TechneLite®
Technetium Tc 99m Generator

www.technelite.com

LANTHEUS' LOW-ENRICHED URANIUM (LEU) TechneLite® GENERATOR

Lantheus Medical Imaging is a global leader in developing, manufacturing, selling and distributing innovative diagnostic imaging agents. Lantheus provides a broad portfolio of products, which are primarily used for the diagnosis of cardiovascular diseases.

Clinicians use our imaging agents and products across a range of imaging modalities, including nuclear imaging, echocardiography and magnetic resonance imaging (MRI).

Our expertise in discovering, developing and commercializing innovative medical imaging agents provides a strong platform to bring forward breakthrough tools for the diagnosis and management of disease.

Lantheus has more than 500 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia.

For more information, visit www.lantheus.com

INNOVATIVE LEU TechneLite® GENERATOR MEETS CMS CRITERIA FOR NON-HEU TC-99M ADD-ON PAYMENT

LEU TechneLite® (Technetium Tc-99m Generator) is a technetium-99m (Tc-99m) generator that provides the essential medical isotope used by hospitals and radiopharmacies to radiolabel a variety of radiopharmaceuticals requiring Tc-99m, which are used in critical diagnostic imaging tests. Lantheus received FDA approval for the commercial use of LEU in 2010 and has used a blend of Highly Enriched Uranium (HEU) and LEU molybdenum-99 (Mo-99) in its TechneLite® generators in the U.S. market since 2011. In January 2013, LEU TechneLite® became the first Tc-99m generator in the United States that contains at least 95 percent non-HEU-sourced Mo-99 that meets the Centers for Medicare and Medicaid Services criteria for the incremental add-on Hospital Outpatient Prospective Payment System (HOPPS) payment. With greater access to LEU Mo-99 through its supply chain diversification strategy, Lantheus can now move closer to its goal of eventually eliminating HEU-sourced Mo-99 from its supply chain.

WHY THE LEU TechneLite® GENERATOR?

Aligns with U.S. Government's Global Nuclear Safety Mandate to Eliminate Use of HEU in Medical Isotope Production

With the introduction of our LEU TechneLite® generator for use in connection with nuclear imaging procedures, Lantheus fully supports the United States government's global nuclear security strategy to encourage reliable supplies of medical radioisotopes produced from non-HEU sources. On January 2, 2013, President Obama signed into law the American Medical Isotopes Production Act of 2011 (AMIPA) as part of the 2013 National Defense Authorization Act. The AMIPA encourages the domestic production of LEU Mo-99 and provides for the eventual prohibition of the export of HEU from the United States.

The company's LEU and HEU-produced TechneLite® generators are equivalent in performance and use as recognized by FDA approval of LEU-produced Mo-99 generators. The only difference between the LEU TechneLite® generator and the standard TechneLite® generator is that LEU TechneLite® is produced using Mo-99 sourced from at least 95 percent LEU instead of HEU.

Meets Centers for Medicare and Medicaid Services (CMS) Reimbursement Guidelines

CMS stipulated in the Medicare payment rules, for Medicare Hospital Outpatients, that CMS will provide an incremental add-on payment for every Tc-99m diagnostic dose produced from non-HEU-sourced Mo-99, such as LEU. Lantheus' LEU TechneLite® generator satisfies the CMS add-on payment requirements.

Leverages Strong Heritage of Manufacturing Excellence and Focus on Customer Service

The LEU TechneLite® generator has its own product item number as well as a visual identifier on the generator can cover, which indicates that it is an LEU TechneLite® generator. In order to meet customer needs, the LEU TechneLite® generator has a dedicated manufacturing run.

Demonstrates Lantheus' Ongoing Commitment to Ensuring Reliable Access to Technetium-99m

As a leader in the radiopharmaceutical business, Lantheus has developed a world class, globally diversified and balanced Mo-99 supply chain for the procurement of Mo-99. The company receives Mo-99 from four of the five major processors and seven of the eight associated reactors. As the industry moves toward LEU-based Mo-99 supply, Lantheus' introduction of the LEU TechneLite® generator and gradual conversion to 100 percent LEU-derived Mo-99 ensures that our customers will have access to Tc-99m, now and in the future.

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HEU VS. LEU TechneLite®: FACT VS. FICTION

MYTH: LEU-sourced Mo-99 is not equivalent to HEU-sourced Mo-99.

