

PACKAGE INSERT DEVIATION
UPDATED: AUGUST 2010

Lymphoscintigraphy

Deviation:

Prepare Tc-99m Sulfur Colloid with a smaller particle size and dilute it with normal saline for subcutaneous or intradermal administration for lymphoscintigraphy including sentinel node localization for melanoma, vulvar, breast and cervical cancer.

1. Add TcO₄ to sulfur colloid. Add at least 100-175 mCi of TcO₄ to kit vial.
2. Add contents of vial A and mix well.
3. Heat @ approx 100 degrees C for 5 minutes.
4. Cool for 3 minutes, then add the contents of vial B and mix.
5. Heat @ 100 degrees C for 2 minutes and cool to room temperature.
6. Filter 1 mL to 3 mL thru a 0.1 µm Millipore filter into a vented tared, sterile vial. If volume in Step 1 is more than 1 mL, a 0.2 µm filter may be used to minimize final volume. Follow with 0.6 mL of normal saline to wash out dead volume of filter.
7. Weigh filled vial and get volume by assuming density is 1 g/mL.
8. Assay the vial for Tc-99m activity.
9. Add enough normal saline to make the final concentration 4.4 mCi/ml @ administration time. (This is 10% higher than 4 µCi/mL to account for nonspecific adherence of the colloid to the vial and septum.)
10. Determine radiochemical purity (>92%) using ITLC-SG strips with normal saline or acetone.
11. Dispense using 1 ml syringes with 30G, ½ inch needle.
12. Dispense 4 x 200 µCi /0.05 mL doses with enough excess to fill the dead space in the syringe hub and needle (0.08mL), 520 µCi /0.13 mL total. Up to 8 doses may be required for some patients.
13. If patients are scheduled more than 3 hours apart, refilter another 1 mL of product to maintain a concentrated solution and therefore a small volume of dispensed material.

Justification:

There is no FDA-approved radiopharmaceutical for lymphoscintigraphy. Sulfur colloid is less than optimal because of its particle size range. This deviation facilitates the preparation of a product with a smaller average particle size and removes all larger (>0.1 um.) particles. This facilitates faster clearance by the lymphatic system. It provides diagnostic information not otherwise available.

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Lymphoscintigraphy Preparation Documentation

SULFUR COLLOID PREP:

1st boil (5 min) finished @ _____

Vial B added (3 min) @ _____

Rx Label: _____

2nd boil (2 min) finished @ _____

FILTERED:

Assay syringe: _____ mCi @ Time: _____

Mass: _____ gm (= Volume, mL)

Rx Label: _____

Assay vial: _____ mCi @ Time: _____

CALCULATE NORMAL SALINE VOLUME:

Activity @ Administration Time : _____ mCi @ Time _____ (Decay correct vial assay)

Total Volume = Act@ Adm Time / 4.4 mCi/mL = _____ mL

Normal Saline volume = Total Volume - Mass = _____ mL

Normal Saline Lot # _____

QUALITY CONTROL:

Calculate % recover = vial assay / syringe assay x 100% = _____%

Chromatography: ITLC-SG with 0.9% NaCl or Acetone

Origin (Tc SC): _____% (Must be >92%)

Solvent Front
(TcO₄ & Tc EDTA): _____%