MPI Xenon Xe 133 is now available in four product configurations—from unit dose to bulk:

- Ventilation Study System (V.S.S.)
- 10 mCi vials
- 20 mCi vials
- 1.3-1.7 Ci ampules (crushable and breaksealed)

### When you like it

MPI Xenon Xe 133 delivery and calibration schedule—utmost convenience and optimal product use:

<table>
<thead>
<tr>
<th>Product</th>
<th>1st Rec.</th>
<th>Calibrated</th>
<th>12:00 Noon</th>
</tr>
</thead>
<tbody>
<tr>
<td>V.S.S.</td>
<td>Monday</td>
<td>Thursday</td>
<td></td>
</tr>
<tr>
<td>10 &amp; 20 mCi vials</td>
<td>Thursday</td>
<td>Monday</td>
<td></td>
</tr>
<tr>
<td>1.3-1.7 Ci Ampules</td>
<td>Monday</td>
<td>Prior Friday</td>
<td></td>
</tr>
</tbody>
</table>

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

**Xenon Xe 133-V.S.S.** For the study of pulmonary ventilation.

**Xenon Xe 133 Gas Ampule & MPI Xenon Xe 133 Gas Vial.**

For the study of pulmonary ventilation and assessment of cerebral blood flow.

**DESCRIPTION:** The Xenon Xe 133-Ventilation Study System consists of a sealed frangible capsule containing 10 millieuries ± 20% of Xenon Xe 133 gas at calibration time and date with less than 1% carrier xenon in air. Xenon Xe 133 Gas vials is supplied as a carrier-free gas in concentrations of 10 to 50 mCi per milliliter of gas for inhalation. Xenon Xe 133 Gas Ampule is supplied as a carrier-free gas in 4 ml crushable or break-sealed glass ampule in concentrations of 0.43 to 0.33 Curie/ml. Xenon Xe 133 is produced by fission of Uranium-235. It is chemically and physiologically related to elemental xenon, a non-radioactive monatomic gas which is physiologically inert except for anesthetic properties as high doses.

**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 radio-pharmaceuticals, 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 menopause. 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. There are no well-controlled studies in pregnant women which allow any conclusions as to the safety of Xenon Xe 133 for the fetus. Xenon Xe 133 should be used in pregnant women only when clearly needed.

Concentrated Xenon Xe 133 gas supplied in ampule must be diluted to the activity range appropriate to the route of administration.

**PRECAUTIONS:** Xenon Xe 133 gas 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.

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 kept free of radioactive contamination to prevent radioactive contamination to the laboratory environment 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.

**HOW SUPPLIED:** Each Ventilation Study System (V.S.S.) contains Xenon Xe 133 in a sealed frangible capsule containing 10 millieuries ± 20% at calibration time and date stated on the label. Each Xenon Xe 133 Gas ampule is supplied in 4 ml crushable or break-sealed ampules containing 1.7 to 1.3 Curies. Each Xenon Xe 133 Gas vial contains 10 or 20 mCi of gas.

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Technetium Tc 99m Normal Serum Albumin (Human) Reagent Kit
DIAGNOSTIC-FOR INTRAVENOUS USE

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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

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

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

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

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

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

Technetium Tc 99m Human Serum Albumin must not be used after three hours from the time of formulation.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Human Serum Albumin should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

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

For ordering, customer service and technical information call toll-free: (800) 431-1146, until 7:00 p.m. Eastern Standard Time. In New York State, call (914) 351-2131, ext. 227.

CintiChem
TECHNETIUM 99m

PACKAGING ADMINISTRATION

DIAGNOSTIC-FOR INTRAVENOUS USE

Technetium Tc 99m Human Serum Albumin (Human) Reagent Kit

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

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

How supplied
Unit dose kit
The kit consists of 10 unit dose reaction vials each containing a lyophilized mixture of 7 mg human serum albumin and 0.06 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment.

Multidose kit
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.

FOR FULL PREPARATION AND PRESCRIBING INFORMATION, SEE PACKAGE INSERTS.

Notes:
1 Refer to package insert for full preparation and prescribing information.
2 Data on file at Union Carbide Corporation, Tuxedo, New York

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Volume 22, Number 3
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The skeletal system
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MPI Thallous Chloride TI 201 can be delivered with other MPI products without an additional delivery charge.