FACT: LEU and HEU-sourced Mo-99 are equivalent in performance and use as recognized by FDA approval of LEU-produced Mo-99 generators. Lantheus' TechneLite® generators, using a blend of HEU and LEU, were approved by the FDA for commercial use in 2010 and have been routinely used in the U.S. market since 2011. The only difference between the LEU TechneLite® generator and the standard TechneLite® generator is that LEU TechneLite® is produced using Mo-99 sourced from at least 95 percent LEU instead of HEU. Lantheus receives LEU-sourced Mo-99 from NTP Radioisotopes and the Australian Nuclear Science and Technology Organization (ANSTO).

MYTH: LEU generators are not the same as HEU generators.

FACT: Lantheus' LEU and HEU generators are equivalent in terms of both elution process and performance. LEU and HEU generators use the exact same isotope – Mo-99 – and the package inserts for both are identical.

MYTH: Radiopharmacies will have to report to the U.S. government how much LEU vs. HEU was used when providing Tc-99m based unit doses.

FACT: There is currently no requirement for a radiopharmacy to report LEU and HEU usage to the U.S. government. When a hospital files for the recently implemented incremental HOPPS add-on payment, it needs to show that it has met the conditions of the new service definition, as it does for any billed service. To facilitate ease of identification in a radiopharmacy, each LEU generator has a unique product number and a visual identifier on the generator can cover. Additionally, Lantheus provides customers with an LEU TechneLite® generator certification document.

MYTH: Switching to LEU will have a negative effect on the Mo-99 supply chain and will exacerbate global shortages.

FACT: The U.S. government and the international community are committed to minimizing — and eventually eliminating — the use of HEU from all civil nuclear applications, at the same time preserving patient access to valuable medical procedures using medical isotopes. Historically, medical isotope production has been a significant consumer of HEU. The U.S. government has been working with reactors and governments outside of the U.S. to encourage the conversion of Mo-99 production from using HEU to LEU. In addition, the U.S. government is currently providing funding for domestic projects that plan to produce Mo-99 using non-HEU based technologies.

MYTH: There is not enough LEU capacity to meet the needs of the Medicare HOPPS population.

FACT: Under a five-year agreement through 2017, Lantheus will receive an increasing supply of LEU-sourced Mo-99 from NTP and ANSTO. Lantheus plans to increase its use of LEU-sourced Mo-99 with a goal of eventually eliminating HEU-sourced Mo-99 from its supply chain. Lantheus believes that it is well-positioned to meet the LEU dose volume needs of the Medicare HOPPS population.

PLEASE SEE BELOW FOR MORE INFORMATION

TechneLite® (Technetium Tc99m Generator)

INDICATIONS AND USAGE:

The TechneLite® generator is a source of sodium pertechnetate Tc-99m for use in the preparation of FDA-approved diagnostic radiopharmaceuticals, as described in the labeling of these diagnostic radiopharmaceutical kits.

Sodium Pertechnetate Tc-99m Injection is used IN ADULTS as an agent for:
- Thyroid Imaging
- Salivary Gland Imaging
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.
- Nasolacrimal Drainage System Imaging

Sodium Pertechnetate Tc-99m Injection is used IN CHILDREN as an agent for:
- Thyroid Imaging
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.

CONTRAINDICATIONS: None known.

Important Safety Information:
Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc-99m Injection.

WARNINGS:

Radiation risks associated with the use of Sodium Pertechnetate Tc-99m Injection 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. Long-term cumulative radiation exposure may be associated with an increased risk of cancer.

PRECAUTIONS:

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of TechneLite®, Technetium Tc-99m Generator, elution. After the termination of the nasolacrimal imaging procedure, blowing the nose and washing the eyes with sterile distilled water or an isotonic sodium chloride solution will further minimize the radiation dose. As in the use of any radioactive material, care should be taken to minimize radiation exposure to patients and occupational workers. Radiopharmaceuticals should be used only by physicians who are qualified by training and experience and who are licensed in the safe handling of radionuclides.

Please see accompanying full Prescribing Information (also available at www.technelite.com)

Lantheus Medical Imaging®

Brands you know. Quality you trust.

