

Simplified Reconstitution Recommendations for DRAXIMAGE® MAA

5 MILLION PARTICLES per VIAL – AUSTRALIA 30000001020

Lot No: 1C267A

Expiry Date: 04/2023

Particles/vial: 5 x 10⁶ / vial

Recommendations

The following table is an example showing the amount of ^{99m}Tc-Sodium Pertechnetate that should be added to a vial of MacroAggregated Albumin of **5 million (5 x 10⁶) particles** to produce a dose of **500,000 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 equations in the **Dosage and Administration** section of the package insert.

Delay in Hours Before Use	Reconstitution Recommendation
0	Add 25 mCi (0.93 GBq) in 8 mL. Each dose is 0.80 mL
1	Add 28 mCi (1.04 GBq) in 8 mL. Each dose is 0.80 mL
2	Add 31 mCi (1.15 GBq) in 8 mL. Each dose is 0.80 mL
3	Add 35 mCi (1.30 GBq) in 8 mL. Each dose is 0.80 mL
4	Add 40 mCi (1.48 GBq) in 8 mL. Each dose is 0.80 mL
5	Add 44 mCi (1.63 GBq) in 8 mL. Each dose is 0.80 mL
6	Add 50 mCi (1.85 GBq) in 8 mL. Each dose is 0.80 mL
7	Add 56 mCi (2.07 GBq) in 8 mL. Each dose is 0.80 mL
8	Add 63 mCi (2.33 GBq) in 8 mL. Each dose is 0.80 mL
9	Add 71 mCi (2.63 GBq) in 8 mL. Each dose is 0.80 mL
10	Add 79 mCi (2.92 GBq) in 8 mL. Each dose is 0.80 mL
11	Add 89 mCi (3.29 GBq) in 8 mL. Each dose is 0.80 mL
12	Add 100 mCi (3.70 GBq) in 8 mL. Each dose is 0.80 mL

To produce doses of 500,000 particles but other than 2.5 mCi (93 MBq) simply adjust the amount of pertechnetate added accordingly. For example to produce a dose of 500,000 particles and 2.0 mCi (74 MBq) at 1 hour post reconstitution add **22 mCi (0.81 GBq)** in 8.0 mL, each dose is 0.80 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 **12.0 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: 1C267A and should not be used to prepare doses for any other batch.

Prepared by: Ali Ait Amir	Approved by: MUSTAPHA TOLLABI M. Tollabi
Date: 20 21 JUN 23	Date: 20 21 JUN 23