PLEASE SEE FOLLOWING PAGE FOR BRIEF SUMMARY OF PRESCRIBING INFORMATION.
DESCRIPTION: MPI Thallous Chloride TI 201. Thallous Chloride TI 201 is supplied in isotonic solution as a sterile, nonpyrogenic diagnostic radiopharmaceutical for intravenous administration. Each ml contains 1 mCi Thallium Chloride TI 201 at calibration time made isotonic with 9 mg sodium chloride and preserved with 0.9% (w/v) benzyl alcohol. The pH is adjusted to between 4.5-7.0 with hydrochloric acid and/or sodium hydroxide. Thallium TI 201 is cyclotron produced. It is essentially carrier free and contains no more than 1% Thallium TI 200 and no more than 1% Thallium TI 202.

CONTRAINdications: None known.

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

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. Thallous Chloride TI 201 should not be used in pregnant women except when benefits clearly outweigh the potential risks.

PRECAUTIONS: Ideality, examinations using radiopharmaceutical drug products especially those effective in nature of women of childbearing capability should be performed during the first ten days following the onset of menses.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are 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.

Carcinogenicity: No long-term animal studies have been performed to evaluate carcinogenic potential.

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

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 ensure minimum radiation exposure to occupational workers.

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.

This drug should not be used six (6) days after the calibrating date.

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

HOW SUPPLIED: MPI Thallous Chloride TI 201. Thallous Chloride TI 201 is available in 2.0 mCi vials.
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THE JOURNAL OF NUCLEAR MEDICINE
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Please refer to the brief prescribing information on the following page.
AN-MDP® (Technetium Tc 99m Medronate Kit)

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

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

CONTRAINDICATIONS. None known.

WARNINGS. This class of compounds is known to complex cations such as calcium. Particular caution should be used with patients who have, or may be predisposed to hypocalcemia (i.e., alkalosis).

PRECAUTIONS. Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Medronate and are NOT to be administered directly to the patient. Technetium Tc 99m Medronate, as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patient consistent with proper patient management.

To minimize radiation dose to the bladder, the patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next 4–6 hours.

Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use. Optimal imaging results are obtained 1–4 hours after administration.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Medronate affects fertility in males and females.

Pregnancy Category C: Animal reproductive studies have not been conducted on Technetium Tc 99m Medronate. It is also not known whether Technetium Tc 99m Medronate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Medronate should be given to a pregnant woman only if clearly needed. 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.

Nursing Mothers: Technetium Tc 99m Medronate is excreted in human milk during lactation, therefore, formula feedings should be substituted for breast feedings.

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

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.

ADVERSE REACTIONS. No adverse reactions specifically attributable to the use of Technetium Tc 99m Medronate have been reported.

DOSE AND ADMINISTRATION. The suggested dose range for i.v. administration, after reconstitution with oxidant-free sodium pertechnetate Tc 99m injection, to be employed in the average patient (70 Kg) is:

Bone imaging: 10–20 millicuries Technetium Tc 99m Medronate. Scanning is optimal at 1–4 hours post-injection. The patient dose should be adjusted by a suitable radioactivity calibration system immediately prior to administration.

HOW SUPPLIED. The AN-MDP® Technetium Tc 99m Medronate Kit is supplied either as a set of 5 or 30 sterile and pyrogen-free vials. Each nitrogen-flushed vial contains a hypodiluted form: mmedronic acid 10 mg, stannous chloride (minimum) 0.51 mg, maximum total stannous and stannic chloride 1.01 mg. The pH is adjusted with HCl or NaOH solutions prior to lyophilization. Included in each 5-vial kit is one package insert and 10 radiation labels. Refrigeration is not necessary. Technetium Tc 99m Medronate Kits contain no preservative. Vials are sealed under nitrogen; air or oxygen is harmful to the contents of the vials and the vials should not be vented.

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Nuclear Medicine Review Syllabus

Peter T. Kirchner, M.D., Editor

The rapid growth of clinical nuclear medicine poses a formidable challenge to the physician who wants to maintain a high level of competence in all areas of nuclear medicine. To help the physician meet this challenge, the Society of Nuclear Medicine has prepared the NUCLEAR MEDICINE REVIEW SYLLABUS, a comprehensive review of the major scientific and clinical advances that have occurred since the early 1970's.