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TechneLite®
Technetium Tc 99m Generator

FOR DIAGNOSTIC USE

DESCRIPTION: Sodium Pertechnetate Tc 99m Injection, as eluted according to the elution instructions with Lantheus Medical Imaging, Inc. TECHNELITE®, Technetium Tc 99m Generator, is in Sodium Chloride 0.9% as a sterile, non-pyrogenic, diagnostic radiopharmaceutical suitable for intravenous injection and direct instillation. The pH is 4.5-7.5. The eluate should be clear, colorless, and free from visible foreign material. Each eluate of the TECHNELITE®, Technetium Tc 99m Generator should not contain more than 0.0056MBq (0.15 microcuries) of Molybdenum Mo99 per 37MBq (1 millicurie) of Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micrograms of aluminum per milliliter of the Technetium Tc 99m 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 later than one (1) working day after the elution (12 hours).

Lantheus Medical Imaging, Inc. TECHNELITE®, Technetium Tc 99m Generator consists of a column containing fission produced Molybdenum Mo99 adsorbed on alumina. The terminally sterilized and sealed column is enclosed in a lead shield; the shield and other components are sealed in a cylindrical plastic container with an attached handle. Built into the top surface are two recessed wells marked SALINE CHARGE and COLLECT. Needles protruding from these two wells accommodate supplied sterile eluant charge vials and sterile eluate collection vials. The eluting solvent consists of Sodium Chloride 0.9%, prepacked into septum-sealed vials.

The eluate collection vial is evacuated, sterile and non-pyrogenic. A sterile 0.22 micrometer bacteriological filter is incorporated between the column outlet and the collection vials. During and subsequent to elution, the eluate collection vial should be kept in a radiation shield. The Generator is shipped with a silicone needle seal over the charge needle and a vented needle cover over the collect needle. A sterile vial containing bacteriostat is supplied for the customer to aseptically reseal the collect needle after each elution.

PHYSICAL CHARACTERISTICS

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data – Technetium Tc 99m

Radiation	Mean %/Disintegration	Mean Energy (keV)
Gamma-2	89.07	140.5

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 5.4 micro-coulombs/Kg-MBq-hr (0.795 R/mCi-hr) at 1cm. The first half-value thickness is 0.023 cm of lead (Pb). To facilitate control of radiation exposure from millicurie amounts of Technetium Tc 99m, for example, the use of a 0.27 cm thick standard radiation elution lead shield will attenuate the radiation emitted by a factor of about 1000. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of lead is shown in Table 2.

NOTE: Because the generator is well contained and essentially dry, there is little likelihood of contamination due to damage in transit.

Table 2. Radiation Attenuation of Technetium Tc 99m by Lead Shielding

Shield Thickness lead (Pb) cm	Coefficient of Attenuation
0.023	0.5
0.09	10^{-1}
0.18	10^{-2}
0.27	10^{-3}
0.33	10^{-4}

Molybdenum Mo99 decays to Technetium Tc 99m with a Molybdenum Mo99 half-life of 66 hours. This means that only 78% of the activity remains after 24 hours; 60% remains after 48 hours, etc. (see Table 3). All units have a minimum of 38 mm, 1.5 inches. (~ 6 half-value layers) of lead surrounding the activity. (See Table 3.)

Table 3. Molybdenum Mo99 Decay Chart Half-Life 66.0 Hours

Days	Percent Remaining	Days	Percent Remaining
0	100	10	8
1	78	11	6
2	60	12	5
3	47	13	4
4	37	14	3
5	28	15	2
6	22	20	0.6
7	17	25	0.2
8	13	30	0.05
9	10		

The physical decay characteristics of Molybdenum Mo99 are such that approximately 88% of the decaying Molybdenum Mo99 atoms form Technetium Tc99m. Since the Molybdenum Mo99 is constantly decaying to fresh Technetium Tc99m, it is possible to elute the generator at any time. However, the total amount of Technetium Tc99m available will depend on the time interval from the previous elution, the quantity of Molydenum Mo99 remaining and the effciency of the elution. Approximately 47% of maximum Technetium Tc 99m is reached after 6 hours and 95% after 23 hours.

The elution vial shield has a wall thickness of 7.9 mm, 0.31 inches, and reduces transmitted Technetium Tc 99m radiation essentially to zero. To correct for physical decay of Tc 99m, the fractions that remain at selected intervals of time are shown in Table 4.

