### Weekday Manufactured

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

<table>
<thead>
<tr>
<th>Gen Size</th>
<th>1 day Post Cal</th>
<th>2 day Post Cal</th>
<th>3 day Post Cal</th>
<th>4 day Post Cal</th>
<th>5 day Post Cal</th>
<th>6 day Post Cal</th>
<th>7 day Post Cal</th>
<th>8 day Post Cal</th>
<th>9 day Post Cal</th>
<th>10 day Post Cal</th>
<th>11 day Post Cal</th>
<th>12 day Post Cal</th>
<th>13 day Post Cal</th>
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<tbody>
<tr>
<td>1000</td>
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<td>535</td>
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<td>101</td>
<td>79</td>
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<tr>
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<td>195</td>
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<td>260</td>
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<tr>
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<td>4013</td>
<td>3147</td>
<td>2447</td>
<td>1902</td>
<td>1478</td>
<td>1148</td>
<td>892</td>
<td>693</td>
<td>539</td>
<td>418</td>
<td>325</td>
<td>253</td>
<td>196</td>
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<tr>
<td>10000</td>
<td>6100</td>
<td>5351</td>
<td>4196</td>
<td>3263</td>
<td>2535</td>
<td>1970</td>
<td>1531</td>
<td>1189</td>
<td>924</td>
<td>718</td>
<td>558</td>
<td>434</td>
<td>337</td>
<td>262</td>
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<td>12500</td>
<td>7626</td>
<td>6689</td>
<td>5245</td>
<td>4078</td>
<td>3169</td>
<td>2463</td>
<td>1913</td>
<td>1487</td>
<td>1155</td>
<td>898</td>
<td>697</td>
<td>542</td>
<td>421</td>
<td>327</td>
</tr>
<tr>
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<td>8026</td>
<td>6294</td>
<td>4894</td>
<td>3803</td>
<td>2955</td>
<td>2296</td>
<td>1784</td>
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<td>1077</td>
<td>837</td>
<td>650</td>
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<tr>
<td>18000</td>
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<td>5873</td>
<td>4564</td>
<td>3546</td>
<td>2755</td>
<td>2141</td>
<td>1663</td>
<td>1293</td>
<td>1004</td>
<td>780</td>
<td>606</td>
<td>471</td>
</tr>
</tbody>
</table>

- 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
DESCRIPTION: Sodium Pertechnetate Tc 99m Injection, as injected according to the elution instruc-
tions with Lantheus Medical Imaging, Inc. TECHNE®LITE, Technetium Tc 99m Generator, is in Sodium Chloride 0.9%, 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 TECHNE®LITE 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, but 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. TECHNE®LITE, Technetium Tc 99m Generator consists of a col-
umn containing fission produced Molybdenum Mo99 adsorbed on alumina. The terminally sterilized and sealed column is encased 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%, prefilled 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

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

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean %Disintegration</th>
<th>Mean Energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>89.07</td>
<td>140.5</td>
</tr>
</tbody>
</table>

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 4.14 micro-coulombs/Kg-MBq-hr (0.705 R/ m/hr) by 1cm. The first half-value thickness is 0.023 cm of lead (Pb). To facilitate control of radiation exposure, equipment to shield or exclude areas where the Technetium Tc 99m Generator is located is recommended. For each use of a 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 interference of various positions of lead is shown in Table 2.

NOTE: Because the generator is well contained and essentially dry, there is little likelihood of contamin-

ation due to damage in transit.

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

<table>
<thead>
<tr>
<th>Shield Thickness (lead)</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.023</td>
<td>0.5</td>
</tr>
<tr>
<td>0.09</td>
<td>10^1</td>
</tr>
<tr>
<td>0.18</td>
<td>10^1</td>
</tr>
<tr>
<td>0.27</td>
<td>10^2</td>
</tr>
<tr>
<td>0.58</td>
<td>10^4</td>
</tr>
</tbody>
</table>

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 Technetium, 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 Molybdenum Mo99 remaining and the efficiency of the elution. Approximately 74% of maximum Technetium Tc99m 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 Tc99m 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 3.

