

**Drytec™****(Technetium Tc99m Generator)**

For the Production of Sodium Pertechnetate Tc99m Injection

Diagnostic Radiopharmaceutical

For intravenous use only

**Rx ONLY****DESCRIPTION**

The Drytec (Technetium Tc99m Generator) is prepared with fission-produced molybdenum Mo99 adsorbed on alumina in a lead-shielded column and provides a means for obtaining sterile pyrogen-free solutions of Sodium Pertechnetate Tc99m Injection in sodium chloride. 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 Mo99 solution pH adjustment. Over the life of the generator, each elution will provide a yield of > 90% of the theoretical amount of technetium Tc99m available from the molybdenum Mo99 on the generator column.

Each eluate of the generator should not contain more than 0.0056 MBq (0.15 µCi) of molybdenum Mo99 per 37 MBq (1 mCi) of technetium Tc99m per administered dose at the time of administration, and not more than 10 µg of aluminum per mL 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.

**PHYSICAL CHARACTERISTICS**

Technetium Tc99m decays by an isomeric transition with a physical half-life of 6.02 hours. The principal photon that is useful for detection and imaging studies is listed in Table 1.

**Table 1. Principal Radiation Emission Data**

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

**EXTERNAL RADIATION**

The specific gamma ray constant for technetium Tc99m is 0.795 R/hr-mCi at 1 cm. The first half-value thickness is 0.023 cm of lead (Pb). A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 0.27 cm of Pb will attenuate the radiation emitted by a factor of about 1000.

**Table 2. Radiation Attenuation by Lead (Pb) Shielding**

Shield Thickness (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 Tc99m with a molybdenum Mo99 half-life of 2.75 days. The physical decay characteristics of molybdenum Mo99 are such that only 86.8% of the decaying molybdenum Mo99 nuclei form technetium Tc99m. Generator elutions may be made at any time, but the amount of technetium Tc99m available will depend on the time interval since the last elution. After six hours approximately 47% of maximum technetium Tc99m is available. Ninety-two percent is reached after 24 hours. To correct for physical decay of each radionuclide, the fractions that remain at selected intervals of time are shown in Tables 3 and 4.

**Table 3. Physical Decay Chart: Molybdenum Mo99 (Half-Life 66 Hours)**

Days	Percent Remaining	Days	Percent Remaining	Days	Percent Remaining
0*	100.0	7	17.1	14	2.9
1	77.7	8	13.3	15	2.3
2	60.4	9	10.3	20	0.6
3	46.9	10	8.0	25	0.2
4	36.5	11	6.3	30	0.1
5	28.4	12	4.9		
6	22.0	13	3.8		

\*Calibration time

**Table 4. Physical Decay Chart: Technetium Tc99m (Half-Life 6.02 Hours)**

Hours	Percent Remaining	Hours	Percent Remaining
0*	100.0	7	44.7
1	89.1	8	39.8
2	79.4	9	35.5
3	70.8	10	31.6
4	63.1	11	28.2
5	56.2	12	25.1
6	50.1		

\*Elution 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 thyroid gland, salivary glands, gastric mucosa, and choroid plexus. 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 Tc99m 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 Drytec (Technetium Tc99m Generator) is a source of sodium pertechnetate Tc99m for use in the preparation of FDA-approved diagnostic radiopharmaceuticals, as described in the labeling of these diagnostic radiopharmaceutical kits.

Sodium Pertechnetate Tc99m Injection is used **IN ADULTS** as an agent for:

Thyroid Imaging  
Salivary Gland Imaging  
Urinary Bladder Imaging (direct isotopic cystography) for detection of vesico-ureteral reflux  
Nasolacrimal Drainage System Imaging (dacryoscintigraphy)

Sodium Pertechnetate Tc99m Injection is used **IN PEDIATRIC PATIENTS** 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 Tc99m Injection are greater in pediatric patients than in adults. In general, the younger the patient, 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 pediatric patients.

Long-term cumulative radiation exposure is associated with increased risk of cancer.

## **PRECAUTIONS**

### **General**

Drytec generators received in advance of the calibration date and time will contain higher amounts of radioactive material. Care should be taken to assure that the generator is properly shielded. 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.

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 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.

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, mutagenic potential, or whether technetium Tc99m may affect fertility in males or females.

