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TECHNETIUM 99m GENERATORS

Technetium Tc 99m Generators for the Production of Sodium Pertechnetate Tc 99m

Featuring:

- Indicated for use in adults and children for urinary bladder imaging (direct isotopic cystography).
- The only Generator with an "open/closed" valve to eliminate possible leakage, both during shipment and in your hot lab.
- Unique horizontal elution procedure increases ease of use and eliminates needle-vial alignment problems.
- A new sterile needle is utilized for each elution, reducing the chances of a septic or pyogenic situation occurring in routine clinical usage. This method is superior to competitive dry column systems where the same needle assembly is used for the life of the product.
- Fission product molybdenum 99 is used in the Technetium 99m Generator to provide Sodium Pertechnetate Tc 99m activity concentrations sufficient for bolus injections.
- Internal saline reservoir eliminates the need to stock saline vials.
- Evacuated elution vials are available in 5cc, 10cc, and 20cc volumes, allowing you to optimize the elution concentration to meet your needs.
- Optimum shielding design minimizes radiation to personnel in work areas, providing maximum protection.
- Generator is compact, providing for optimum maneuverability. Generator handle and shipping carton provide for ease in handling and lifting.

TECHNETIUM Tc 99m GENERATOR for the Production of Sodium Pertechnetate Tc 99m

DESCRIPTION: The Technetium Tc 99m Generator is prepared with fission produced Molybdenum Mo 99 absorbed on alumina in a lead-shielded column and provides a means for obtaining sterile ocean-line solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The eluate should be cloud-free. With a pH of 4.5-7.5, 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.

Each eluate of the generator should not contain more than 0.15 microcurie of the Molybdenum Mo 99 per milliliter Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micrograms of aluminum per milliliter of the generator eluate, both of which must be determined by the user before administration.

INDICATIONS AND USAGE: Sodium Pertechnetate Tc 99m is used IN ADULTS as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; placental localization; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesico-urethral reflux.

Sodium Pertechnetate Tc 99m is used IN CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesico-urethral reflux.

CONTRAINDICATIONS: None known.

WARNINGS: Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults. 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 seriously by all benefit-risk assessments involving children.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards. Ideally, examination by a radiopharmacist, especially those reactive in nature, of a woman’s childbearing capability should be performed during the first few (approximately 10) days following the onset of menstruation.

Nursing Mothers

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

Pediatric Use

See Indications and Usage, dosage and administration. See also description of additional risk under WARNINGS. 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 in your area.

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: Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

HOW SUPPLIED: Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes from 300 millicuries up to 16,000 millicuries (in approximately 830 millicuries increments) of Technetium Mo 99 as of 10:00 P.M. Eastern Time of the day of calibration. The TECHNETIUM Tc 99m GENERATOR consists of 1) sterile generator, 2) Sodium Chloride Injection source, 3) 10 cc sterile evacuated vials, 4) sterile needles, 5) elution vial seal, 6) finished drug labels. Elution vials in 5 cc and 20 cc sizes are available upon request.

Initial order only

The TECHNETIUM Tc 99m GENERATOR should not be used after sixteen (16) days from the date and time of calibration.

Jointly manufactured by:
CINTICHEM, INC.
Tuxedo, N.Y. 10987

and
UNION CARBIDE CORPORATION
Tuxedo, N.Y. 10987

June, 1983

Circle Reader Service No. 1
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Circle Reader Service No. 6
Efficient departmental management is no longer an elective procedure for nuclear medicine. In the cost-conscious environment of today's hospital, administrators are looking more carefully at departmental budgets. At the same time, attending physicians are ordering tests more selectively, basing their decisions both on the diagnostic information they need and the cost-effectiveness of the study.

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This means that you are being asked to become more of a businessman, adding terms like "efficiency" and "productivity" to your medical vocabulary. Now you have to know the real operating costs of your department. What, for example, does it cost to perform a bone scan? Or a thallium study? Are most costs attributable to staff? To equipment? Or to supplies? Can changes in scheduling, inventory or procedure mix reduce these costs?

