



Table 4. Radiation Dose Estimates for Tc 99m Mertiatide

	8-day Old		1-year Old**		5-year Old**		10-year Old**		15-year Old		Adult	
Assumed Weight (kg)	3.4		9.8		19		32		57		70	
Tc 99m Mertiatide Dose	37 MBq (1 mCi)		72.52 MBq (1.96 mCi)		140.6 MBq (3.8 mCi)		236.8 MBq (6.4 mCi)		370 MBq (10 mCi)		370 MBq (10 mCi)	
Organ	mSv	rem	mSv	rem	mSv	rem	mSv	rem	mSv	rem	mSv	rem
Gallbladder Wall	2.701	0.27	2.466	0.235	1.547	0.160	1.658	0.166	1.961	0.200	1.628	0.160
Lower Large Intestine Wall	1.739	0.17	1.595	0.161	2.250	0.220	2.368	0.237	4.070	0.400	3.256	0.330
Small Intestine	0.518	0.052	0.5439	0.055	1.195	0.122	1.397	0.141	2.035	0.200	1.628	0.160
Upper Large Intestine Wall	0.962	0.096	0.943	0.096	1.828	0.186	2.0365	0.205	2.442	0.250	1.887	0.190
Kidneys	1.406	0.14	1.088	0.112	1.308	0.129	1.5155	0.154	1.739	0.180	1.443	0.140
Liver	0.3219	0.032	0.3046	0.031	0.394	0.038	0.4262	0.0435	0.481	0.048	0.3626	0.036
Ovaries	0.592	0.058	0.6164	0.061	1.322	0.133	1.5392	0.154	3.330	0.330	2.5900	0.260
Red Marrow	0.1628	0.016	0.1595	0.0161	0.281	0.0277	0.3552	0.0352	0.629	0.063	0.4810	0.050
Testes	0.518	0.051	0.5294	0.053	1.0826	0.110	1.1840	0.122	2.368	0.240	1.628	0.160
Urinary Bladder Wall	11.470	1.1	9.428	0.921	21.090	2.090	23.680	2.368	59.20	6.00	48.1000	4.80
Total Body	0.2405	0.024	0.2176	0.022	0.3656	0.0365	0.4026	0.0410	0.814	0.081	0.6660	0.065

\* Calculated by Oak Ridge Associated Universities, based upon the pediatric phantom series of Christy and Eckerman of Oak Ridge National Laboratories. The adult radiation absorbed doses were calculated based on data from ten normal volunteers using the Medical Internal Radiation Dose Committee (MIRD) schema.

\*\*Radioactive doses for 1-, 5-, and 10-year olds are based on a maximum dose of 7.4 MBq/kg (200  $\mu$ Ci/kg).

#### INSTRUCTIONS FOR THE PREPARATION OF TECHNETIUM Tc 99m MERTIATIDE

**Note:** Read complete directions thoroughly before starting preparation procedure.

##### Procedural Precautions and Notes

- Solutions of sodium pertechnetate Tc 99m which contain oxidizing agents (i.e., sodium hypochlorite or hydrogen peroxide) should not be used.
- NOTE:** Do not use Tc 99m eluate more than 6 hours after its elution from the generator.
- All transfers and vial stopper entries must be done using aseptic technique.
- The water bath used for heating the contents of the reaction vial must be at a continuous rolling boil during the heating step of the preparation procedure. The vial should be in direct contact with the rolling boil water of the bath, and the level of the bath must be at least even with the level of the contents of the vial.
- The temperature of a lead incubation shield should be allowed to reach the temperature of the water bath before incubating the reaction vial. The shield should be designed so that water flows through the interior of the shield.

**Note 1:** Wear waterproof gloves during the entire preparation procedure and during subsequent patient dose withdrawals from the reaction vial.

**Note 2:** Make all transfers of sodium pertechnetate Tc 99m solution during the preparation procedure with an adequately shielded syringe.

**Note 3:** Keep the radioactive preparation in the lead shield described below (with cap in place) during the useful life of the radioactive preparation. Maintain adequate shielding during the life of the product and use a shielded, sterile syringe for withdrawing and injecting the preparation.

##### Procedure for the Preparation of Technetium Tc 99m Mertiatide

- Prepare a rolling boil water bath containing a vial shield with openings cut in it to allow the water to circulate through the shield. The openings should be oriented to prevent radiation leakage.
- Place the reaction vial in a lead dispensing shield fitted with a lid and with a minimum wall thickness of 1/8 inch.
- Swab the rubber stopper of the reaction vial with an appropriate antiseptic. Insert a filter-containing venting needle (provided) through the vial stopper. Inject 4 to 10 milliliters of sodium pertechnetate Tc 99m solution
- 9.
- The radiochemical purity of the reconstituted solution must be checked prior to administration to the patient. If the radiochemical purity is less than 90%, the product must not be used.
- Store the reaction vial containing the technetium Tc 99m mertiatide at room temperature (15° to 30°C) until use. The technetium Tc 99m mertiatide preparation must be used within six hours of preparation.

containing 740 megabecquerels (20 mCi) to 3.70 gigabecquerels (100 mCi) into the vial. If required, use nonbacteriostatic normal saline to dilute the sodium pertechnetate Tc 99m solution to the desired concentration prior to addition to the vial.