### **Pregnancy Category C**

Animal reproductive studies have not been conducted with technetium Tc99m. It is also not known whether technetium Tc99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc99m should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

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

### **Nursing Mothers**

Technetium Tc99m 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**.

**ADVERSE REACTIONS**

Allergic reactions including anaphylaxis have been reported infrequently following the administration of sodium pertechnetate Tc99m.

**DOSAGE AND ADMINISTRATION**

Sodium Pertechnetate Tc99m Injection is usually administered by intravascular injection. For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc99m Injection is instilled 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 Tc99m 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 ranges employed for various diagnostic indications in average ADULT patients (70 kg) are:

<b>Indication</b>	<b>Megabecquerels (MBq)</b>	<b>Millicuries (mCi)</b>
Vesico-ureteral imaging	18.5 - 37	0.5 - 1
Thyroid gland imaging	37 - 370	1 - 10
Salivary gland imaging	37 - 185	1 - 5
Nasolacrimal drainage system imaging	3.70 (max.)	0.100 (max.)

The recommended dosage ranges in PEDIATRIC PATIENTS are:

Vesico-ureteral imaging	18.5 - 37 MBq (0.5 - 1 mCi)
Thyroid gland imaging	2.2 - 2.96 MBq (60 - 80 µCi) per kg body weight.

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

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 crystal clear and contain no particulate matter.

**RADIATION DOSIMETRY**

The estimated absorbed radiation doses to an average ADULT and PEDIATRIC patient from an intravenous injection of a maximum dose of 1110 MBq (30 mCi) of Sodium Pertechnetate Tc99m Injection distributed uniformly in the total body are shown in Tables 5 and 6.

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

<b>Organ</b>	<b>Absorbed Radiation Dose Per Unit Activity Administered (mGy/mCi)</b>
Adrenals	0.14
Urinary Bladder Wall	0.67
Bone Surfaces	0.20
Brain	0.07
Breasts	0.07
Gallbladder Wall	0.27
Stomach Wall	0.96
Small Intestine	0.59
ULI Wall	2.11
LLI Wall	7.77
Heart Wall	0.12
Kidneys	0.19
Liver	0.14
Lungs	0.09
Muscle	0.12
Ovaries	0.37
Pancreas	0.21
Red Marrow	0.13
Skin	0.07
Spleen	0.16
Testes	0.10
Thymus	0.09
Thyroid	0.81
Uterus	0.30
Remaining Tissues	0.13
<b>Effective Dose (mSv/mCi)</b>	<b>0.48</b>

NOTE: To obtain radiation absorbed dose in rads 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 Per Unit Activity (mGy/mCi) from Intravenous Injection**

Age	15 years	10 years	5 years	1 year
<b>Organ</b>				
Adrenals	0.17	0.27	0.41	0.70
Urinary Bladder Wall	0.85	1.11	1.22	2.22
Bone Surfaces	0.24	0.36	0.52	0.96
Brain	0.09	0.15	0.24	0.44
Breasts	0.09	0.13	0.21	0.41
Gallbladder Wall	0.37	0.59	0.85	1.30
Stomach Wall	1.26	1.78	2.89	5.92
Small Intestine	0.74	1.15	1.74	3.03
ULI Wall	2.70	4.44	7.40	14.06
LLI Wall	1.04	1.67	2.66	4.81
Heart Wall	0.15	0.23	0.34	0.63
Kidneys	0.22	0.32	0.48	0.78
Liver	0.18	0.30	0.48	0.81
Lungs	0.13	0.19	0.29	0.52
Muscle	0.15	0.22	0.33	0.59
Ovaries	0.37	0.67	0.96	1.67
Pancreas	0.27	0.41	0.59	1
Red Marrow	0.17	0.24	0.33	0.56
Skin	0.08	0.13	0.21	0.37
Spleen	0.2	0.30	0.44	0.78
Testes	0.14	0.22	0.32	0.59
Thymus	0.12	0.17	0.28	0.52
Thyroid	1.33	2.04	4.44	8.14
Uterus	0.37	0.56	0.81	1.37
Remaining Tissues	0.13	0.24	0.36	0.63
<b>Effective Dose (mSv/mCi)</b>	0.63	0.96	1.55	2.92

NOTE: To obtain radiation absorbed dose in rads 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 Tc99m Injection for imaging the nasolacrimal drainage system are shown in Table 7.

