumin (human) - 1.0mg Normal human serum albumin - 10mg

Sodium chloride - 10mg

Stannous chloride dihydrate, maximum - 0.07mg

Each vial contains 3.6-6.5 x 10^e aggregated albumin particles. PULMOLITE contains no preservative; after reconstitution the shielded vial should be stored at 2° to 8°C.

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Indications: Inhalation of Xenon Xe 133 gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

Contraindications: To date, no known contraindications to the use of Xenon Xe 133 gas have been reported.

Warnings: This radiopharmaceutical should not be administered to pregnant or lactating women 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 per-formed during the first few (approximately 10) days following the onset of the menses

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radioqualified by specific training in the safe use and handing or radio-nuclides produced by nuclear reactor or particle accelerator, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides. **Precautions:** As in the use of any other radioactive material care should be taken to incure minimum radiation exposure to the nation. Consistbe taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. Expired Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental agency regulations. Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic. Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems. Adverse Reactions: To date, no adverse reactions based on the use of Xenon Xe 133 gas have been reported. Dosage and Administration: Xenon Xe 133 gas is administered by

inhalation from closed respirator systems or spirometers. The suggested activity range employed for inhalation by the average adult patient (70 kg) is:

Pulmonary function including imaging: in 3 liters of air.

Cerebral blood flow: 10-30 mCi in 3 liters of air.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. **How Supplied:** The Xenon Xe 133 gas is supplied as part of the Calidose¹⁴ system, consisting of 2 ml unit dose vials and the Calidose dispenser* for shielded dispensing.

Normally vials containing either 10 or 20 mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100 mCi/vial are available.

*Patent Pending

Cat. No. NRP-186



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Description

Each vial of the kit contains a lyophilized mixture of 5 mg of sterile, pyrogen-free Pentetate Calcium Trisodium and 0.25 mg Stannous Chloride. Sodium hydroxide and / or hydrochloric acid may have been used to adjust the pH.

When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the vial, a chelate, Technetium Tc 99m Pentetate is formed. The precise structure of the chelate is unknown at this time. Administration is by intravenous injection for diagnostic use.

Physical Characteristics

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

Table I. Principal Radiation Emission Data

Rediation	Meen % Disintegration	Mean Energy [keV]	
Gamma-2	87.9	140.5	

External Radiation

The specific gamma ray constant for Tc 99m is 0.8 R/mCi-hr at 1 cm. The first half value layer is 0.2 mm of Pb. To facilitate control of the radiation exposure from millicurie amounts of this radionuclide, the use of a 2.7 mm thickness of Pb will attenuate the radiation emitted by a factor of 1.000. Table II. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) mm	Coefficient of Attenuation
0.2	0.5
0.95	10-1
1.8	10 ⁻²
2.7	10 ⁻³
3.6	10-4
4.5	10.5

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.

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after 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
-5	1.777	5	0.563
-4	1.584	6	0.502
-3	1.412	7	0.447
2	1.259	8	0.399
-1	1.122	9	0.355
0.	1.000	10	0.317
1	0.891	11	0.282
2	0.795	12	0.252
3	0.708	18	0.126
4	0.631	24	0.063

*Calibration Time

Clinical Pharmacology

Following its intravenous administration Technetium Tc 99m Pentetate rapidly Following its intravenous administration Technetium Tc 99m Pentetate rapidly distributes itself throughout the extracellular fluid space from where it is (promptly) cleared from the body by glomerular filtration. There should be little or no binding of the chelate by the renal parenchyma. A variable percentage of the Technetium Tc 99m Pentetate binds to serum proteins; this ranges from 3.7% following the single injection to approximately 10% if the material is continuously infused. Although the chelate gives useful information on the glomerular filtration rate, the variable percent which is protein the full the serue of the serue distributes of the serue the bits to be by the the set of the serue the set of the serue the set of the set of the serue the set of the bound leads to a measured glomerular filtration rate which is lower than the glomerular filtration rate as determined by inulin clearances.

Technetium Tc 99m Pentetate tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. The chelate does not accumulate in the choroid plexus.

Since Technetium Tc 99m Pentetate is excreted by glomerular filtration, the images of the kidneys obtained in the first few minutes after injection represent the v-scular pool within the kidney. Subsequent images of the kidneys represent radioactivity which is in the urine of both the collecting system and the renal pelvis.