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

<table>
<thead>
<tr>
<th>Days</th>
<th>Percent Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>1</td>
<td>71</td>
</tr>
<tr>
<td>3</td>
<td>62</td>
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<tr>
<td>7</td>
<td>47</td>
</tr>
<tr>
<td>28</td>
<td>26</td>
</tr>
<tr>
<td>111</td>
<td>17</td>
</tr>
<tr>
<td>259</td>
<td>13</td>
</tr>
<tr>
<td>740</td>
<td>8</td>
</tr>
</tbody>
</table>

The recommended dosage range in PEDIATRIC PATIENTS is:

<table>
<thead>
<tr>
<th>Organ</th>
<th>Absorbed Radiation Dose (mGy) for a 1110 MBq (30mCi) dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenals</td>
<td>4.1</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>20</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>6.2</td>
</tr>
<tr>
<td>Brain</td>
<td>2.2</td>
</tr>
<tr>
<td>Breasts</td>
<td>2.2</td>
</tr>
</tbody>
</table>

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 surface area of 0.015 MBq/m2 in normal individuals, 0.021 MBq/m2 in patients with phacoemulsification and 0.027 MBq/m2 in patients with infected conjunctiva due to chronic dacryocystitis. 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 Technetium 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
- 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 firm-
ly into account in all benefit-risk assessments involving children.

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

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 colleagues and medical personnel.

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.

Because the generator is well contained and essentially dry, there is little likelihood of contamination under WARNINGS.

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

Geriatric Use

Clinical studies of Technetium® 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 Generator. For imaging the urinary bladder and ureters (direct isotopic cystography), the bladder Sodium Pertechnetate Tc 99m is administered by direct instillation asymptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 300 mL of sterile saline directly into the bladder. The dosage employs varying with each diagnostic procedure. When imaging the nasaoscleral 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

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

The recommended dosage range in PEDIATRIC PATIENTS is:

- Vesico-ureteral Imaging: 8.5 to 37MBq (0.2 to 1 mCi)
- Thyroid Imaging: 2.2 to 9.0MBq (60 to 250µCi/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 dose is an average ADULT and Pediatric patient from an intra-
venous 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.
**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 vial. Discard as radioactive waste.
5. Remove filter-foam seal from charge vial and insert collector vial. **Discard as radioactive waste.**
6. Remove needle guard from enteric needle and inject sterile Sodium Pertechnetate Tc 99m. **Discard as radioactive waste.**
7. Remove vented needle cover from collector well. **Discard as radioactive waste.**
8. Insert shielded collection vial into the generator. **Discard as radioactive waste.**
9. After elution has been completed, remove shield containing the collection vial. Obtain the collect vial and if elution does not commence, use a second shielded collection vial. **Discard as radioactive waste.**
10. A shielded syringe when introducing the Sodium Pertechnetate Tc 99m solution into mixing vials. **Discard as radioactive waste.**
11. Use a shielded syringe when introducing the Sodium Pertechnetate Tc 99m solution into mixing vials. **Discard as radioactive waste.**
12. Under a shielded syringe when introducing the Sodium Pertechnetate Tc 99m solution into mixing vials. **Discard as radioactive waste.**
13. Maintain adequate shielding during the radioactive preparation by using a lead 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®, 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 the expiration time stated on the labeling for the prepared drug, whichever is earlier. Each eluate should meet or exceed the purity requirements of the current United States Pharmacopeia, that is, not more than 0.05MBCi (0.15 microcurie) of Molybdenum 99 per 37MBCi (1 millimole) of Technetium 99m per administered dose at the time of administration.

**RADIOIMMUNOASSAY METHOD**

This method is based on the fact that most Technetium Tc 99m radiation can be readily shielded and is restricted to the more energetic gamma rays from Molybdenum Mo99 (739KeV and 778KeV) are counted in the generator eluate. The TECHNELITE®, 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 the expiration time stated on the labeling for the prepared drug, whichever is earlier. Each eluate should meet or exceed the purity requirements of the current United States Pharmacopeia, that is, not more than 0.05MBCi (0.15 microcurie) of Molybdenum 99 per 37MBCi (1 millimole) of Technetium 99m per administered dose at the time of administration.