**Table 7. Absorbed Radiation Doses from Dacryoscintigraphy**

Organ	Absorbed Radiation Dose	
	mGy/3.7 MBq	rad/100 $\mu$ Ci
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 37 MBq (1 mCi) of Sodium Pertechnetate Tc99m 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

Sodium Pertechnetate Tc99m Injection is supplied as a molybdenum Mo99 / Drytec (Technetium Tc99m Generator) in sizes of molybdenum Mo99 from 2.5 GBq up to 100 GBq, 68 mCi up to 2703 mCi, at reference date and time specified on the generator label.

The Drytec (Technetium Tc99m Generator) contains the following amount of molybdenum Mo99 at the reference time and date stated on the label.

NDC #	Mo99 (GBq)	Mo99 (mCi)	NDC #	Mo99 (GBq)	Mo99 (mCi)
17156-601-51	2.5	68	17156-610-60	15	405
17156-602-52	4	108	17156-611-61	20	541
17156-603-53	5	135	17156-612-62	25	676
17156-604-54	6	162	17156-613-63	30	811
17156-605-55	7.5	203	17156-614-64	40	1,081
17156-606-56	8.5	230	17156-615-65	50	1,351
17156-607-57	9	243	17156-616-66	60	1,622
17156-608-58	10	270	17156-617-67	75	2,027
17156-609-59	12.5	338	17156-618-68	100	2,703

The Drytec (Technetium Tc99m Generator) consists of:

1. Sterile generator
2. Elution pack

The following items are provided in the **Elution pack**:

- 5 x 30 mL Evacuated vials for collection of the generator eluate
- 5 x 20 mL Saline eluent vials each containing Sodium Chloride Injection 0.9% USP. Not for direct administration.
- 3 Sterile inlet spike protectors - to maintain sterility of the generator system if the saline vial is removed between elutions
- 5 Sterile closed cell foam collection needle protectors - to maintain sterility of the generator system between elutions
- 5 Spare sterile needles - to enable the user to replace the collection needle
- 6 Courtesy labels - to record the activity, volume and time of elution
- 1 Package insert

Additional quantities of these components are supplied at the customer's request to allow further elution of the generator. Additional components will be supplied as either one of the following two packs:

### **Saline vials pack**

The saline vials pack is available in 5 mL, 10 mL or 20 mL volume to allow the generator eluate to be collected at varying radioactive concentrations. Each pack contains 20 vials of Sodium Chloride Injection 0.9% USP, not for direct administration, packed in an outer carton.

### **Evacuated vials pack**

Each evacuated vials pack contains the following components for the elution of the generator packed in an outer carton.

- 10 x 30 mL Evacuated vials for collection of the generator eluate
- 6 Sterile inlet spike protectors - to maintain sterility of the generator system if the saline vial is removed between elutions
- 10 Sterile closed cell foam collection needle protectors - to maintain sterility of the generator system between elutions
- 10 Spare sterile needles - to enable the user to replace the collection needle
- 12 Courtesy labels - to record the activity, volume and time of elution

### **Storage**

Store the generator and the eluate, Sodium Pertechnetate Tc99m Injection, below 25°C (77°F). Do not freeze.

Store the saline eluent vial below 25°C (77°F). Do not freeze.

Storage should be in accordance with local regulations for radioactive materials.

### **PREPARATION**

This radiopharmaceutical may be received, used and administered only by authorized persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of the regulatory authorities (see **DISPOSAL**).

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc. Take appropriate radiation protection precautions in accordance with national regulations.

## Instructions for elution of the Drytec (Technetium Tc99m Generator)

### Elution instructions

The facilities used for elutions should comply with the appropriate regulations for safe radiological handling. Strict aseptic techniques should be used during the elution of the generator to ensure sterility of the generator eluate. To avoid unsatisfactory performance it is important to adhere to the following sequence of elution steps.