At NEN/Du Pont we've developed a computer-based program to help you determine and analyze costs. Then, you can use the results to increase productivity in your department. It's called Financial Management Analysis (FMA) and it's available to all our customers.

FMA—A Management Program For You
Here's how it works. Your NEN/Du Pont representative will help you collect such data as costs for personnel, supplies and instrumentation, the number and kind of studies you perform and the time the studies take. Then, this input will be analyzed by the computer to show your costs per study, how your staff is being utilized and what your total costs are for every category, from film processing to maintenance. The program can even compare your figures with those of other departments at similar hospitals throughout the country. Your representative will present your FMA in a written report, and will review it with you to help you increase the efficiency of your department.

Ask your representative about FMA for your department. And about our other programs to help you meet the challenges of nuclear medicine in the '80s. Our goal is Imaging Excellence: enhancing the image of your department while improving the images in your department.

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Circle Reader Service No. 9
TISSUE POLYPEPTIDE ANTIGEN

A VALUABLE TOOL IN CANCER RESEARCH AND TREATMENT

Tissue Polypeptide Antigen (TPA) is a protein related to cytoplasmic intermediate filaments of cells in interior epithelium. Since carcinomas originate in interior epithelium, TPA is therefore present in carcinoma cells. Serum or plasma TPA measurements are useful in monitoring tumour activity; its character as a specific label of interior epithelial cells also makes immunohistochemical staining of TPA an important technique, both for research and in routine therapy.

Two TPA positive cells from a transitional cell carcinoma of urinary bladder epithelium invading a deeper layer of the bladder wall. PAP/haematoxylin staining. Microphotograph by courtesy of Dr P. Oehr, University Clinic, Bonn.

TPA staining of HeLa cell by indirect immunofluorescence. The cellular distribution of TPA corresponds to that of intermediate filaments. Microphotograph by courtesy of Dr V. Björklund, National Bacteriological Laboratories, Stockholm.

TPA products available from Sangtec Medical:
1. Detection in serum and plasma by Radioimmunoassay using Prolifigen® RIA kit.
   For monitoring cancer therapy and to detect tumour recurrence.
2. Detection in tissue by immunohistochemistry using rabbit anti-TPA:B1 antiserum.
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The Standard 10"-12" Mobile Gamma Camera—Obsolescence and Waste.

Until recently, the only way to do bedside nuclear studies was with the so-called "standard" field-of-view (10"-12") mobile camera. For most other studies in the department, a stationary, large field-of-view camera (15"-16") was needed. To do both mobile and stationary studies, two cameras are required. This is wasteful. A solution to this cost ineffective approach is the large field-of-view mobile camera (15¾") Apex 409M, recently introduced by Elscint.

The first gamma cameras were introduced in the 1960's to an enthusiastic marketplace. Equipped with 10"-12" detectors, they were billed as general purpose for the study of many organs, large and small.

But as often occurs with the introduction of new technologies, their many shortcomings soon became evident. Their 10"-12" field-of-view detectors were either too small or too large for most organ imaging. (The notable exception, then and now, was the adult brain.)

Specialized collimators were soon added: diverging for large organ studies (i.e., lungs, lungs with heart, liver and spleen, etc.); and converging for smaller organs. Even at their best, these techniques forced unwealce compromises in spatial resolution and distortion.

Large field-of-view cameras with 15"-16" detectors were introduced a decade later, gradually replacing the so-called "standard" cameras. (Actually the term "standard" field-of-view came into use at that time to distinguish between the larger and smaller sized cameras.)

Today, most Nuclear Medicine Departments use a large field-of-view stationary camera as their versatile, general purpose gamma camera, and large field-of-view mobile gamma cameras should be used for the same reasons: They have more applications, provide more and better information, and act as a backup to the stationary camera.

Nuclear Cardiology—Different Problems, Different Solution

The standard field-of-view is not only too small for most organ studies; it is too large for most cardiology studies. A much better size is the 8" detector available only in the Elscint Apex 200 Series of cameras. It is the ideal size for Nuclear Cardiology... not too large, and not too small. Its useful area is 30% larger than the other "cardiology" Anger type mobile camera that has recently been introduced.