Table 4. Physical Decay Chart: Technetium Tc 99m Half-Life 6 Hours

Hours	Percent Remaining	Hours	Percent Remaining
0*	100.0	9	35
1	89	10	32
2	79	11	28
3	71	12	25
4	63	14	20
5	56	16	16
6	50	18	13
7	45	24	6
8	40		

*Calibration Time

CLINICAL PHARMACOLOGY: The pertechnetate ion distributes in the body similarly to the iodide ion but is not organified when trapped in the thyroid gland. It also concentrates in the choroid plexus, thyroid gland, salivary glands, and stomach. However, in contrast to the iodide ion, the pertechnetate ion is released unchanged from the thyroid gland.

After intravascular administration the pertechnetate ion gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

Following the administration of Sodium Pertechnetate Tc 99m Injection as an eye drop, the drug mixes with tears within the conjunctival space. Within seconds to minutes it leaves the conjunctival space and escapes into the inferior meatus of the nose through the nasolacrimal drainage system. During this process the pertechnetate ion passes through the canaliculi, the lacrimal sac and the nasolacrimal duct. In the event of any anatomical or functional blockage of the drainage system there will be a backflow resulting in tearing (epiphora). Thus the pertechnetate escapes the conjunctival space in the tears.

While the major part of the pertechnetate escapes within a few minutes of normal drainage and tearing, it has been documented that there is some degree of transconjunctival absorption with a fractional turnover rate of 0.015/min in normal individuals, 0.021/min in patients without any sac and 0.027/min in patients with inflamed conjunctiva due to chronic dacryocystitis. Individual values may vary but these rates are probably representative and indicate that the maximum possible pertechnetate absorbed will remain below one thousandth of that used in other routine diagnostic procedures.

INDICATIONS AND USAGE:

The Technelite generator is a source of sodium pertechnetate Tc 99m for use in the preparation of FDA-approved diagnostic radiopharmaceuticals, as described in the labeling of these diagnostic radiopharmaceutical kits.

Sodium Pertechnetate Tc 99m Injection is used IN ADULTS as an agent for:
- Thyroid Imaging
- Salivary Gland Imaging
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux
- Nasolacrimal Drainage System Imaging

Sodium Pertechnetate Tc 99m Injection is used IN CHILDREN as an agent for:
- Thyroid Imaging
- Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux

CONTRAINDICATIONS: None known.

WARNINGS: Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection 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.

Long-term cumulative radiation exposure may be associated with an increased risk of cancer.

PRECAUTIONS:

General

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 ensure minimum radiation exposure to occupational workers.

Since the eluate does not contain an antimicrobial agent, it should not be used after 12 hours from the time of TECHNELITE®, Technetium Tc 99m Generator elution.

After the termination of the nasolacrimal imaging procedure, blowing the nose and washing the eyes with sterile distilled water or an isotonic sodium chloride solution will further minimize the radiation dose.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe 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 animal studies have been performed to evaluate carcinogenic potential or whether Sodium Pertechnetate Tc 99m affects fertility in males or females.

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 reproduction capacity. Sodium Pertechnetate Tc 99m 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

Sodium Pertechnetate Tc 99m is excreted in human milk during lactation; therefore formula feedings should be substituted for breast feeding.

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

Pediatric Use

See INDICATIONS and DOSAGE AND ADMINISTRATION sections. Also see the description of additional risks under WARNINGS.

Geriatric Use

Clinical studies of Technelite® did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

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

DOSAGE AND ADMINISTRATION: Sodium Pertechnetate Tc 99m Injection is usually administered by intravascular injection. For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc 99m Injection is administered by direct instillation aseptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 200 mL of sterile saline directly into the bladder. The dosage employed varies with each diagnostic procedure. When imaging the nasolacrimal drainage system, instill the Sodium Pertechnetate Tc 99m Injection by the use of a device such as a micropipette or similar method which will ensure the accuracy of the dose.

