

11.2 Physical Characteristics

Technetium Tc-99m

Technetium Tc-99m decays by isomeric transition with a physical half-life of 6.01 hours. The principal photon that is useful for detection and imaging studies is shown in Table 8.

Radiation	Mean Percent Per Disintegration	Energy (keV)
Gamma-2	88.5	140.5

The air-kerma-rate (exposure-rate) constant for technetium Tc-99m is 5.23 m²-pGy-(MBq)⁻¹·s⁻¹ [0.795 cm²-R-(mCi)⁻¹·h⁻¹]. A range of values for the relative radiation attenuation by the various thicknesses of Pb is shown in Table 9. For example, the use of 3 mm thickness of Pb will attenuate the radiation exposure by a factor of about 1,000.

Shield Thickness (Pb) mm	Coefficient of Attenuation
0.25	0.5
1	10 ⁻¹
2	10 ⁻²
3	10 ⁻³
4	10 ⁻⁴

Molybdenum Mo-99

Molybdenum Mo-99 decays to technetium Tc-99m with a molybdenum Mo-99 half-life of 66 hours. This means that 77.7% of the activity remains after 24 hours; 60.4% remains after 48 hours (see Table 10).

Days	Percent Remaining	Days	Percent Remaining
0*	100	10	8
1	77.7	11	6.3
2	60.4	12	4.9
3	46.9	13	3.8
4	36.5	14	2.9
5	28.4	15	2.3
6	22	20	0.6
7	17.1	25	0.2
8	13.3	30	0.1
9	10.3		

* calibration time

The physical decay characteristics of molybdenum Mo-99 are such that 88.6% of the decaying molybdenum Mo-99 atoms form Technetium Tc-99m. RadioGenix System elutions may be made at any time, but the amount of technetium Tc-99m available will depend on the time interval measured from the last elution cycle. Eluting the RadioGenix System every 24 hours will provide the maximal yield of Sodium Pertechnetate Tc-99m.

To correct for physical decay of technetium Tc-99m, the fractions that remain at selected intervals of time are shown in Table 11.

Hours	Percent Remaining	Hours	Percent Remaining
0*	100	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		

* calibration time

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The pertechnetate ion distributes in the body similarly to the iodide ion, but is not organified. In contrast to the iodide ion, the pertechnetate is released unchanged from the thyroid gland.

12.2 Pharmacodynamics

Pertechnetate concentrates in the thyroid gland, salivary glands, gastric mucosa and choroid plexus. After intravenous administration, it equilibrates with the extracellular space.

Following the administration of Sodium Pertechnetate Tc-99m 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 ions pass 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. The majority of the pertechnetate escapes within a few minutes of normal drainage and tearing.

12.3 Pharmacokinetics

Times to peak concentrations of pertechnetate following intravenous administration are 3.5 hours for cerebral spinal fluid (CSF) and 0.25 to 2 hours for thyroid (euthyroid patients).

The disappearance of pertechnetate from plasma is biexponential with an initial phase of 10 minutes and a terminal phase of 3 hours. The corresponding phases in CSF are less than 1 hour and 11-12 hours, respectively.

Distribution: Pertechnetate distributes throughout the body concentrating in the gastric mucosa, thyroid gland, salivary glands, and urinary bladder.

Elimination:

Excretion: Elimination by urinary route is 27% in 1 day, 31% in 4 days, and 34% in 8 days based on rate of excretion.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or to determine whether Sodium Pertechnetate Tc 99m Injection may affect fertility in males or females.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

The RadioGenix System is a technetium Tc 99m generator supplied and installed by NorthStar Medical Radioisotopes, LLC. It produces Sodium Pertechnetate Tc 99m Injection, USP from a non-uranium potassium molybdate Mo-99 source solution. The potassium molybdate Mo-99 source solution is shielded within a source container which completely encases a vial that contains 29 mL of solution. NorthStar supplies potassium molybdate Mo-99 solution with the referenced calibration date and time specified on the container label (Table 12).

Mo-99 Activity at Time of Calibration	Product Number	NDC Number
Curies	Gigabecquerels	
7.5	277.5	40008000-75 71612-075-02
12	444	40008000-12 71612-120-02
15	555	40008000-15 71612-150-02
19	703	40008000-19 71612-190-02

The following kit and packs and consumables (Tables 13-22) are used in the operation of the RadioGenix System as described in the Operator Guide, RadioGenix System 1.2 (SYS-0060) P/N 40010570.