**NOTE:** Make sure the water bath is at boiling temperature before adding sodium pertechnetate Tc 99m to the reaction vial.

Immediately following the addition of sodium pertechnetate Tc 99m solution to the reaction vial, withdraw the syringe plunger to a volume of 2 mL, thus removing 2 mL of argon gas and adding 2 mL of filtered air to the vial. The air is required to oxidize excess stannous ion. Remove both needles from the vial.

**NOTE:** The addition of 2 mL air is required to prevent the progressive formation of technetium Tc 99m labeled impurities.

Invert the reaction vial several times to obtain complete mixing.

Immediately transfer the reaction vial to the water bath. Place it inside the lead shield which has been equilibrated to the temperature of the boiling water bath. Allow the reaction vial to incubate for 10 minutes.

**NOTE:** The reaction vial **MUST** be placed in the boiling water bath within 5 minutes of the addition of sodium pertechnetate Tc 99m solution.

Remove the reaction vial from the boiling water bath and place in the lead dispensing shield. Allow the contents of the vial to cool for approximately 15 minutes to reach body temperature. Using proper shielding, the vial contents should be visually inspected.

The solution should be clear and free of particulate matter. If not, the preparation should not be used.

Assay the reaction vial using a suitable radioactivity calibration system. Record the date, time, total technetium Tc 99m activity, volume, and technetium Tc 99m concentration on the radioassay information label and affix the label to the lead dispensing shield.

**The radiochemical purity of the reconstituted solution must be checked prior to administration to the patient. If the radiochemical purity is less than 90%, the product must not be used.**

Store the reaction vial containing the technetium Tc 99m mertiatide at room temperature (15° to 30°C) until use. The technetium Tc 99m mertiatide preparation must be used within six hours of preparation.

#### RECOMMENDED METHOD FOR DETERMINATION OF RADIOCHEMICAL PURITY OF Technescan MAG3™

##### Required Materials:

Waters Sep-Pak™ C18 Cartridges, Part #51910, 200 proof ethanol 0.9% Sodium Chloride Injection, USP 0.001N hydrochloric acid\* 1:1 ethanol/saline solution\*\* Disposable syringes: 10 mL, no needle required 1 mL, with needle Disposable culture tubes or vials, minimum 15 mL capacity Ion chamber for measurement of radioactive samples.

\*May be prepared by diluting 1 mL of 0.10N hydrochloric acid to 100 mL with Water for Injection, USP, or by other appropriate dilution of more concentrated hydrochloric acid. For example, 0.1 mL of 36% (~1.6N) hydrochloric acid diluted to a total volume of 1,150 mL.

\*\*Prepared by mixing equal volumes of the 200 proof ethanol and 0.9% Sodium Chloride Injection, USP.

##### Preparation of Sep-Pak Cartridge

- Using a 10 mL syringe, push 10 mL of 200 proof ethanol through the Sep-Pak cartridge. Discard the eluate.
- Similarly, flush the cartridge with 10 mL of the 0.001N hydrochloric acid. Discard the eluate.
- Drain the cartridge by pushing 5 mL of air through the cartridge with the syringe. Discard the eluate.

##### Sample Analysis

- Apply 0.1 mL of the technetium Tc 99m mertiatide preparation to the head of the cartridge through the longer end of the cartridge using a 1 mL syringe with needle.

**Note:** The cartridge and all solutions eluted from it will be radioactive after this step.

- With a disposable 10 mL syringe, slowly push 10 mL of 0.001N hydrochloric acid through the cartridge. Collect this fraction in a culture tube or vial for counting.
- Similarly, elute the cartridge with 10 mL of the 1:1 ethanol/saline solution. Be sure that this solution is pushed through the cartridge slowly so that the elution occurs in a drop-wise manner. Collect this 10 mL fraction in a second culture tube or vial for counting.
- Place the Sep-Pak cartridge in a third culture tube or vial for counting.

##### Counting

- Assay the activity of the first sample elution in an ion chamber. This fraction contains the hydrophilic impurities (free pertechnetate, technetium tartrate, etc.) and a fraction of reduced-hydrolyzed technetium.

**Technescan MAG3™  
Kit for the  
Preparation of  
Technetium  
Tc 99m Mertiatide**

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2. Assay the activity of the second elution. This fraction contains the technetium Tc 99m mertiatide complex.

3. Assay the activity of the Sep-Pak cartridge in the third culture tube or vial. This component contains the remaining reduced-hydrolyzed technetium and non-elutable impurities.

##### Calculations

1. Percent technetium Tc 99m mertiatide =  $\frac{\text{Activity of 2nd (ethanol/saline) fraction}}{\text{Total activity of all three fractions}} \times 100\%$

2. Percent hydrophilic impurities =  $\frac{\text{Activity of 1st (0.001N HCl acid) fraction}}{\text{Total activity of all three fractions}} \times 100\%$

3. Percent non-elutable impurities =  $\frac{\text{Activity remaining on Sep-Pak cartridge}}{\text{Total activity of all three fractions}} \times 100\%$

This reagent kit is approved for distribution to persons licensed by the U.S. Nuclear Regulatory Commission to use byproduct material identified in Section 35.200 or under an equivalent license of an Agreement State.

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Manufactured by:  
Curium US LLC  
2703 Wagner Place  
Maryland Heights, MO 63043

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R03/2025

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