Indications and Usage

Technetium Tc 99m Pentetate may be used to perform kidney imaging, brain imaging, to assess renal perfusion, and to estimate glomerular filtration rate.

Contraindications

None known

Warnings

Technetium Tc 99m Pentetate 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 child-bearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Precautions

Technetium Tc 99m Pentetate 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.

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible for the next 4-8 hours

Technetium Tc 99m Pentetate should be formulated within one (1) hour prior to clinical

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. Technetium Tc 99m Pentetate 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 Pentetate have been reported.

Dosage and Administration

The suggested dose range for I.V. administration to be employed in the average patient (70 kg) is

Kidney imaging and glomerular filtration rate estimation 3 to 5 mCi.

Brain imaging or renal perfusion: 10 to 20 mCi.

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

Redigetimaceuticals should be used only by physicians who are qualified by training andexperienced 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.

The components of the Technetium Tc 99m Pentetate Kit (Chelate) are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during addition of perfechnetate solution and the withdrawal of doses for patient administration.

Technetium Tc 99m Pentetate is prepared by simply adding 1 to 10 ml of Sodium Pertechnetate Tc 99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Tc 99m Pentetate.

Radiation Dosimetry

The estimated absorbed radiation doses¹ to an average patient (70 kg) from an intravenous injection of a maximum dose of 20 millicuries of Tc 99m Pentetate are shown in Table IV

Table IV. Radiation Doses

Tissue	Absorbed Radiation Dose	[rads/20 mCi]	
Kidneys		1.8	
Whole Body		0.12	
Bladder Wall	2-hr. void	2.3	
	4.8-hr. void	5.4	
Testes	2-hr. void	0.15	
	4.8-hr. void	0.21	
Ovaries	2-hr, void	0.22	
	4.8-hr. void	0.31	

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

How Supplied

A. 6 sterile immediate drug containers each containing: (Lyophilized)

- -5.0 mg CaNa₃DTPA
- -0.25 mg stannous chloride
- -Excess CaCl₂ and NaCl
- -NaOH and /or HCI to adjust pH
- -Nitrogen gas
- 8. 6 radioactivity string labels for the immediate drug container.
- C. 6 radioactivity labels for the lead shield.
- E. Trinstruction card.

Preparation

- Preparation DO NOT USE IF THERE IS A VACUUM IN THE IMMEDIATE DRUG CONTAINER OR IF AIR IS INJECTED INTO THE CONTAINER WHEN THE DOSE IS WITHDRAWN. FORMULATE WITHIN ONE HOUR PRIOR TO CLINICAL USE. 1. Fix the string radioactivity label to the neck of the immediate drug container. 2. Remove the flip-cap from the container and place the container in the lead shield. 3. Use a germicide to swab the septum of the sterile reaction container. 4. Asoptically inject into the immediate drug container 1 to 10 ml of sterile non-pyrogenic 0.9% Sodium Chloride solution containing radioactive Sodium Pertechnetate Tc-99m and withdraw an equal volume of nitrogen gas. Do not allow air to enter container. Do not use Technetium Tc-99m solution if it contains foreign matter. 5. Dissolve and mix well by gently shaking the container in the shield for 30 seconds to one mixe.
- 6.
- Measure and record the Tc-99m radioactivity and calibration data on the string radioactivity label and on the large radioactivity label. Enter the time of expiration in the space provided and fix the label to the shield.
- 7. Maintain adequate shielding at all times.

This reagent kit is approved by the California Department of Health for distribution to persons licensed pursuant to Sections 35.14 and 35.100, Group III of 10 CFR 35, or under equivalent licenses of Agreement States.



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INDICATIONS

Potassium perchlorate should be administered to minimize the accumulation of pertechnetate Tc-99m in the choroid plexus and in the salivary and thyroid glands in those patients receiving sodium pertechnetate Tc-99m injection for brain and blood pool imaging and placenta localization.

CONTRAINDICATIONS

None.