Apex 200 Cameras come with a powerful onboard computer for Multigated, First Pass, Thallium and other studies. They are also ideal for Pediatric Nuclear Medicine.

Summary

Whatever the application, a "standard" field-of-view camera is not the answer. For all-purpose Nuclear Medicine, the answer is the Apex 409M (the "standard" is too small); for Nuclear Cardiology or Pediatrics, the answer is the Apex 200 series (the "standard" is too large).

For more information regarding the all-purpose Apex 409M gamma camera from Elscint, please turn the page.
The Old Standard
for Mobile Gamma Cameras.
250-300mm

Advantage Elscint
The big difference with the Apex 409M is the obvious one, but not the only one. With roughly the same outside dimensions as the “standard” mobile models these cameras offer you much more. Benefits like...
- A built-in computer system, complete with Winchester disk and 512x acquisition matrix for bedside image acquisition, storage, manipulation, and processing.
- High countrate capability of up to 500,000 cps.
- Off-center zoom.
- Perfect linearity ≤ .7mm.
- Tripex uniformity just 2% differential and 3% integral.
- Multigated acquisition and live display as standard features.
- Three forward and three reverse motorized speeds for ease of travel.
All of these, and more, for about the same price as “standard” models.

Cameras shown are approximately half-size.
There are times when a product's benefits are pretty obvious and this is one of those times. The product is called the Apex 409M and you can only get it from Elscint.

Never before could you perform 400mm large field-of-view studies at the patient's bedside, because never before could you buy a mobile large field-of-view gamma camera.

The Outdated Standard of the Sixties, Replaced by Eighties' State-of-the-Art

In the past, the only way to perform bedside studies of organs larger than the brain was by using diverging collimators with a 250-300mm “standard” field-of-view camera: a method riddled with shortcomings. But now, thanks to today’s technology, Elscint has developed a camera so advanced, it offers you both stationary camera performance and mobile camera convenience. No other camera can make this claim.

The Apex 409M from Elscint. The first mobile nuclear camera with a 400mm large field-of-view. It should replace “standard” mobile cameras for good, just as “standard” stationary cameras were replaced years ago by LFOV’s.

Why settle for less? Contact Elscint.

The New Standard for Mobile Gamma Cameras. 400mm
Finally, the First Nuclear Imaging System that Combines Easy Maneuverability and Large Field of View Performance.

Elscint's All-Purpose Apex 409M

The APEX™ 409M is a large field-of-view (400mm) motor-driven mobile camera complete with a powerful on-board computer. It is the ideal system for general Nuclear Medicine studies, combining the advanced features of Elscint's digital gamma camera with the power of sophisticated computer technology. And its easy maneuverability provides bedside imaging and enables camera sharing between several departments.

Other unique features are:
- "On-the-fly" corrections of energy aberrations and spatial distortions, providing excellent image quality in a wide count rate range.
- Digital Guard™—a computerized control of system stability
- High resolution imaging for static studies
- High count rate and high frame rate for First Pass studies
- Up to 64 frames/cycle for multigated studies
- Preset acquisition protocols
- Hardcopy can be generated during acquisition via the x,y,z outputs, or post acquisition from the memory.
- A comprehensive processing package including image processing, histogram processing and various clinical programs for cardiac, lung, kidney and brain studies.

For more information about the APEX 409M and other gamma cameras from Elscint, just fill out and return this coupon.

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The only MAA product indicated for use in isotopic venography

Please see adjacent page for brief summary.

SQUIBB Diagnostics

Volume 26 • Number 1 • January 1985
DESCRIPTION
Macrotec is a sterile, nonpyrogenic, lyophilized preparation of albumin aggregated. Each 5 mL vial of Macrotec contains 5.5 mg of Albumin Aggregated, 10.0 mg Albumin Human, 0.06 mg (minimum) stannous chloride (maximum stannic and stannous chloride 0.16 mg), 1.8 mg of sodium chloride with trace amounts of sodium acetate, acetic acid and hydrochloric acid. Macrotec contains no preservatives. The pH of the reconstituted product is between 3.8 and 8.0.