### FIRST ELUTION

- (1) Remove the generator and accompanying accessories from their packaging. Place the generator on a flat, level surface, in a suitably authorized and shielded location. **Do not remove** the spike and needle protectors until you are ready to carry out the first elution.
- (2) Select a saline vial containing the required volume of saline.
- (3) Remove the flip-top from the saline vial and swab the saline vial closure using a bactericidal swab and allow to dry.
- (4) Remove the spike protector.
- (5) Place the saline vial onto the spike, ensuring that it is fully pushed to the bottom of the inlet well. Partial rotation will assist the positioning of the vial.
- (6) Select an evacuated collection vial, remove the flip top cap, and swab the collection vial closure using a bactericidal swab and allow to dry. Prior to placing the collection vial inside the collection vial shield, remove the shield lid and ensure that the vial contact surfaces of the shield have been swabbed using the bactericidal swab provided. Replace the collection vial shield screw-locked cap. The collection shield push-fit top is not required until the elution has been completed.
- (7) Remove the collection point protector by turning it counter-clockwise. Ensure that the luer type filter attached to the collection point protector is also removed. **Retain the collection point protector for use when returning the generator.** Immediately fit a collection needle provided in the accessory pack. Do not remove the collection needle sheath until you are ready to place the collection vial on the needle.
- (8) Remove the collection needle sheath and place the collection vial shield on to the collection needle, aligning the side location into its guide, and the window to the front. Push down to ensure that the vial is fully located on the collection needle.
- (9) Allow at least 3 minutes for the elution to complete. Elution is complete when all vigorous bubbling has ceased inside the collection vial. **Do not remove either the saline vial or collection vial until after elution is complete.**
- (10) Slowly remove the collection vial shield to prevent damage to the collection needle and replace the push-fit top for added radiation protection.
- (11) Cover with a new collection needle protector from the accessory pack to preserve sterility.
- (12) To preserve sterility leave the empty saline vial in place until the next elution.

## **SUBSEQUENT ELUTIONS**

Using a new sanitized saline vial of the required volume repeat steps 5–12.

If the collection needle needs to be changed, remove the damaged needle and swab the collection well to ensure sterility is maintained and fit a new needle. Place a collection needle protector over the new needle.

Following expiry, a spare spike protector and the retained collection point protector should be used to cover the spike and collection point respectively.

## **ELUTION VOLUME AND YIELD OF TECHNETIUM Tc99m**

Due to the elution characteristics of the different column designs, the recommended minimum elution volume for lead shielded generators is 5 mL (2.5 to 30 GBq Mo99). For depleted uranium shielded generators (40 to 100 GBq Mo99) the recommended minimum elution volume is 10 mL. If 5 mL elutions are used a higher radioactive concentration will be obtained, but a small yield reduction is likely.

The Drytec Technetium Tc99m Generator is calibrated in terms of the amount of molybdenum Mo99 loaded on the column. The available technetium Tc99m at any time depends on the time before or after reference (due to the decay of molybdenum Mo99, the time elapsed since the previous elution (due to “growth” of technetium Tc99m) and on the decay characteristics of molybdenum Mo99 (86.8% of all decay yields technetium Tc99m). The percentages listed in Tables 9 and 10 may be used to calculate the available technetium Tc99m activity using the following method.

First, multiply the stated reference activity by the appropriate factor from Table 9 (which allows for decay of molybdenum Mo99). Then multiply the product by the appropriate percentage from Table 10 (which allows for the growth of technetium Tc99m and for decay characteristics of molybdenum Mo99).

The actual yield of technetium Tc99m will vary slightly due to variation in elution efficiency from generator to generator. It will typically not be less than 90% of the available technetium Tc99m activity.

**Table 9: Molybdenum Mo99 decay factors at various times from generator reference time (molybdenum Mo99 half-life 66 hours)**