The suggested dose range employed for various diagnostic indications in the average ADULT PATIENT (70kg) is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Thyroid Gland Imaging	37 to 370MBq (1 to 10mCi)
Salivary Gland Imaging	37 to 185MBq (1 to 5mCi)
Nasolacrimal Drainage System	Maximum 3.7MBq (100µCi)

The recommended dosage range in PEDIATRIC PATIENTS is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Thyroid Gland Imaging	2.22 to 2.96MBq (60 to 80µCi)/kg body weight

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. The solution to be administered as the patient dose should be clear and contain no particulate matter. Do not use an eluate of the TECHNELITE®, Technetium Tc 99m Generator later than one (1) working day after elution (12 hours).

RADIATION DOSIMETRY

The estimated absorbed radiation doses to an average ADULT and Pediatric patient from an intravenous injection of a maximum dose of 1110MBq (30 millicuries) of Sodium Pertechnetate Tc 99m Injection distributed uniformly in the total body are shown in Tables 5 and 6.

Table 5. Adult Absorbed Radiation Doses (mGy) from Intravenous Injection

Organ	Absorbed Radiation Dose (mGy) for a 1110 MBq (30mCi) dose
Adrenals	4.1
Urinary Bladder Wall	20
Bone Surfaces	6.2
Brain	2.2
Breasts	2

Gallbladder Wall	8.3
Stomach Wall	29
Small Intestines	18
ULI Wall	63
LLI Wall	23
Heart Wall	3.5
Kidneys	6
Liver	4.7
Lungs	2.9
Muscle	3.6
Ovaries	11
Pancreas	6.3
Red Marrow	4.1
Skin	2
Spleen	4.8
Testes	3.1
Thymus	2.7
Thyroid	24
Uterus	9
Remaining Tissues	3.9
Effective Dose (mSv)	14

To obtain radiation absorbed dose in rads (30 mCi dose) from the above table, divide individual organ values by a factor of 10 (does not apply for effective dose).

Table 6. Pediatric Absorbed Radiation Doses (mGy) from Intravenous Injection

Age	**15 years**	**10 years**	**5 years**	**1 year**
Administered activity in MBq (mCi)	**1110 (30)**	**740 (20)**	**555 (15)**	**370 (10)**
Organ				
Adrenals	5.3	5.4	6.2	7.1
Urinary Bladder Wall	26	22	18	22
Bone Surfaces	7.6	7.5	8.1	10
Brain	2.8	3.1	3.7	4.5
Breasts	2.6	2.6	3.2	4.1
Gallbladder Wall	11	12	13	13
Stomach Wall	38	36	43	59
Small Intestine	22	23	26	30
ULI Wall	81	89	110	140
LLI Wall	31	33	40	48
Heart Wall	4.5	4.6	5.2	6.4
Kidneys	7.2	6.9	7.8	8.5
Liver	6	6.7	8	9.1
Lungs	3.8	3.8	4.4	5.3
Muscle	4.5	4.5	5	6
Ovaries	14	13	14	17
Pancreas	8.1	8.2	8.9	10
Red Marrow	5.1	5	5.2	6
Skin	2.5	2.6	3.2	3.8
Spleen	6	6	6.7	7.8
Testes	4.1	4.3	4.9	6
Thymus	3.6	3.5	4.2	5.3
Thyroid	40	41	67	81
Uterus	11	11	12	14
Remaining Tissues	4.8	4.8	5.4	6.4
Effective Dose (mSv)	19	19	23	29

To obtain radiation absorbed dose in rads (30 mCi dose) from the above table, divide individual organ values by a factor of 10 (does not apply for effective dose).

The estimated absorbed radiation doses to an average ADULT from the instillation of Sodium Pertechnetate Tc 99m Injection for imaging the nasolacrimal drainage system are shown in Table 7.

Table 7. Absorbed Radiation Dose from Dacryoscintigraphy Using Sodium Pertechnetate Tc 99m

	Absorbed Dose	
Target Organ	mGy/ 3.7MBq	(rad/ 100µCi)
Eye Lens:		
If lacrimal fluid turnover is 16%/min	0.140	0.014
If lacrimal fluid turnover is 100%/min	0.022	0.002
If drainage system is blocked	4.020	0.402
Total Body*	0.011	0.001
Ovaries*	0.030	0.003
Testes*	0.009	0.001
Thyroid*	0.130	0.013

*Assuming no blockage of drainage system.

In pediatric patients, an average 30 minute exposure to 37MBq (1 millicurie) of Sodium Pertechnetate Tc 99m Injection following instillation for direct cystography, results in an estimated absorbed radiation dose shown in Table 8.

