

## Weekday Manufactured

Expected mCi of Tc 99m at 8:00 a.m. EST

Gen Size	1 day Post Cal	2 day Post Cal	3 day Post Cal	4 day Post Cal	5 day Post Cal	6 day Post Cal	7 day Post Cal	8 day Post Cal	9 day Post Cal	10 day Post Cal	11 day Post Cal	12 day Post Cal	13 day Post Cal	14 day Post Cal
1000	610	535	420	326	254	197	153	119	92	72	56	43	34	26
2000	1220	1070	839	653	507	394	306	238	185	144	112	87	67	52
2500	1525	1338	1049	816	634	493	383	297	231	180	139	108	84	65
3000	1830	1605	1259	979	761	591	459	357	277	215	167	130	101	79
4000	2440	2140	1678	1305	1014	788	612	476	370	287	223	173	135	105
4500	2745	2408	1888	1468	1141	887	689	535	416	323	251	195	152	118
5000	3050	2675	2098	1631	1268	985	765	595	462	359	279	217	168	131
6000	3660	3211	2518	1958	1521	1182	918	714	554	431	335	260	202	157
7500	4575	4013	3147	2447	1902	1478	1148	892	693	539	418	325	253	196
10000	6100	5351	4196	3263	2535	1970	1531	1189	924	718	558	434	337	262
12500	7626	6689	5245	4078	3169	2463	1913	1487	1155	898	697	542	421	327
15000	9151	8026	6294	4894	3803	2955	2296	1784	1386	1077	837	650	505	393
18000	10981	9632	7553	5873	4564	3546	2755	2141	1663	1293	1004	780	606	471

- Calibration is 12 Noon EST on day of manufacture
- Manufacture Day: Monday, Tuesday, and Friday (subject to change)
- Expected mCi of Tc 99m assumes 90% elution efficiency on that day



# 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 0.023cm 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 <sup>-1</sup>
0.18	10 <sup>-2</sup>
0.27	10 <sup>-3</sup>
0.33	10 <sup>-4</sup>

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 Tc 99m. Since the Molybdenum Mo99 is constantly decaying to fresh Technetium Tc 99m, it is possible to elute the generator at any time. However, the total amount of Technetium Tc 99m available will depend on the time interval from the previous elution, the quantity of Molybdenum Mo99 remaining and the efficiency 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

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,



\*\*\*NOTE 2 (partial eluting generator): If the saline charge vial does not fully empty or the expected eluate volume is not recovered, remove the evacuated collection vial and the saline charge vial. Insert a new saline charge vial and a new evacuated collection vial. Allow the elution process to complete. If the replacement saline charge vial does not fully empty or the expected eluate volume is not recovered in the replacement collection vial, contact Lantheus Medical Imaging, Inc. DO NOT USE ELUATE COLLECTED FROM A PARTIALLY ELUTED GENERATOR.

**Caution: Tampering with the internal components could compromise sterility and present a radiation hazard. This generator should not be dismantled.**

9. 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.**
10. Perform the Assay and Radiometric Molybdenum Test Procedures described below for each elution performed.
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 is to be determined at the time of each elution prior to administration, and from that ratio, the expiration time (up to 12 hours) of the eluate mathematically determined. Each eluate must 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:

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

Divide this number by the mCi of Technetium Tc 99m. This result ( $\mu\text{Ci Mo99/mCi Tc 99m}$ ) 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 (0.15 $\mu\text{Ci Mo99/mCi Tc 99m}$ ) at the time of administration to each patient. If this limit is exceeded, the eluate should not be used. Discard the eluate and contact Lantheus Medical Imaging, Inc.

#### 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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<http://www.lantheus.com/patents/index.html>



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