Days from generator reference time												
(hrs)	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0	1
2.00	13.8123	10.7349	8.3432	6.4844	5.0397	3.9169	3.0442	2.3660	1.8388	1.4291	1.1107	0.8633
4.00	13.5252	10.5118	8.1698	6.3496	4.9349	3.8354	2.9809	2.3168	1.8006	1.3994	1.0876	0.8453
6.00	13.2441	10.2933	8.0000	6.2176	4.8324	3.7557	2.9190	2.2686	1.7632	1.3704	1.0650	0.8278
8.00	12.9688	10.0794	7.8337	6.0884	4.7319	3.6777	2.8583	2.2215	1.7265	1.3419	1.0429	0.8105
10.00	12.6992	9.8699	7.6709	5.9618	4.6336	3.6012	2.7989	2.1753	1.6906	1.3140	1.0212	0.7937
12.00	12.4353	9.6647	7.5114	5.8379	4.5373	3.5264	2.7407	2.1301	1.6555	1.2867	1.0000	0.7772
14.00	12.1768	9.4638	7.3553	5.7166	4.4429	3.4531	2.6837	2.0858	1.6211	1.2599	0.9792	0.7610
16.00	11.9237	9.2671	7.2024	5.5978	4.3506	3.3813	2.6280	2.0425	1.5874	1.2337	0.9589	0.7452
18.00	11.6758	9.0745	7.0527	5.4814	4.2602	3.3110	2.5733	2.0000	1.5544	1.2081	0.9389	0.7297
20.00	11.4332	8.8859	6.9061	5.3675	4.1716	3.2422	2.5198	1.9584	1.5221	1.1830	0.9194	0.7146
22.00	11.1955	8.7012	6.7626	5.2559	4.0849	3.1748	2.4675	1.9177	1.4905	1.1584	0.9003	0.6997
24.00	10.9628	8.5203	6.6220	5.1467	4.0000	3.1088	2.4162	1.8779	1.4595	1.1343	0.8816	0.6852

Days from generator reference time													
(hrs)	2	3	4	5	6	7	8	9	10	11	12	13	14
2.00	0.6709	0.5215	0.4053	0.3150	0.2448	0.1903	0.1479	0.1149	0.0893	0.0694	0.0540	0.0419	0.0326
4.00	0.6570	0.5106	0.3969	0.3084	0.2397	0.1863	0.1448	0.1125	0.0875	0.0680	0.0528	0.0411	0.0319
6.00	0.6433	0.5000	0.3886	0.3020	0.2347	0.1824	0.1418	0.1102	0.0856	0.0666	0.0517	0.0402	0.0313
8.00	0.6300	0.4896	0.3805	0.2957	0.2299	0.1786	0.1388	0.1079	0.0839	0.0652	0.0507	0.0394	0.0306
10.00	0.6169	0.4794	0.3726	0.2896	0.2251	0.1749	0.1360	0.1057	0.0821	0.0638	0.0496	0.0386	0.0300
12.00	0.6040	0.4695	0.3649	0.2836	0.2204	0.1713	0.1331	0.1035	0.0804	0.0625	0.0486	0.0378	0.0293
14.00	0.5915	0.4597	0.3573	0.2777	0.2158	0.1677	0.1304	0.1013	0.0787	0.0612	0.0476	0.0370	0.0287
16.00	0.5792	0.4502	0.3499	0.2719	0.2113	0.1642	0.1277	0.0992	0.0771	0.0599	0.0466	0.0362	0.0281
18.00	0.5672	0.4408	0.3426	0.2663	0.2069	0.1608	0.1250	0.0972	0.0755	0.0587	0.0456	0.0354	0.0275
20.00	0.5554	0.4316	0.3355	0.2607	0.2026	0.1575	0.1224	0.0951	0.0739	0.0575	0.0447	0.0347	0.0270
22.00	0.5438	0.4227	0.3285	0.2553	0.1984	0.1542	0.1199	0.0932	0.0724	0.0563	0.0437	0.0340	0.0264
24.00	0.5325	0.4139	0.3217	0.2500	0.1943	0.1510	0.1174	0.0912	0.0709	0.0551	0.0428	0.0333	0.0259

**Table 10: Factors allowing for growth of technetium Tc99m at various times following the previous elution of technetium Tc99 half-life 6.02 hours)**

Hours	Factor										
1	0.094	9	0.579	17	0.788	25	0.879	33	0.918	41	0.936
2	0.179	10	0.615	18	0.804	26	0.884	34	0.921	42	0.937
3	0.256	11	0.648	19	0.818	27	0.892	35	0.924	43	0.938
4	0.324	12	0.678	20	0.831	28	0.898	36	0.926	44	0.940
5	0.386	13	0.705	21	0.843	29	0.903	37	0.929	45	0.941
6	0.442	14	0.729	22	0.853	30	0.907	38	0.930	46	0.941
7	0.492	15	0.751	23	0.863	31	0.911	39	0.932	47	0.941
8	0.538	16	0.771	24	0.871	32	0.915	40	0.934	48	0.942

### TECHNETIUM Tc99m ASSAY PROCEDURE

The Sodium Pertechnetate Tc99m Injection 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 Tc99m and molybdenum Mo99 activity in the generator eluate. The molybdenum Mo99 / technetium Tc99m 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 0.0056 MBq (0.15  $\mu$ Ci) of molybdenum Mo99 per 37 MBq (1 mCi) of technetium Tc99m per administered dose at the time of administration.