The aggregated particles are formed by denaturation of Albumin Human in a heating and precipitation process. Each vial contains 13-18 million particles, 90% of which are between 10 and 50 microns in size. The average size is 20 to 40 microns; no particles are greater than 150 microns.

Reconstitution of Macrotec with sterile sodium pertechnetate Tc99m forms an aqueous suspension of Technetium Tc99m Albumin Aggregated for diagnostic use by intravenous injection. No less than 90% of the pertechnetate Tc99m added to the reaction vial is bound to the aggregates at preparation time and remains bound throughout the 6-hour lifetime of the suspension.

INDICATIONS AND USAGE
Lung imaging
Macrotec (Technetium Tc 99m Albumin Aggregated Injection) is a lung imaging agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children. It is useful in the early detection of pulmonary emboli and in the evaluation of the status of the pulmonary circulation in such conditions as pulmonary neoplasm, pulmonary tuberculosis and emphysema.

Isotopic Venography
Macrotec is also indicated for use in isotopic venography as an adjunct in the screening, diagnosis, and management of deep vein thrombosis in the lower extremities.

Combined isotopic venography of the lower extremities and the pulmonary vasculature may be performed.

CONTRAINdications
Technetium Tc 99m Albumin Aggregated Injection should not be administered to patients with severe pulmonary hypertension.

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

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

PRECAUTIONS
General
In patients with right to left heart shunts, additional risk may exist due to the rapid entry of Albumin Aggregated into the systemic circulation. The safety of this agent in such patients has not been established.

Hypersensitivity reactions are possible whenever protein-containing materials such as pertechnetate labeled Albumin Aggregated are used in man. Epinephrine, antihistamines and corticosteroids should be kept available for immediate use.

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

The components of the Macrotec (Technetium Tc 99m Albumin Aggregated Kit) are sterile and non-pyrogenic. It is essential to follow directions carefully and adhere to strict aseptic procedures during preparation.

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are NOT to be administered directly to the patient.

The contents of the kit before preparation are not radioactive. However, after the sodium pertechnetate Tc99m is added, adequate shielding of the final preparation must be maintained.

The technetium Tc 99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate Tc99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc99m Albumin Aggregated Injection should be stored at 2-8°C and discarded 6 hours after formulation.

Technetium Tc99m Albumin Aggregated Injection is a physically unstable suspension and consequently the particles settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactive particles.

If blood is drawn into the syringe, unnecessary delay prior to injection may result in clot formation.

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

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to clinical personnel.

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

Pregnancy Category C
Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc 99m Albumin Aggregated Injection. It is also not known whether Technetium Tc 99m Albumin Aggregated Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc 99m Albumin Aggregated Injection 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 is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use
The lowest possible number of particles should be used in the right-to-left shunting, in neonates and in severe pulmonary disease.

ADVERSE REACTIONS
Although adverse reactions specifically attributable to the Technetium Tc 99m Albumin Aggregated Injection have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

HOW SUPPLIED
Macrotec (Technetium Tc 99m Albumin Aggregated) is supplied as a kit containing 10 reaction vials (5 mL size).
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The Cardiac Phantom design uses rotating ellipsoids to simulate the beating left atrium and ventricle at variable heart beats. A static background, representing the right heart, aorta and general background tissue is situated adjacent to the rotating ellipsoids. By varying the concentration of Tc99m in the ellipsoids, adjusting the rate of rotation (variable pulse rate) and attenuator thickness, a wide variety of controlled patient conditions may be simulated in terms of background level, heart rate (20 to 200 beats per minute), ejection fraction (25%, 50%, 75%) and wall motion (mm displacement from end diastole to end systole). An ECG pulse is generated for each simulated heart beat.

