

Simplified Reconstitution Recommendations for DRAxIMAGE - MAA Kit

Lot No: 8L262

Expiry Date: 20 OC

Particles/Vial: 4 X 10⁶/vial

Recommendations

The following table shows the amount of ^{99m}Tc-Sodium Pertechnetate that should be added to a vial of MacroAggregated Albumin (MAA, Lot : 8L262) to produce a standardized dose of 350,000 particles and 2.5 mCi (93 MBq) of ^{99m}Tc for a 70 kg adult. Since MAA requires not only a specific amount of ^{99m}Tc but also a specific number of particles, the reconstitution of the kit requires more care. The table assumes that all doses will be used at the same time period. To produce paediatric doses or doses for mixed time periods please refer to the chart on page 4 and the equations on page 5 of the package insert.

To produce doses of 350,000 particles but other than 2.5 mCi (93 MBq) simply adjust the amount of pertechnetate added accordingly. For example to produce a dose of 350,000 particles and 2.0 mCi (74 MBq) at 1 hour post reconstitution add 26 mCi (0.95 GBq) in 8.0 mL, each dose is 0.70 mL.

Delay in Hours Before Use	Reconstitution Recommendation
0	Add 29 mCi (1.06 GBq) in 8 mL. Each dose is 0.70 mL
1	Add 32 mCi (1.19 GBq) in 8 mL. Each dose is 0.70 mL
2	Add 36 mCi (1.33 GBq) in 8 mL. Each dose is 0.70 mL
3	Add 40 mCi (1.49 GBq) in 8 mL. Each dose is 0.70 mL
4	Add 45 mCi (1.67 GBq) in 8 mL. Each dose is 0.70 mL
5	Add 51 mCi (1.88 GBq) in 8 mL. Each dose is 0.70 mL
6	Add 57 mCi (2.11 GBq) in 8 mL. Each dose is 0.70 mL
7	Add 64 mCi (2.36 GBq) in 8 mL. Each dose is 0.70 mL
8	Add 72 mCi (2.65 GBq) in 8 mL. Each dose is 0.70 mL

Note:

- 1) It is not recommended that the vial be reconstituted with saline and that aliquots then be mixed with ^{99m}Tc-sodium pertechnetate in another container.
- 2) It is not recommended that the vial be reconstituted with saline and then frozen. Once reconstituted the maximum shelf life is 8.0 hours
- 3) This table is intended only as a simplification of the Dosage and Administration section in the package insert. There has been no change in the product or in its method of use.

Please Note: This chart is specific for Lot No: 8L262 and should not be used to prepare doses for any other batch.

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Date: <i>2019 JN 03</i>	Date: <i>2019 JN 03</i>