The 619 page NUCLEAR MEDICINE REVIEW SYLLABUS offers a detailed overview of 12 major topic areas in nuclear medicine. Within each chapter there is a clear, timely review of the subject and a substantial bibliography locating additional information. A 32-page index makes all of the volume's data instantly accessible.

The NUCLEAR MEDICINE REVIEW SYLLABUS has chapters on:
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- Gastroenterology
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- Radiation Effects and Protection
- Hematology-Oncology
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- Central Nervous System
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This highly readable guide to current practice was prepared by more than fifty recognized authorities, with each chapter written by acknowledged experts in the field.

The NUCLEAR MEDICINE REVIEW SYLLABUS will prove valuable to the practicing physician who wants to keep in touch with current clinical practice in all aspects of nuclear medicine. Those seeking certification will find the SYLLABUS extremely useful as a tool for final review.

Copies are available now at $30.00 each (plus $2.50 per copy for postage and handling). All orders must be prepaid or accompanied by a purchase order. Checks must be in U.S. funds only. Order from: Book Order Dept., Society of Nuclear Medicine, 475 Park Avenue South, New York, NY 10016.

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(In Missouri, 314-895-2405 collect)

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I123...
A Superior Thyroid Agent

Sodium Iodide I123 is superior to I131 because of its low radiation dose to the patient, its short half-life of 13.2 hours, and its imaging energy of 159 KeV.

For a Consistent Quality Image.....Sodium Iodide I123

DESCRIPTION: Sodium iodide I123 for diagnostic use is supplied as capsules and in vials as an aqueous solution for oral administration. At calibration time, each capsule has an activity of 100 microcuries and each vial contains solution with a total specific concentration of two millicuries per ml.

INDICATIONS: Sodium iodide I123 is indicated for use in the diagnosis of thyroid function and imaging.

CONTRAINDICATIONS: None known.

WARNINGS: This radiopharmaceutical 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 radiopharmaceuticals, especially those effective in nature, in women of child-bearing capability should be performed during the first few (approximately 10) days following the onset of menses. However, when studies of thyroid function are clinically indicated for members of these special population groups, use of I123 would be preferable to the use of I131 in order to minimize radiation dosage.

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. Sodium iodide I123 should be used in pregnant women only when clearly needed.

PRECAUTIONS: Sodium iodide I123, as well as other radioactive drugs, must be handled with care. Appropriate safety measures should be used to minimize radiation exposure to other persons. Care should also be taken to minimize radiation exposure to patient consistent with proper patient management. The prescribed sodium iodide I123 dose should be administered as soon as practicable in order to minimize the fraction of radiation exposure due to relative increase of radionuclidic contaminants with time.

The uptake of I123 may be decreased by recent administration of iodinated contrast materials, by intake of stable iodine in any form, or by thyroid, anti-thyroid, and certain other drugs. Accordingly, the patient should be questioned carefully regarding diet, previous medication, and procedures involving radiographic contrast media.

ADVERSE REACTIONS: There were nine adverse reactions reported in a series of 1,393 administrations. None of these were attributed to I123. Five adverse reactions, consisting of gastric upset and vomiting, were attributed to a filler in the capsule. Two cases of headache and one case of nausea and weakness were attributed to the fasting state. One case of garlic odor on the breath was presumed to be attributable to the presence of tellurium.

DOSE AND ADMINISTRATION: The recommended oral dose range for diagnostic studies of thyroid function in the average adult patient (70 kg) is from 100 to 400 microcuries. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Concentration of I123 in the thyroid gland should be measured in accordance with standardized procedures.

SPECIAL CONSIDERATION: 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.

HOW SUPPLIED: Sodium iodide I123 for oral administration is supplied in aqueous solution in glass vials of 1mCi and in capsules of 100 μCi.
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ASSAYER I is a dosecalibrator unsurpassed in reliability, accuracy, and linearity with a unique method of isotope selection—an optical scanner.