WARNINGS

Potassium perchlorate has been administered chronically in doses of 200-1000 mg per day for the treatment of hyperthyroidism. Fever, rash, lymphadenopathy, renal damage, agranulocytosis, and fatal aplastic anemia have all been reported as complications of this therapy. Because several alternative therapies for hyperthyroidism are available, Perchloracap Capsules are not recommended for treatment of this condition. These adverse effects are dose related and have not been observed in patients receiving single doses of potassium perchlorate under the conditions described under Dosage and Administration.

Use in Pregnancy: The safety of this drug in pregnant women is not known and the agent should not be administered during pregnancy or lactation unless the information to be gained outweighs the predicted hazard.

Do not administer Perchloracap Capsules that have been subjected to excessive heat and/or moisture as manifested by deformation and/or discoloration of the capsule.

To prevent loss of the desiccated atmosphere always replace the bottle cap immediately after use.

ADVERSE REACTIONS

Gastric irritation has been reported in therapeutic doses of perchlorate greater than one gram per day. The possibility of temporary local gastric irritation exists with the administration of subtherapeutic doses in capsule form.

DOSAGE AND ADMINISTRATION

The usual adult dose is 200 to 400 milligrams of potassium perchlorate administered orally one-half to one hour before injection of sodium pertechnetate Tc-99m. The maximum dose should not exceed one gram. Perchloracap Capsules should be administered with several ounces of water to prevent gastric irritation.

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

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 brain and bone scans are indicated, the brain scan should be performed first, if feasible. Alternatively, another brain 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 99m Tc 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 99m Tc 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 proper 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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RADIOPHARMACEUTICALSILeft lateralFor brief summary of prescribing information, please see next page.

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When injected intravenously, TechneScan PYP Tc 99m has a specific affinity for areas of altered osteogenesis. It is also concentrated in the injured myo-cardium, primarily in areas of irreversibly damaged myocardial cells.

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INDICATIONS AND USAGE

TechneScan PYP Tc 99m is a skeletal imaging agent used to demonstrate areas of altered osteogenesis, and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.

As an adjunct in the diagnosis of confirmed myocardial infarction (ECG and serum enzymes positive), the incidence of false negative images has been found to be 6 percent. False negative images can also occur if made too early in the evolutionary phase of the infarct or too late in the resolution phase. In a limited study involving 22 patients in whom the ECG was positive and serum enzymes questionable or negative, but in whom the final diagnosis of acute myocardial infarction was made, the incidence of false negative images was 23 percent. The incidence of false positive images has been found to be 7 to 9 percent. False positive images have also been reported following coronary by-pass graft surgery, in unstable angina pectoris, old myocardial infarcts and in cardiac confusions.

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.

Warning: Preliminary reports indicate impairment of brain scans using Tc 99m pertechnetate which have been preceded by bone scan. The impairment may result in false positives or false negatives. It is recommended, where feasible, that brain scans precede bone imaging procedures.

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 TechneScan PYP Kit must be maintained at refrigerator temperature until use.

The contents of the TechneScan PYP reaction vial are intended only for use in the preparation of Technetium Tc 99m Stannous Pyrophosphate and are not to be directly administered to the patient.

Sodium pertechnetate Tc-99m solutions containing an oxidizing agent are *not* suitable for use with the **TechneScan PYP Kit**.

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.

TechneScan PYP Tc 99m should not be used more than six hours after preparation.

PRECAUTIONS

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.

Bone Imaging

Both prior to and following TechneScan PYP Tc 99m administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the **TechneScan PYP Tc 99m** injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

Cardiac Imaging

Patient's cardiac condition should be stable before beginning the cardiac imaging procedure.

If not contraindicated by the cardiac status, patients should be encouraged to injest fluids and to void frequently in order to reduce unnecessary radiation exposure.

Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing the three recommended projections.

ADVERSE REACTIONS None.

DOSAGE AND ADMINISTRATION

The recommended adult dose of TechneScan PYP is:

- 1. Skeletal Imaging 5 to 15 millicuries (1 to 14 milligrams stannous pyrophosphate).
- 2. Cardiac Imaging 10 to 15 millicuries (4 to 7 milligrams of stannous pyrophosphate).

