**Sunday Manufactured**

*Expected mCi of Tc 99m at 2:00 a.m. EST*

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</table>

- Calibration is Sunday, 12 Noon EST
- Manufacture Day: Sunday (U)
- Expected mCi of Tc 99m assumes 90% elution efficiency on that day
The pertechnetate ion is released unchanged from the thyroid gland. However, in contrast to the iodide ion, the pertechnetate ion but is not organified when trapped in the thyroid gland. It also concentrates in the choroid plexus, mixes with tears within the conjunctival space. Within seconds to minutes it leaves the conjunctival collection and enters 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 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 fraction of one to 0.1%14 in normal individuals, 0.15%/min in patients with chronic prostatic hyperplasia and 0.02%/min in patients with inflamed conjunctiva due to chronic dacryoconjunctivitis. Individual values may vary but these rates are probably representative and indicate that the maximum possible pertechnetate absorption 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 F-123-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
- Nocasciomatic Drainage System Imaging
- Thyroid Imaging

Sodium Pertechnetate Tc 99m Injection is used in CHILDREN as an agent for:

- Thyroid Imaging

CONTRAINdications:

None known.

WARNINGS:

Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection are greater for children than in adults and, in general, the younger the child greater the risk of greater absorbed radiation doses and longer life-expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

PRECAUTIONS:

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

Since the elute does not contain an antimicrobial agent, it should not be used later than one (1) working day after elution (12 hours).

As in the use of any radioactive material, care should be taken to minimize radiation exposure to any individual's eyes.

No animal studies have been performed to evaluate carcinogenic potential or whether Sodium Pertechnetate Tc 99m affects fertility in male or female experimental animals.

Pregnancy Category C

Animal reproductive studies have not been conducted with Sodium Pertechnetate Tc 99m. It is 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.

Ideal 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.

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 as in the young unless expected benefits to be gained outweigh the potential risks.

Pediatric Use

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

- Vessico-ureteral Imaging
- Thyroid Gland Imaging
- Salivary Gland Imaging
- Nocasciomatic Drainage System Imaging

No animal studies have been performed to evaluate carcinogenic potential or whether Sodium Pertechnetate Tc 99m affects fertility in male or female experimental animals.

Pregnancy Category C

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Pediatric Use

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

- Vessico-ureteral Imaging
- Thyroid Gland Imaging
- Salivary Gland Imaging
- Nocasciomatic Drainage System Imaging

The recommended dosage range in PEDIATRIC PATIENTS is:

- Vessico-ureteral Imaging
- Thyroid Gland Imaging

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration whenever solution and container permit. The solution to be administered as the patient dose should be substituted for breast feeding.

The specified radiation dose, if any, should be administered to pregnant or lactating women unless expected benefits to be gained outweigh the potential risks.

WARNINGS:

Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection are greater for children than in adults and, in general, the younger the child greater the risk of greater absorbed radiation doses and longer life-expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

PRECAUTIONS:

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

Since the elute 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 radia-

CONTRAINdications:

None known.

WARNINGS:

Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection are greater for children than in adults and, in general, the younger the child greater the risk of 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.

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, the salivary glands, 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 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 fraction of one to 0.1%/min in normal individuals, 0.15%/min in patients with chronic prostatic hyperplasia and 0.02%/min in patients with inflamed conjunctiva due to chronic dacryoconjunctivitis. Individual values may vary but these rates are probably representative and indicate that the maximum possible pertechnetate absorption will remain below one thousandth of that used in other routine diagnostic procedures.

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Long-term cumulative radiation exposure may be associated with an increased risk of cancer.
Gallbladder Wall 8.3
Gastric Wall 29
Small Intestines 18
Liver 3.5
Kidneys 9.1
Liver 4.7
Lungs 2.9
Muscle 3.6
Ovaries 11.1
Pancreas 6.3
Red Marrow 4.1
Spleen 4.8
Stomach 3.1
Thymus 2.7
Table 6. Pediatric Absorbed Radiation Dose (mGy) from Intravenous Injection

<table>
<thead>
<tr>
<th>Age</th>
<th>15 years</th>
<th>10 years</th>
<th>5 years</th>
<th>1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administered activity in MBq (mCi)</td>
<td>1110 (30)</td>
<td>740 (20)</td>
<td>555 (15)</td>
<td>370 (10)</td>
</tr>
<tr>
<td>Organ</td>
<td>Adrenal</td>
<td>5.3</td>
<td>5.4</td>
<td>6.2</td>
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<td>Bladder Wall</td>
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<td>Bone Surface</td>
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<td>7.5</td>
<td>8.1</td>
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<td>3.1</td>
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<td>Breast</td>
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<td>Gallbladder Wall</td>
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<td>12</td>
<td>13</td>
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<td></td>
<td>Gastrointestinal Wall</td>
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<td>26</td>
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<td></td>
<td>LIVER</td>
<td>81</td>
<td>89</td>
<td>110</td>
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<td>Heart Wall</td>
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<td>4.6</td>
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<td>VESY</td>
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<td>12</td>
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</table>

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

Table 7. Absorbed Radiation Dose from Dacryoscintigraphy

Using Sodium Pertechnetate Tc 99m

<table>
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<th>Organ</th>
<th>Effective Dose (mGy)</th>
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<td>Eye Lens</td>
<td>0.023</td>
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<tr>
<td>IFI</td>
<td>0.103</td>
</tr>
<tr>
<td>Testes</td>
<td>0.005</td>
</tr>
</tbody>
</table>

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

Table 8. Pediatric Absorbed Radiation Dose from Cystography

<table>
<thead>
<tr>
<th>Age</th>
<th>Bladder wall dose, mGy (rad)</th>
<th>Gonadal dose, mGy (rad)</th>
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<tbody>
<tr>
<td>1 year</td>
<td>3.6 (0.36)</td>
<td>0.15 (0.015)</td>
</tr>
<tr>
<td>10 years</td>
<td>2.0 (0.2)</td>
<td>0.05 (0.006)</td>
</tr>
<tr>
<td>15 years</td>
<td>1.3 (0.13)</td>
<td>0.06 (0.006)</td>
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</table>

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 list identification label affixed to the generator.

Table 9. Available Quantities of Radioactivity

Dose of 37MBq (1 millicurie) of Sodium Pertechnetate

DISPOSAL: All components shipped with the TECHNELITE®, Technetium Tc 99m Generator should be managed in accordance with applicable federal, state and local regulations.

COLORIMETRIC ALUMINUM ION TEST PROCEDURE

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

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 reconstituted, this end of the Technetium Tc 99m radiopharmaceutical is radioactive 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.

Each generator is supplied with the following standard components:

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

First order generators are shipped with the following accessory components:

- 2 Elution Shields

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