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THE JOURNAL OF NUCLEAR MEDICINE
Diagnosis: arteriovenous malformation

Imaging information:
- Instrument: Ohio Nuclear Series 100 Gamma Camera
- Scan time: 90 minutes postinjection
- Counts: 400 K
- Dose: 15 mCi GLUCOSCAN

GLUCOSCAN™
Technetium Tc 99m Gluceptate Sodium Kit

New England Nuclear®

Please see following page for brief prescribing information.
GLUCOSCAN
Technetium Tc 99m Glucopate Sodium Kit

INDICATIONS AND USES: Technetium Tc 99m Glucopate Sodium is used for brain imaging.
       Technetium Tc 99m Glucopate Sodium is indicated for renal perfusion imaging as an aid in the diagnosis, localization, and evaluation of kidney disease. It may provide useful information about renal size, shape, and position and may delineate lesions affecting renal blood flow.

CONTRAINDICATIONS: None known.

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

Ideally examinations using radiopharmaceuticals—the especially those elective in nature—of a woman of childbearing capability should be performed during the first ten days following the onset of the menses. Dehydration and/or patient positioning may result in failure to visualize urinary excretory structures in the presence of normal function. Adequate patient fluid intake and repositioning may reduce the incidence of such false positive studies.

PRECAUTIONS: Technetium Tc 99m Glucopate Sodium, as well as any radiopharmaceutical 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 Glucopate Sodium depends on the maintenance of pH 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 biological distribution of the prepared agent, and its use is not recommended.

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

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Glucopate Sodium is used to be 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: Although infrequent, erythema has been reported in association with the use of Technetium Tc 99m Glucopate Sodium.

DOSE AND ADMINISTRATION: The recommended dose for the average (70kg) adult patient is 10-20 millicuries for both renal and brain imaging. Technetium Tc 99m Glucopate Sodium is intended for intravenous administration.

Technetium Tc 99m Glucopate Sodium should be used within six hours after aseptic reconstitution with sodium pertechnetate Tc 99m. For optimal results, this time should be minimized. The reaction vial contains no bacteriostat. Optimal results for both renal and brain imaging are obtained one hour after administration. Studies have shown that although optimal target-to-background ratios for brain lesions are obtained at two hours post-injection, there is no improvement in diagnostic efficacy after one hour.

Radiopharmaceuticals should be used by persons with specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate governmental agencies authorized to license the use of radionuclides. The components of the New England Nuclear GLUCOSCAN Kit 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 pertechnetate solution and the withdrawal of doses for patient administration.

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

Gluceptate Sodium — 200mg

Maximum Tin — 0.07mg

Stannous Chloride (min.) — 0.06mg

Prior to lyophilization the pH is adjusted with hydrochloric acid and/or sodium hydroxide solution. Store vials at room temperature (15-30°C). Included in each of five vial kit is one package insert and six radiation labels. Included in each thirty vial kit is one package insert and thirty-six radiation labels.

The contents of the kit vials are not radioactive; however, after reconstitution with sodium pertechnetate Tc 99m the contents are radioactive and adequate shielding and handling precautions must be maintained.

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

Catalog Number NRP-180 (5 vial kit)
Catalog Number NRP-180C (30 vial kit)

August 1978

Galium Citrate Ga67

INDICATIONS AND USES: Galium Citrate Ga67 may be useful in demonstrating the extent of the extent of the following malignancies: Hodgkin's disease, lymphomas and bronchogenic carcinoma. Positive Ga67 uptake in the absence of prior symptoms warrants follow-up as an indication of a potential disease state.

Galium Citrate Ga 67 may be useful as an aid in detecting some acute inflammatory lesions.

CONTRAINDICATIONS: None known.

WARNINGS: Galium 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 radiopharmaceuticals should be performed by persons with specific training in the safe use and handling of radionuclides prepared 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.

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

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Galium Citrate Ga 67 should be used in pregnant women only when clearly needed. Galium Citrate Ga 67 has been found to accumulate in breast milk and should not be used in nursing mothers.

Safety and effectiveness in children have not been established. Galium Citrate Ga 67 localization cannot differentiate between tumor and acute inflammation, and other diagnostic studies must be added to define the underlying pathology.

The expiration date of the drug is seven days after the date of calibration.