TechneScan PYP Tc 99m is injected intravenously over a 10- to 20-second period. For optimal results, bone imaging should be done 1 to 6 hours following administration. Cardiac imaging should be done 60 to 90 minutes following administration. The acute myocardial infarct can be visualized from 24 hours to 9 days following onset of symptoms, with maximum localization at 48 to 72 hours. Cardiac imaging should be done with a gamma scintillation camera. It is recommended that images be made of the anterior, left anterior oblique and left lateral projections.

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

HOW SUPPLIED

Catalog Number-094 TechneScan PYP Kit **Kit Contains:**

5-Stannous Pyrophosphate Reaction Vials (Lyophilized) for the preparation of Technetium Tc 99m Stannous Pyrophosphate.

Reaction Vial Contains:

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- The use of positron-emitting radiopharmaceuticals.
- Modular electronics, designed for ease of service and high reliability.
- Rapid, flexible scan capabilities, automatic bed indexing, high-resolution display, and adaptable data processing.

The ECAT (Emission Computerized Axial Tomographic) whole-body scanner uses positron-emitting radio-pharmaceuticals for patient imaging.

Developed and manufactured by the Life Sciences Division of Ortec Inc., the ECAT represents an accumulation of the extensive line of research instruments which Ortec supplies. Data acquisition is achieved with standard NIM and CAMAC modules identical to those proven reliable throughout the world in research, industrial, and clinical laboratories. It is this modular approach that not only helps prevent obsolescence but also provides for ease of service should the need ever arise.

The ECAT measures and locates the concentration of a positron-emitting radiopharmaceutical compound, such as ⁶⁸Ga-EDTA, ¹¹CO, or ¹³NH₃, administered to the patient. When a positron annihilates, two gamma rays are emitted in opposite directions. By detecting these gamma rays with electronically collimated opposing detector banks, the ray projection in which the annihilation occurred is determined. This method of detection provides for high resolution, high contrast, and high sensitivity in a format uniquely suited to reconstruction tomography. Compiling, sorting, and processing these data with a reconstruction algorithm results in a cross-sectional image similar to the images generated by transmission CAT (TCAT) scanners. The difference is that Ortec ECAT images are a measure of the physiology, or function, rather than the morphology, or density, of the structure.

For more information, call or write Life Sciences Division, Ortec Incorporated, 100 Midland Road, Oak Ridge, TN 37830; (615) 482-4411. ECAT trademark owned by Ortec Incorporated.



The count is the same. The cost is not.

Nalge introduces the FILMWARE[™] Scintillation Tube system for equivalent counting efficiency, plus exceptional economy from carrier to cocktail.

The new Nalge FILMWARE Scintillation Tube revolutionizes liquid scintillation counting by combining the advantages and eliminating the disadvantages of glass and plastic vials.

Like glass, FILMWARE tubes are transparent. Like glass, they have extremely low permeability to toluene. But they permit no adsorption of liquids, proteins, or ions to change the geometry of the system. And FILMWARE tubes contribute a background of less than half that of low-potassium glass.

Like plastic, FILMWARE tubes are unbreakable. But, made of two layers of plastic, they're 500 times less permeable to toluene than polyethylene. And they can't swell, jamming the counter and creating the hazard of fire.

Heat-sealed FILMWARE tubes eliminate the danger of contamination when vials break during troublesome capping, and they cost less than replacement caps—about 2.8¢ apiece.

New geometry for real economy.

What's more, you save by using less cocktail. FILMWARE tubes are available in 3-ml and 10-ml sizes, but they provide an accurate count with as little as 1 ml of cocktail. In the tube, 1 ml is distributed vertically, to assure optimal exposure to the photomultiplier. The 10-ml tube easily accommodates filter papers, yet you need only 1-2 ml of cocktail for an efficient count.

One-sixth the disposal volume.

With FILMWARE tubes, you reduce the cost and volume of disposal, too. Over 12,000 samples can be emptied into a standard drum. Six times more than is possible when you use glass or plastic vials. FILMWARE tubes can be incinerated, left intact, or snipped open for emptying. Cost savings are estimated at 75%.

The elements of the system.

Counting with the Nalge FILMWARE Scintillation Tube takes no longer than the system using standard vials. FILMWARE tubes are specially designed to stay open for easy filling.

The optional, reusable carrier vials are straight-walled, for easy insertion of the tubes.