**COLORIMETRIC ALUMINUM ION TEST PROCEDURE**

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

**Effective Dose (mSv)**

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effective Dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
<td>2.7</td>
</tr>
<tr>
<td>Liver</td>
<td>2.9</td>
</tr>
<tr>
<td>Lumgs</td>
<td>4.7</td>
</tr>
<tr>
<td>Muscle</td>
<td>3.6</td>
</tr>
<tr>
<td>Oral</td>
<td>11.1</td>
</tr>
<tr>
<td>Pancreas</td>
<td>6.3</td>
</tr>
<tr>
<td>Kidney</td>
<td>4.1</td>
</tr>
<tr>
<td>Spleen</td>
<td>4.8</td>
</tr>
<tr>
<td>Rectum</td>
<td>3.1</td>
</tr>
<tr>
<td>Thymus</td>
<td>2.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>14</td>
</tr>
</tbody>
</table>

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

**Absorbed Radiation Dose from Intravenous Injection**

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>Absorbed Dose</th>
<th>mGy (rad)</th>
<th>3/7MBCi of Tc 99m</th>
<th>100µCi Mo99</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Lens</td>
<td>0.140</td>
<td>0.011</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If lacrimal fluid turnover is 16%/min</td>
<td>0.022</td>
<td>0.003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If lacrimal fluid turnover is 100%/min</td>
<td>0.006</td>
<td>0.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If drainage system is blocked</td>
<td>0.200</td>
<td>0.025</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**4. Compute Molybdenum Mo99 activity in the eluate as follows:**

\[
\mu\text{Ci Mo99} = \mu\text{Ci simulated Mo99} \times \frac{\text{net cpm Eluate}}{\text{net cpm simulated Mo99 reference source}}
\]

**5. Compute Molybdenum Mo99 activity in the eluate as follows:**

\[
\mu\text{Ci Mo99} = \mu\text{Ci simulated Mo99} \times \frac{\text{net cpm Eluate}}{\text{net cpm simulated Mo99 reference source}}
\]

**HOW SUPPLIED:** Lanthesc Medical Imaging TECHNELITE®. Tc 99m Generator Eluate is available in the following quantities of activity 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**

<table>
<thead>
<tr>
<th>NDC #</th>
<th>GBq of Mo99</th>
<th>GBq of Mo99</th>
<th>GBq of Mo99</th>
<th>GBq of Mo99</th>
</tr>
</thead>
<tbody>
<tr>
<td>11994-000-36</td>
<td>37.0</td>
<td>1</td>
<td>11994-091-36</td>
<td>37.0</td>
</tr>
<tr>
<td>11994-000-73</td>
<td>74.0</td>
<td>2</td>
<td>11994-091-73</td>
<td>74.0</td>
</tr>
<tr>
<td>11994-000-92</td>
<td>92.5</td>
<td>2.5</td>
<td>11994-091-92</td>
<td>92.5</td>
</tr>
<tr>
<td>11994-000-01</td>
<td>111.0</td>
<td>3</td>
<td>11994-091-01</td>
<td>111.0</td>
</tr>
</tbody>
</table>

**Table 10. Pediatric Absorbed Radiation Doses from Dacryoscintigraphy**

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>Absorbed Dose</th>
<th>mGy (rad)</th>
<th>3/7MBCi of Tc 99m</th>
<th>100µCi Mo99</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Lens</td>
<td>0.140</td>
<td>0.011</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If lacrimal fluid turnover is 16%/min</td>
<td>0.022</td>
<td>0.003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If lacrimal fluid turnover is 100%/min</td>
<td>0.006</td>
<td>0.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If drainage system is blocked</td>
<td>0.200</td>
<td>0.025</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 11. Pediatric Absorbed Radiation Doses (mGy) from Intravenous Injection**

<table>
<thead>
<tr>
<th>Organ</th>
<th>Effective Dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
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</tr>
<tr>
<td>Liver</td>
<td>2.9</td>
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<tr>
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<tr>
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<tr>
<td>Kidney</td>
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</tr>
<tr>
<td>Spleen</td>
<td>4.8</td>
</tr>
<tr>
<td>Rectum</td>
<td>3.1</td>
</tr>
<tr>
<td>Thymus</td>
<td>2.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>14</td>
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**Table 12. Pediatric Absorbed Radiation Doses from Cystography**

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<tr>
<th>Organ</th>
<th>Effective Dose (mSv)</th>
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