Component Description	Component Part Number	Qty.
Catheter	77P07937	1
Air Filter*	77C01237	1
Manifold	12D09657	1
Absorbent Cloth†	73C05400	1
Black Cap†	77C01489	1
Female Luer Cap*†	77C05449	1
Male Luer Cap*†	77C05450	1

† Only used in the removal of a source vessel

Component Description	Component Part Number	Qty.
Primary Separation Cartridge (PSC)*	40P09852	1
Hydrogen Peroxide Wipe*	16C07455	4
Tubing Assembly*	77P09748	1

Component Description	Component Part Number	Qty.
Tc-99m Product Cartridge (TPC)*	40P09853	1
Tc-99m Collection Vial	77C01318	1
Product Port Cap*	77C05449	1
Alcohol Wipe*	16C02704	2
Tc-99m Collection Vial Shield Label	53D09964	1
Tc-99m Collection Vial Label	53D06431	1

Component Description	Component Part Number	Qty.
Blank Primary Separation Cartridge (PSC)*	40P09749	1
Blank Tc-99m Product Cartridge (TPC)*	40P09850	1
Air Filter*	77C01237	1
Product Port Cap*	77C05449	1
Luer Plugs	77C05450	3
Purge Water Container	77C05585	1
Hydrogen Peroxide Wipe*	16C07455	9
Product Vial Label	53D06430	1
Tubing Assembly	77P09800	1
Product Vial	77C01318	1

Component Description	Component Part Number	Qty.
Discarded Material Container	12D05146	1
Silicone Tubing	77C05431	1
Luer Cap*	77C05449	1

Component Description	Component Part Number	Qty.
Discarded Material Container	12D05146	1
Silicone Tubing	77C05431	1
Luer Cap*	77C05449	1
DMC Return Pack	40P10086	1

Component Description	Component Part Number	Qty.
Hydrogen Peroxide Wipe*	16C07455	1
Saline Tubing*	77P09747	1

The following consumables are shipped in bulk to the customer from NorthStar:

Component Description	Component Part Number	Qty.
Sterile Water for Injection, Bag, 250 mL*	16C04488	24

Component Description	Component Part Number	Qty.
5M Sodium Hydroxide (NaOH), NF, 120 mL*	16P09302	6

Component Description	Component Manufacturer NDC	Qty.
NaCl, Injection 0.9%, 250 mL Bag, USP*	0264-7800-20	12, 24, 36
NaCl, Injection 0.9%, 500 mL Bag, USP*	0264-7800-10	12, 24, 36
NaCl, Injection 0.9%, 500 mL Bottle, USP*	0264-7800-01	12, 24, 36
NaCl, Injection 0.9%, 250 mL Bag, USP*	0338-0049-02	12, 24, 36
NaCl, Injection 0.9%, 500 mL Bag, USP*	0338-0049-03	12, 24, 36
NaCl, Injection 0.9%, 250 mL Bag, USP*	0409-7983-02	12, 24, 36
NaCl, Injection 0.9%, 500 mL Bag, USP*	0409-7983-03	12, 24, 36

* Indicates sterile components

16.2 Storage and Handling

Storage

- Receipt, transfer, storage, handling, possession, or use of the potassium molybdate Mo-99 source solution, Sodium Pertechnetate Tc 99m Injection, and radioactive components of the RadioGenix System are subject to the radioactive material regulations and licensing requirements of the U.S. Nuclear Regulatory Commission, Agreement States, or Licensing States.
- Install and operate RadioGenix System 1.2, and store the potassium molybdate Mo-99 source solutions, reagent, kit, and packs [Sterilization Pack for RadioGenix System 1.2 (PN 40P09444), PSC Pack for RadioGenix System 1.2 (PN 40P09451), Elution Pack for RadioGenix System 1.2 (PN 40P09452), Discarded Material Pack for RadioGenix System 1.2 (PN 40P09854), Discarded Material Type A Pack for RadioGenix System 1.2 (PN 40P09855), Source Vessel Kit for RadioGenix System 1.2 (PN 40P07954), and Saline Tubing Pack for RadioGenix System 1.2 (PN 40P09453), NaOH for RadioGenix System 1.2 (PN 16P09302), and Saline (PN 16C09849)] at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Disposal

- The maximum use period of a RadioGenix System and ozone generator is one year from the date of installation. After expiry, have NorthStar perform annual preventative maintenance and recertify the RadioGenix System.
- When the potassium molybdate Mo-99 source has reached the end of its useful life or expiration date, remove the source vessel from the RadioGenix System and return it to NorthStar for processing.
- Dispose of the radioactive waste (discarded material) container in accordance with applicable regulations.

17 PATIENT COUNSELING INFORMATION

Administration Instructions:

Intravenous or Intravesicular Administration

Advise patients to hydrate before (4 hours) and after administration and to void as soon as the imaging study is completed and as often as possible thereafter for the next 12 hours to minimize radiation exposure [see *Dosage and Administration (2.2) and Warnings and Precautions (5.1)*].

Ophthalmic Administration

After the termination of the nasolacrimal imaging procedure, advise patient to blow their nose and/or wash their eyes with sterile distilled water to further minimize the radiation dose [see *Dosage and Administration (2.2) and Warnings and Precautions (5.1)*].

Pregnancy:

Advise pregnant women of the risk of fetal exposure to radiation dose if they undergo a radionuclide procedure [see *Use in Specific Populations (8.1)*].

Lactation:

Advise a lactating woman that exposure of the infant to technetium Tc-99m through breast milk can be minimized if breastfeeding is interrupted when technetium Tc-99m is administered. Advise a lactating woman to pump and discard breast milk for 12 to 24 hours based on the injected dose [see *Use in Specific Populations (8.2)*].

Manufactured and Distributed by:

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