### RADIOMETRIC MOLYBDENUM TEST PROCEDURE

This method is based on the fact that most technetium Tc99m 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 Sodium Pertechnetate Tc99m Injection eluate may be assayed for molybdenum Mo99 activity as follows:

1. A cesium Cs137 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 Tc99m eluate in its lead shield (thereby shielding out technetium Tc99m) by placing over the well or probe.
4. Count the cesium Cs137 reference source in the same shield geometry for the same time period.
5. Compute molybdenum Mo99 activity in the Sodium Pertechnetate Tc99m Injection 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 Tc99m. This result ( $\mu\text{Ci Mo99/mCi Tc99m}$ ) can be converted to MBq Mo99/MBq Tc99m 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 0.0056 MBq of molybdenum Mo99 per 37 MBq of technetium Tc99m ( $0.15 \mu\text{Ci of Mo99 / mCi of Tc99m}$ ) at the time of administration to each patient.

### **MOLYBDENUM Mo99 BREAKTHROUGH TEST**

1. Determine the amount of technetium Tc99m eluted (MBq, mCi).
2. Place the Sodium Pertechnetate Tc99m Injection eluate in a lead container. Place lid on container and put the entire container in the chamber.
3. Record the amount of molybdenum Mo99 (MBq, mCi) on the most sensitive scale.
4. Divide the MBq, mCi molybdenum Mo99 by the MBq, mCi technetium Tc99m. Correct for decay and shielding effect, if necessary.

The molybdenum Mo99/technetium Tc99m ratio should be determined at the time of elution prior to administration, and from that ratio, the expiration time (up to twelve hours) of the eluate mathematically determined. Each Sodium Pertechnetate Tc99m Injection eluate should meet or exceed purity requirement of the current official United States Pharmacopeia.

### **COLORIMETRIC ALUMINIUM TEST PROCEDURE**

Obtain an aluminium ion indicator kit and determine the aluminium ion concentration of the Sodium Pertechnetate Tc99m Injection eluate per the manufacturer's instructions. The concentration must not exceed  $10 \mu\text{g/mL}$  of eluate.

**DISPOSAL:** All components shipped with the Drytec (Technetium Tc99m Generator) should be monitored for contamination prior to disposing into routine trash systems. The technetium Tc99m 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; **full return instructions of generators to GE Healthcare are provided separately and are available upon request.**

### **EXPIRATION DATE**

The expiry date for the generator is 24 days from the date of manufacture. The reference and expiry dates are stated on the generator label. The Drytec (Technetium Tc99m Generator) should not be used after expiration date.

For multidose use, the Sodium Pertechnetate Tc99m Injection eluate should be used within twelve (12) hours of the generator elution time. If the eluate is used to reconstitute a kit, the radio-labeled kit should not be used after twelve (12) hours from the time of generator elution or six (6) hours after reconstitution of the kit, whichever is earlier.

The shelf-life for the sodium chloride eluent is 3 years.

Since the Sodium Pertechnetate Tc99m Injection eluate does not contain an antimicrobial agent, it should not be used after twelve hours from the time of generator elution.

## **DISPOSAL**

Expired generators containing lead shielding (2.5 to 30 GBq Mo99) could normally be disposed of by the user as radioactive waste in accordance with the conditions specified by the local regulatory authority. If local regulations for disposal require that the generator be dismantled, please contact GE Healthcare. Arrangements may be made for the return of lead shielded generators to GE Healthcare if required.

Generators containing depleted uranium and tungsten shielding (40 to 100 GBq Mo99) must be returned to GE Healthcare after expiry. Full return instructions describing how to return generators to GE Healthcare are provided separately. Users are reminded that all packaging, documentation and methods of transportation used must be in compliance with international transport regulations and all local regulations and codes of practice that relate to such matters. This generator is approved for use by persons licensed by the Illinois Emergency Management Agency pursuant to Section 330.260(a), (b) or (c) and 32 IL. Adm. Code 335.4010 or under equivalent licenses of the US NRC or an Agreement State.

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