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About The Society

Benefits of Membership

- **The Journal of Nuclear Medicine**: a subscription to the official publication of The Society of Nuclear Medicine and the most prominent journal in the field. Published monthly, it provides the membership with up-to-date information on current developments in nuclear medicine.
- **Annual Meetings**: discounts to scientific, clinical, and continuing education presentations, as well as commercial exhibits, to keep abreast of the latest developments.
- **Membership Directory**: distributed biannually, at no extra cost, to the entire membership.
- **Books and Monographs**: discounts on selected new topics published by the Society.
- **Audiovisuals**: discounts on slide/tape programs covering a wide variety of subjects designed for classroom use and self-instruction.
- **Pamphlets**: on a number of topics including how to present scientific papers and how to prepare scientific exhibits.
- **Awards**: presented to Society members for outstanding achievements and contributions to the field.
- **Continuing Education Credit**: for meeting courses, audiovisuals, and exhibits; approved for AMA Category 1 credit.
- **Research and Fellowship Support**: through SNM Education and Research Foundation.
- **Placement Service at Annual Meeting**: for those members seeking career opportunities in the field.
- **Effective Government Relations**: through committees and lobbying efforts.

Organization

The Society of Nuclear Medicine (SNM) is a multi-disciplinary organization of physicians, physicists, chemists, radiopharmacists, technologists, and others interested in the diagnostic, therapeutic, and investigational use of radiopharmaceuticals. Founded in Seattle, Washington in 1954, it is the largest scientific organization dedicated to nuclear medicine.

Membership Categories

**FULL** members are physicians or scientists with an advanced degree who have valid credentials indicating their professional interest in nuclear medicine.

**ASSOCIATE** members are scientists or technologists with a BA or BS or equivalent qualifications.

**TECHNOLOGIST** members are those who have valid credentials indicating their professional interest in the technology of nuclear medicine.

**AFFILIATE** members are persons who have an active interest in the objectives of the Society and who are not qualified for other categories of membership.

**IN-TRAINING** members are those who present a letter from the director of a training program certifying that they are in training and may be admitted to membership as an in-training Full, Associate, or Technologist member.

See Reader Service Card to request a membership application.

Objectives

- Maintain an organization supported by professionals of varied backgrounds who have a common interest in the clinical and scientific discipline of nuclear medicine;
- hold meetings and seminars to communicate new knowledge acquired and provide continuing medical education;
- advance the highest standards in the practice of nuclear medicine;
- disseminate information by means of journals, books, monographs, and audiovisuals;
- promote and maintain the highest standards of education and research.

Chapters

The Society is composed of individuals who are members of 16 regional chapters throughout the United States and Canada. Those who do not reside within this geographic area are considered to be "Members-at-Large."

SNM Councils

To satisfy the needs of those individual disciplines within nuclear medicine, the Society has established special interest Councils that function autonomously within the Society and are open to all interested Society members: Academic, Computer, Correlative Imaging, Instrumentation, Radioassay, and Radiopharmaceutical Science.

Technologist Section

Membership in the Technologist Section is open to any member of the Society, regardless of category, who can provide evidence of training and/or experience in nuclear medicine technology. Members receive all Section benefits, including a subscription to the Journal of Nuclear Medicine Technology.
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Chromatography of Technetium-99m Radiopharmaceuticals—A Practical Guide

By Philip J. Robbins

To provide up-to-date information about the most accurate procedures for ensuring quality control of radiopharmaceuticals, The Society of Nuclear Medicine presents Chromatography of Technetium-99m Radiopharmaceuticals—A Practical Guide.

This new manual offers readers a collection of miniaturized chromatographic methods for the rapid and precise determination of the radiochemical purity of commonly used Tc-99m radiopharmaceuticals.

Topics covered include the nature and source of impurities, principles and classic techniques of chromatography, methods for counting miniature chromatographic strips, and pitfalls of miniature methods and how to avoid them. Also contained herein is a listing of each radiopharmaceutical with the USP criteria for radiochemical purity, typical scans of impure products, and standards and interlaboratory comparisons for miniaturized systems.

Prepared to aid nuclear medicine personnel in implementing voluntary quality-assurance programs, the material may also be used as a training resource for individuals preparing for professional licensure and certification.

