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

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

DESCRIPTION: The Technetium Tc 99m Generator is prepared with fissile produced Molybdenum Mo 99 absorbed on alumina in a lead shielded column and provides a means for obtaining sterile pyrogen free solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The eluate should be crystal clear. 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, the elution will contain a yield of 89% 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 microcuries of the Molybdenum Mo 99 per milliliter. Technetium Tc 99m per milliliter dosed at the time of administration, and not more than 10 micrograms of aluminum per millilitre of the generator eluate, both of which must be determined by the user before administration.

Since the eluate does not contain an antimicrobial agent, it should not be used after twelve hours from the time of generator elution.

INDICATIONS AND USES: Sodium Pertechnetate Tc 99m is used in ADULTS as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; sublingual gland imaging; placenta 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 the 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 firmly into account in all benefit-risk assessments involving children.

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

Since the eluate does not contain an antimicrobial agent, it should not be used after twelve hours from the time of generator elution.

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, examinations using radiopharmaceuticals, especially those effective 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, and therefore formula feedings should be substituted for breast feedings.

Pediatric Use

See INDICATIONS AND USE, 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.

The generator should not be used after 16 days from the date of manufacture or 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 630 millcuries up to 16,000 millcuries (in approximately 830 millcurie increments) of Molybdenum 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 shield* 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.

For multiple use, the eluate should be used within 12 hours of the generator elution time. If the eluate is used to reconstitute a kit, the radiolabeled kit should not be used after 12 hours from the time of generator elution or 6 hours after reconstitution of the kit, whichever is earlier.

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Imaging techniques currently used to evaluate myocardial infarction (MI) have a major drawback: They do not permit differentiation between myocardial necrosis and ischemia in the early hours following infarction. Thallium-201, for example, concentrates only in normal myocardial cells. The bone scanning agent technetium-99m pyrophosphate is taken up by necrotic, as well as by some reversibly damaged cells, and also by overlapping ribs.

These agents are of limited use for differentiating between irreversible necrosis and severe ischemia. Yet the ability to make that distinction—and make it quickly—could significantly improve management of cardiac patients.

Myoscint™, an imaging agent based on a monoclonal antibody specific to cardiac myosin, may fill this void in cardiac imaging technology. Because this MAb binds solely to the intracellular myosin that is exposed on cell death, Myoscint concentrates only in necrotic cells. It therefore permits precise localization of unsalvageable tissue.

**Improved MI diagnosis may result**

Myoscint (antimyosin) may permit MI detection and localization in situations that may otherwise be difficult to interpret.

A recent study demonstrates the potential utility of Myoscint imaging. A 73-year-old female patient with unstable angina pectoris underwent coronary angiography which revealed an 80% diameter stenosis of the left anterior descending coronary artery and a 35% lesion of the left circumflex coronary artery. Because of continued symptoms, percutaneous transluminal coronary angioplasty (PTCA) was performed and resulted in successful revascularization. Twenty-four hours later, she developed severe chest pain and electrocardiographic changes consistent with an acute myocardial infarction. The subsequent clinical course was uncomplicated, and the creatine kinase level peaked at 840 IU, with a positive MB fraction.

Indium-111 labeled Myoscint was injected without incident approximately 48 hours after onset of chest pain. Serial images were obtained thereafter at 17 and 41 hours post antimyosin injection. Initial planar imaging (shown in the accompanying figure in the vertical long axis orientation) was performed several days later and demonstrated a moderate-sized perfusion defect, corresponding in location to the area of necrosis on the indium-111 Myoscint image. Pre-discharge left ventricular ejection fraction obtained by radionuclide angiography was 38%.

This patient example demonstrates the ability of indium-111 labeled Myoscint to document and localize myocardial necrosis in a patient with unstable ischemic heart disease. The Myoscint study clearly documented an extensive area of irreversible damage and helped differentiate scar from transient myocardial ischemia.

**Ongoing Myoscint research**

Myoscint is being evaluated extensively in conjunction with traditional imaging techniques, including early thallium-201 imaging, contrast ventriculography, and gated radionuclide angiography (wall motion studies). This research continues to verify Myoscint's efficacy for identifying zones of acute myocardial necrosis.

**Available for investigational use**

Myoscint is now available for investigational use only. If you would like more information on this product, or other biotechnological products under development at Centocor, please call us, toll free.

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ACADEMIC POSITION, either as an instructor or assistant professor, is available starting July 1, 1986. Experience in teaching, research and patient care is desirable for the position. Please send CV to: C. Park, MD, Director, Nuclear Medicine, Thomas Jefferson University Hospital, 11th & Walnut St., Philadelphia, PA 19107. TJUH is an Equal Opportunity/Affirmative Action Employer.

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Enquiries, along with a curriculum vitae and the names of three referees, should be forwarded to:

Dr. G. B. Adams
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