Table 8. Pediatric Absorbed Radiation Dose from Cystography

Age	**Bladder wall dose, mGy (rad)**	**Gonadal dose, mGy (rad)**
1 year	3.6 (0.36)	0.15 (0.015)
5 years	2.0 (0.2)	0.095 (0.0095)
10 years	1.3 (0.13)	0.066 (0.0066)
15 years	0.92 (0.092)	0.046 (0.0046)

HOW SUPPLIED: Lantheus Medical Imaging TECHNELITE®, Technetium Tc 99m Generator is available in the following quantities of radioactivity of Mo99 on the calibration date (date of manufacture) as specified on the product lot identification label affixed to the generator:

Table 9. Available Quantities of Radioactivity

High Enriched Uranium (HEU)			**Low Enriched Uranium (LEU)**		
NDC #	GBq of Mo99	Ci of Mo99	NDC #	GBq of Mo99	Ci of Mo99
11994-090-36	37.0	1	11994-091-36	37.0	1
11994-090-73	74.0	2	11994-091-73	74.0	2
11994-090-92	92.5	2.5	11994-091-92	92.5	2.5
11994-090-01	111.0	3	11994-091-01	111.0	3
11994-090-03	148.0	4	11994-091-03	148.0	4
11994-090-04	166.5	4.5	11994-091-04	166.5	4.5
11994-090-05	185.0	5	11994-091-05	185.0	5
11994-090-06	222.0	6	11994-091-06	222.0	6
11994-090-07	277.5	7.5	11994-091-07	277.5	7.5
11994-090-09	370.0	10	11994-091-09	370.0	10
11994-090-10	462.5	12.5	11994-091-10	462.5	12.5
11994-090-11	555.0	15	11994-091-11	555.0	15
11994-090-12	666.0	18	11994-091-12	666.0	18
11994-090-13	740.0	20	11994-091-13	740.0	20

Each generator is supplied with the following standard components:

1 Collect Needle Seal Vial
6 Eluant Charge Vials (may be supplied separately)
6 Eluate Collection Vials (may be supplied separately)
1 Package Insert
6 Radiation Labels (Collection Vial)
6 Radiation Labels (Eluting Shield)

First order generators are shipped with the following accessory components:

2 Eluting Shields

Extra quantities of these components may be obtained at the customer's request.

STORAGE: Controlled room temperature 20° to 25°C (68° to 77°F) [See USP].

EXPIRATION: The expiration time of the Sodium Pertechnetate Tc 99m solution is not later than 12 hours after elution. If the eluate is to be used to reconstitute a kit for the preparation of a Technetium Tc 99m radiopharmaceutical, the kit should not be used after 12 hours from time of Generator elution or after the expiration time stated on the labeling for the prepared drug, whichever is earlier.

The generator should not be used after the expiration date stated on the label.

ELUTION INSTRUCTIONS – TOTAL ELUTION METHOD

1. Waterproof gloves should be worn during elution.
2. Remove dust (clear plastic) cover of generator.
3. Perform all subsequent operations aseptically.
4. Remove silicone needle seal from eluant charge well. **Discard as radioactive waste.**
5. Remove flip-off seal and swab septum of eluant charge vial with a bactericide (such as 70% isopropyl alcohol), allow to dry, and insert the vial into charge well. Vial should be firmly inserted to assure puncture of septum. Caution: Excessive use of bactericides containing alcohol may adversely affect Technetium Tc99m yield.
6. Open elution shield base and insert an eluate collection vial from which the flip-off seal has been removed. Screw base back on securely. Swab the exposed vial septum with a bactericide and allow to dry.
7. Remove vented needle cover from collect well. **Discard as radioactive waste.**
8. Insert shielded eluate collection vial in collect well. Elution should commence within 30 seconds and can be visually checked by the appearance of bubbles in the eluant charge vial.*****NOTE:* If bubbles do not appear in the eluant charge vial within 30 seconds, either one of the vials has not been properly placed on its needle or the eluate vial has no vacuum. Remove the eluate collection vial to prevent vacuum loss; then remove and reinsert the charge vial. Reinsert the eluate collection vial and if elution does not commence, use a second shielded collection vial. **Caution: Tampering with the internal components could compromise sterility and present a radiation hazard. This generator should not be dismantled.**
9. To assure proper yield and functioning, elution must proceed to completion as evidenced by emptying of the charge vial. Allow generator to elute for at least 3 minutes after the charge has been drained, or for a total of 6 minutes.
10. After elution has been completed, remove shield containing the collection vial. Obtain the collect needle seal vial, and using a bactericide, swab the septum of the collect needle seal vial and insert over the collect needle. The eluant vial is sterile and should stay in place until the next elution, functioning as a seal for the needles within the charge well. **Upon initiating the next elution, discard the empty eluant vial as radioactive waste.**
11. Fill out and attach the appropriate supplied pressure sensitive radioactivity labels to the elution shield containing the filled eluate collection vial. Do not use an eluate of the Technetium Tc 99m Generator later than 1 working day after the time of elution (12 hours).
12. Use a shielded syringe when introducing the Sodium Pertechnetate Tc 99m solution into mixing vials.
13. Maintain adequate shielding during the life of the radioactive preparation by using a lead vial shield and cover, and use a shielded syringe for withdrawing and injecting the preparation.