Ordering Information:
Add $2.50 postage and handling for each book ordered. Prepayment required in U.S. funds drawn on U.S. banks only. For payments made in U.S. dollars, but drawn on a foreign bank, add a bank processing fee of $4.50 for Canadian bank drafts or $40.00 for all other foreign bank drafts. Check or purchase order must accompany all orders. Make checks payable to: The Society of Nuclear Medicine. Prices are in U.S. dollars and are subject to change without notice.

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

WARNINGS: The possibility of anaphylactic 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.

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

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Aggregated Albumin and are NOT to be administered directly to the patient.

Technetium Tc 99m Aggregated Albumin, as well as any radioactive drug, 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.

Technetium Tc 99m Aggregated Albumin should be formulated within eight (8) hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Aggregated Albumin affects fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m Aggregated Albumin. It is not known whether Technetium Tc 99m Aggregated Albumin can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m 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 Aggregated Albumin is excreted in human milk during lactation, therefore, formula feedings should be substituted for breast feeding.

Pediatric Use

Safety and effectiveness in children below the age of 18 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 authority 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 Technetium Tc 99m-labeled aggregated albumin are used in man. Epinephrine, antihistamines, and corticosteroid agents should be available for use.

DOSE AND ADMINISTRATION: The recommended intravenous dose range for the average patient (70 kg) is 1 to 4 millicuries. The volume of the dose may vary from 0.2 to 1.8 ml.

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 8 ml with fresh, preservative-free sodium chloride injection (U.S.P.).

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

(See please complete prescribing information.)

HOW SUPPLIED: PULMOLITE® Technetium Tc 99m Aggregated Albumin Kit is supplied in kits of five or thirty vials, sterile and non-pyrogenic, each vial containing in lyophilized form:

Aggregated albumin (human)–1.0 ml
Normal human serum albumin–1.0 ml
Sodium chloride–10 mg
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Each vial contains 3.6-6.5 x 10^11 aggregated albumin particles.

Before reconstitution, store at room temperature 10°–30°C.

PULMOLITE contains no preservative; after reconstitution, the shielded vial should be stored at 2° to 8°C.

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The components of the Technetium Tc 99m Aggregated Albumin 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.

Technetium Tc 99m Aggregated Albumin is prepared by adding 2-8 ml of oxidant-free sodium pertechnetate Tc 99m solution to the vial and swirling for about one minute. Shaking should be utilized when preparing the Technetium Tc 99m Aggregated Albumin.

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Thallous Chloride Ti 201
For complete prescribing information consult package insert, a brief summary of which follows:

DESCRIPTION: Thallous Chloride Ti 201 is supplied in isotonic solution as a sterile, nonpyrogenic diagnostic radiopharmaceutical for intravenous administration. Each unit dose contains 1 milliliter and each milliliter contains 2 milliliters of Thallous Chloride Ti 201 at calibration time, pH adjusted to 5.0–6.0 with hydrochloric acid and/or sodium hydroxide. Contains no bacteriostatic preservative. Thallium Ti 201 is cyclotron produced and is essentially carrier-free. Radiouclide purity at calibration time is at least 98.0% with less than 1.0% Thallium Ti 200, 1.0% Thallium 202 and 0.2% Lead Pb 203. The concentration of each radionuclide contaminant changes with time.

INDICATION AND USAGE: Thallous Chloride Ti 201 may be used in cardiac imaging to define the extent 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: 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 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.

PRECAUTIONS

General
Do not use after the expiration time and date (4 days after calibration time) stated on the label.
Discard vial after single use. Do not use if contents are turbid.
The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Ideally, examinations using radiopharmaceuticals, especially those elective in nature on a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Thallous Chloride Ti 201 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 patient consistent with proper patient management.

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or whether Thallous Chloride Ti 201 affects fertility in males or females.

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Animal reproduction studies have not been conducted with Thallous Chloride Ti 201. It is also not known whether Thallous Chloride Ti 201 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thallous Chloride Ti 201 should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Thallous Chloride Ti 201 is administered to a nursing woman.

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

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

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