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

DOSE AND ADMINISTRATION: The recommended adult (70kg) dose of Galium Citrate Ga 67 is 2-5mCi. Galium Citrate Ga 67 is intended for intravenous administration.

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 excreted in nature of a false positive study.

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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.

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Catalog Number NRP-121

December 1979

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Gallium Citrate Ga 67

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<th>STAT INCUBATION:</th>
<th>15 minutes at 37°C</th>
<th>1 minute</th>
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<tr>
<td>SENSITIVITY:</td>
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<td>0.3 µM</td>
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<tr>
<td>EXOGENOUS INTERFERENCE:</td>
<td>None</td>
<td>Lyptic Icterous Hemolysis</td>
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<tr>
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<td>7</td>
<td>6</td>
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<tr>
<td>PRICE:</td>
<td>*57½ cents per tube</td>
<td>$1.86 per tube</td>
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¹¹0 CFR, Part 20, Sec. 20.103 and Appendix B, Table 1.

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*In a recent independent survey of 400 nuclear medicine departments.
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Edited by
Vincent J. Sodd, Ph.D.,
David R. Allen, Ph.D.,
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Thallium imaging in acute myocardial infarction

Lewis C. Becker, MD
Associate Professor of Medicine
Director, Nuclear Cardiology
The Johns Hopkins Medical Institutions
Baltimore, Maryland

One of the most significant findings to come from our clinical research over the past several years has been the observation that thallium-201 imaging, performed early after onset of symptoms, can reliably distinguish high-risk and low-risk groups of hemodynamically stable patients with acute myocardial infarction. The value of such a prognostic indicator in the management of acute MI is evident. Patients determined to be at low risk could be ambuluted earlier and perhaps discharged sooner than in current practice; in the future, such patients might be placed early in a progressive-care-type unit rather than be maintained in the more expensive coronary care unit.

Patients at higher risk might be found to require more intensive monitoring for even longer periods than today. And following discharge, these patients could justifiably be subjected to much closer and long-lasting followup. Most important, reliable identification of patients at high risk would permit earlier initiation of aggressive treatment directed at limiting the extent of infarction.

Predicting mortality

Our recently reported study covered 42 consecutive patients determined by conventional means (history, ECG, serum creatine kinase) to have suffered an acute MI. These were Killip class I or II patients—the largest group of MI patients, and those normally considered to be at relatively low risk. All 42 patients were admitted within 12 hours of onset of chest pain, and underwent thallium imaging within 15 hours of onset.

The thallium images—in the anterior, 40° LAO, and 60° LAO views—were interpreted both subjectively and by a computer-assisted quantitative technique. For each interpretive approach, scores for all views were summed to give a total "defect score"—the lower the score, the smaller the area of thallium defect, with a total defect score of 7 corresponding to reduction in thallium uptake involving approximately 40% of the left ventricle in at least two views. The total defect scores were then correlated with the patients' subsequent clinical course and with other clinical indices believed to have prognostic value—previous history of MI, anterior location of MI, alveolar infiltrates on admission, peak CK greater than 1,000 IU/liter, age, and sex.

Of the 42 patients, 35 survived the initial hospitalization. These survivors were followed for 6 to 20 months after discharge.

What were our results? Nonsurvivors had significantly larger thallium defects than survivors. The mean score for nonsurvivors was 14.3 vs 2.3 for survivors. In the 13 patients with a score greater than 7—ie, 40% or more involvement—the inhospital mortality was 46%; at 6 months it was 62%; and at last followup (mean 9 months) it was 92%. In the group of patients with a total defect score less than 7, the inhospital mortality was 3%; at 6 months and at last followup, it was, respectively, 7% and 7%.

These data conclusively showed that the thallium study performed within hours of admission could identify apparently stable MI patients at high-risk for mortality. In addition, when we compared the predictiveness of the thallium score with the other clinical indices—history, MI location, enzymes, etc—singly and in combination, the thallium study was significantly better.