The optional, three-tiered rack provides easy access to the tubes for filling and holds 10-ml FILMWARE tubes without the carrier vials.

The heat sealer seals the tubes in about 2 seconds. It operates at 350° F, well below the ignition temperature of toluene. Tubes can be resealed after an internal standard is added by snipping the tops or puncturing them with a syringe.

Count your savings.

Application of the Nalge FILMWARE Scintillation Tube system can lower liquid scintillation counting costs dramatically, even though current cocktail, vial, and disposal costs vary. To learn how the system can contribute to your

counting operation, contact your Nalge representative. And for an explanatory brochure, write: Nalgene Labware Division, P.O. Box 365, Rochester, New York 14602.

SYBRON Nalge



1. Place FILMWARE tube into a wide-mouth vial. 2. Dispense as little as 1 ml of cocktail into tube. 3. Pipet sample into each tube. 4. Seal the tubes shut. 5. Tuck tubes down into carrier. Nalge Company Division of Sybron Corporation

Meletron



The dosecalibrator that calibrates itself (almost)

Radx has now programmed its new Meletron to read its own calibration factors. The Meletron programmable microprocessor allows you to check each of the Isotope Selector Keys for proper multiplication factors.

Radx employs direct mathematical manipulation for the various radionuclides (other dosecalibrators vary the resistance to alter the signal from the ionization chamber to the digital meter) and these factors can now be recalled from memory and displayed on the digital readout. Since each radionuclide has a finite and discrete mathematical factor, the ability to recall and display this factor (as triggered by the Isotope Selector Key) will remove any doubt concerning this aspect of dosecalibration.

Area radiation can also be monitored by the new Meletron. With the key out, "Background – Error" will flash when the radiation level exceeds approximately 2.0 mr/hr (with an unshielded unit).

Area monitoring is standard on Meletron; an extra cost option on other dosecalibrators. Hard copy data of your radionuclide calibrations is another RADX first. The Melecord prints; time, date, volume, calibration, patient dose, radionuclide — plus it calculates and then prints the volume to administer. Easy compliance with NRC requirements is also assured by Melefile, the RADX record keeping system which provides data cards, tab cards and a compact file to keep them in.

Obsolescence is eliminated. The Meletron employs the latest in microprocessor technology. The highly reliable microprocessor is readily programmable to perform a wide variety of functions. Further program modifications may be added to your unit in the field, as they are developed.



For a permanent solution to your dosecalibration and record-keeping problems, call RADX — the innovators in nuclear medicine. RADX, P. O. Box 19164, Houston, Texas 77024, 713/468-9628.

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Scans courtesy of Ultrasound Diagnostic Services Phoenix Arizona



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The RAO view shows akinesis of the lower antero-lateral wall and apex; and contraction of the inferior wall and high up the antero-lateral wall. The LAO view shows good contrac-

÷.

RAO, SYSTOLE

tion posteriorly and akinesis of the septal aspect of the chamber. Patient was injected IV with 20mCi of ^{99m}Tclabelled Human Serum Albumin. The agent was prepared using the New



LAO, DIASTOLE

LAO, SYSTOLE

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No knobs, no meters, no errors

The spartan panel above tells the second-best part of our story. If you want to photograph peak systole, press the SYSTOLE button. If, say, you want systole only at full expiration, press the EXPIRATION button as well. If only breathing is relevant, don't press the heart button.

The Brattle is connected to the patient and to your gamma (or x-ray or ultrasonic) camera. Whenever the patient is in the selected phase, both the scope and the scaler on your gamma camera are gated ON, and film is exposed. Otherwise, they are OFF.

Brattles lock onto patients – and stay locked on

It doesn't matter if the patient's heart rate and breathing depth change while he's under the collimator because we stay right with him. Brattles contain an ECG to track heart, a plethysmograph to track respiration, and a tiny computer to deduce systole and diastole times from the heart signal. And because it's all built in, your operator need not be a physiologist.

We don't cover our trackswe print them

The panel lights flash whenever the patient reaches the selected phases; and pushing the RECORDER-ON button gets you an ECG tracing marked with breathing and cameraon times. You can verify function before, during and after exposure.

A single pair of axillary electrodes captures both heart and breath

It's easy. And we supply disposable, pre-filled electrodes.

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