ASSAY INSTRUCTIONS FOR THE TECHNELITE®, TECHNETIUM Tc 99m GENERATOR ELUATE

The TECHNELITE®, Technetium Tc 99m Generator Eluate may be assayed using an ionization chamber dose calibrator. The manufacturer's instructions for operation of the dose calibrator should be followed for measurement of Technetium Tc 99m and Molybdenum Mo99 activity in the generator eluate. The Molybdenum 99/Technetium 99m ratio should be determined at the time of elution prior to administration, and from that ratio, the expiration time (up to 12 hours) of the eluate mathematically determined. Each eluate should meet or exceed the purity requirements of the current United States Pharmacopeia; that is, not more than 0.0056MBq (0.15 microcurie) of Molybdenum 99 per 37MBq (1 millicurie) of Technetium 99m per administered dose at the time of administration.

RADIOMETRIC MOLYBDENUM TEST PROCEDURE

This method is based on the fact that most Technetium Tc 99m radiation can be readily shielded and only the more energetic gamma rays from Molybdenum Mo99 (739KeV and 778KeV) are counted in the 550-850KeV energy range. The entire eluate may be assayed for Molybdenum Mo99 activity as follows:

1. A Cesium Cs 137 reference source which has the same geometry as the generator eluate must be used to standardize the well counter.
2. Determine the background after setting the window to the 550-850KeV energy range.
3. Count the Technetium Tc 99m eluate in its lead shield (thereby shielding out Technetium Tc 99m) by placing over the well or probe.
4. Count the Cs 137 reference source in the same shield geometry for the same time period.
5. Compute Molybdenum Mo99 activity in the eluate as follows:

$$\frac{\text{µCi Molybdenum}}{\text{Mo99 (total)}} = \frac{\text{µCi simulated Mo99} \times \text{net cpm Eluate}}{\text{net cpm simulated Mo99 reference source}}$$

Divide this number by the mCi of Technetium Tc 99m. This result (µCi Mo99/mCi Tc 99m) can be converted to MBq Mo99/MBq Tc 99m by multiplying by 10^{-3}. The U.S. Pharmacopeia and the U.S. Nuclear Regulatory Commission or equivalent Agreement State regulations specify a limit of 0.00015MBq Molybdenum Mo99 per MBq of Technetium Tc 99m (0.15µCi Mo99/mCi Tc 99m) at the time of administration to each patient.

COLORIMETRIC ALUMINUM ION TEST PROCEDURE

Obtain an aluminum ion indicator kit and determine the aluminum ion concentration of the eluate per the manufacturer's instructions. The concentration must not exceed 10 micrograms per milliliter of eluate.

DISPOSAL: All components shipped with the TECHNELITE®, Technetium Tc 99m Generator should be monitored for contamination prior to disposing into routine trash systems. The Technetium Tc 99m should not be disposed of into routine trash systems. The generator should be disposed through a USNRC or Agreement State licensed disposal agency or by a method approved by the appropriate regulatory authority. Spent generators may be returned; **complete return instructions are available on request.**

This radioactive drug is approved for distribution to persons licensed pursuant to the Code of Massachusetts Regulations 105 CMR 120.100 for the uses listed in 105 CMR 120.547 or 120.552 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

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