We were, of course, very excited by our results. But, because this was a retrospective study, we felt it important to validate the findings prospectively. Over a 6-month period, we studied more than 90 consecutive patients admitted to the CCU with documented or strongly suspected MI. We applied the same scoring system and same dividing line (score 7)—and confirmed our ability to use thallium imaging to distinguish between high-risk and low-risk groups. The mortality rates of the two groups were almost identical to those established in the earlier retrospective study.
Irreversible damage and reversible ischemia

We believe the thallium study accurately predicts prognosis in MI patients because the size of the defect reflects the total hypoperfused mass of the left ventricular myocardium—both infarcted and ischemic areas. We know from observations of other investigators that the thallium defect tends to diminish with time after an acute MI. Thus the image recorded immediately after admission will show a larger defect than those recorded on serial followup over subsequent days. Our own pathologic studies have demonstrated that large thallium defects seen on post-MI images may be associated with small areas of infarct on postmortem examination.

Together, these findings strongly support the concept that areas of reduced or absent thallium on the initial post-MI images represent both ischemia and infarction, and that the "filling-in" seen on followup imaging represents resolution of ischemia due to resolution of coronary artery spasm or enlargement of coronary collaterals. Thus, the post-MI study identifies myocardium irreversibly damaged by previous infarction, and surrounding areas of severe ischemia that are at risk for necrosis either immediately or at some future time.

Clinical implications

In our patients, the highest percentage of inhospital deaths was due to sudden pump failure—possibly due to the large total volume of compromised myocardium. Postdischarge deaths were generally related to a new ischemic event. In both of these high-risk groups, the thallium study might have helped in patient management decisions. For those patients who died while in the hospital, more aggressive support might have been indicated; those whose deaths occurred posthospitalization might have been identified as candidates for coronary artery bypass.

References


Please see following page for brief summary of prescribing information.
INDICATIONS AND USAGE: Thallous Chloride TI 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction. It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINDICATIONS: None known.

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

Ideally, examinations using radiopharmaceutical drug products — especially those elective in nature — of women of childbearing capability should be performed during the first ten days of menstrual cycle.

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

Thallous Chloride TI 201, as all radioactive materials, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

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

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

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

Safety and effectiveness in children have not been established.

The expiration date for Thallous Chloride TI 201 is six days postcalibration.

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

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

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

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

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

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

How Supplied: Thallous Chloride TI 201 for intravenous administration is supplied as a sterile, non- pyrogenic solution containing at calibration time, 1mCi/ml of Thallous Chloride, 3mg/ml sodium chloride, and 0.5mg/ml of benzyl alcohol. The pH is adjusted to be between 4.5-5.5 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 1.5, 3.0, 4.5, 6.0 and 9.0 millicuries of Thallous Chloride TI 201.

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

Catalog Number NRP-427 May 1980

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*A “wet system” Technetium Tc 99m Generator consists of a shielded column containing Molybdenum Mo 99 and an internal self-contained saline supply.

FOR FULL PRESCRIBING INFORMATION, REFER TO FOLLOWING PAGE.
The Union Carbide TECHNETIUM Tc 99m GENERATOR provides a means of obtaining a sterile, pyrogen-free solution of Sodium Pertechnetate Tc 99m in isotonic saline from elution of the generator containing Molybdenum Mo 99. Hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. Over the life of the generator, an elution will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the generator column.

### Clinical Pharmacology

Following intravenous administration, the pertechnetate ion distributes in the body similarly to the iodide ion, but it is not orgnaized when trapped in the thyroid gland. Sodium Pertechnetate Tc 99m tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It also concentrates in the thyroid gland, stomach, and choroid plexus.

After intravascular administration, it remains in the circulatory system for sufficient time to permit blood pool, organ perfusion, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

### Indications and Usage

Sodium Pertechnetate Tc 99m is used as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; placenta localization; and blood pool imaging including radionuclide angiography.

Sodium Pertechnetate Tc 99m is used in children as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; and blood pool imaging including radionuclide angiography.

### Contraindications

None known.

### Warnings

Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults and, in general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

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

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

### Precautions

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

### Pregnancy Category

C. Animal reproductive studies have not been conducted with Sodium Pertechnetate Tc 99m. It is also not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Pertechnetate Tc 99m should be given to a pregnant woman only if 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.

The generator should not be used after 16 days from the date and time of calibration. At time of administration, the solution should be crystal clear.

### Adverse Reactions

No adverse reactions have been reported with the use of this radiopharmaceutical.

### Dosage and Administration

Sodium Pertechnetate Tc 99m is usually administered by intravascular injection, but can be given orally. The dosage employed varies with each diagnostic procedure.

The suggested intravenous dose range employed for various diagnostic indications are as follows:

**IN AVERAGE ADULT (70kg) PATIENTS:**

- Brain imaging: 10 to 20 millicuries
- Thyroid imaging: 1 to 10 millicuries
- Salivary gland imaging: 1 to 5 millicuries
- Placenta localization: 1 to 3 millicuries
- Blood pool imaging: 10 to 30 millicuries

**IN PEDIATRIC PATIENTS:**

- Brain imaging: 140-280 microcuries/kg body weight. A minimum dose of 3-5 microcuries/kg body weight is recommended if cerebral radionuclide angiography is performed as part of the brain imaging procedure.
- Thyroid imaging: 60-80 microcuries/kg body weight.
- Blood pool imaging: 140-280 microcuries/kg body weight. A minimum dose of 3-5 microcuries/kg body weight should be administered to patients in whom cerebral radionuclide angiography is performed as part of the brain imaging procedure.

**NOTE:** Up to 1 gram of pharmaceutical grade potassium perchlorate is used in children for brain or blood pool imaging. Administration of potassium perchlorate is especially important in newborns and infants to minimize the absorbed radiation dose to the thyroid gland.

The patient's diet should be managed by a suitable radiodiagnostic evaluation system immediately prior to administration.

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever the solution and container permit.

### How Supplied

Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes from 80 microcuries (up to 16,000 millicuries in approximately 820 microcurie increments) of Molybdenum Mo 99 as of noon of the day of calibration. The TECHNETIUM Tc 99m GENERATOR consists of:

1. sterile generator,
2. Sodium Chloride Injection source,
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SECTION

This section in the Journal of Nuclear Medicine contains "Positions Open," "Positions Wanted," "For Sale," and "Equipment Wanted" listings. Non-display "Positions Wanted" ads by members of the Society are billed at 70¢ per word for each insertion with no minimum rate. Non-display "Positions Wanted" ads by nonmembers and all nondisplay "Positions Open," "For Sale" and "Equipment Wanted" ads by members and nonmembers are charged at 90¢ per word. Display advertisements are accepted at $150 for ¼ page, $205 for ½ page, $325 for ¾ page, and $560 for a full page.

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See brief summary on following page.

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TechneScan® PYP®
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BRIEF SUMMARY

CLINICAL PHARMACOLOGY

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

One to two hours after intravenous injection of TechneScan PYP Tc 99m, an estimated 40 to 50 percent of the injected dose has been taken up by the skeleton and approximately 0.01 to 0.02 percent per gram of acutely infarcted myocardium. Within a period of one hour, 10 to 11 percent remains in the vascular system, declining to approximately 2 to 3 percent twenty-four hours post injection. The average urinary excretion was observed to be about 40 percent of the administered dose after 24 hours.

TechneScan PYP also has an affinity for red blood cells. When administered 30 minutes prior to the intravenous administration of sodium pertechnetate Tc-99m approximately 76 percent of the injected activity remains in the blood pool providing excellent images of the cardiac chambers.

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 contusions.

TechneScan PYP is a blood pool imaging agent which may be used for gated cardiac blood pool imaging. When administered intravenously 30 minutes prior to the intravenous administration of sodium pertechnetate Tc-99m approximately 76 percent of the injected activity remains in the blood pool.

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 pertechnetate Tc-99m 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.

ADVERSE REACTIONS

None.

HOW SUPPLIED

Catalog Number—094 TechneScan PYP Technetium Tc-99m Pyrophosphate Kit.

Kit Contains:

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

Reaction Vial Contains:

12.0 mg sodium pyrophosphate and 3.4 mg stannous chloride (lyophilized). Hydrochloric acid is added for pH adjustment prior to lyophilization.

5—Radioassay Information String Tags.
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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 contraction posteriorly and akinesis of the septal aspect of the chamber. Patient was injected IV with 20mCi of 99mTc-labelled Human Serum Albumin. The agent was prepared using the New England Nuclear Electrolysis Kit for labelling HSA. Write or call for a portfolio of Brattle-gated lung, liver and heart studies.

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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.

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