Simplified Reconstitution Recommendations for DRAXIMAGE - MAA Kit

6 MILLION PARTICLES per VIAL - CANADA 500150

Lot No:

1L260A

Expiry Date:

2023 - NOV

Particles: 6 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 of **6 million** (6 x 10⁶) **particles** to produce a standardized dose of **350,000 particles** and **93 MBq (2.5 mCi)** 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 **Dosage and Administration** section of the package insert.

Delay in Hours Before Use	Reconstitution Recommendation	
0	Add 1.59 GBq (43 mCi) in 8 mL. Each dose is 0.47 mL	
1	Add 1.78 GBq (48 mCi) in 8 mL. Each dose is 0.47 mL	
2	Add 2.00 GBq (54 mCi) in 8 mL. Each dose is 0.47 mL	
3	Add 2.24 GBq (61 mCi) in 8 mL. Each dose is 0.47 mL	
4	Add 2.51 GBq (68 mCi) in 8 mL. Each dose is 0.47 mL	
5	Add 2.82 GBq (76 mCi) in 8 mL. Each dose is 0.47 mL	
6	Add 3.16 GBq (85 mCi) in 8 mL. Each dose is 0.47 mL	
7	Add 3.54 GBq (95 mCi) in 8 mL. Each dose is 0.47 mL	
8	Add 3.98 GBq (107 mCi) in 8 mL. Each dose is 0.47 mL	

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 **1.42 GBq (38 mCi)** in 8.0 mL, each dose is 0.42mL.

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 <u>not</u> 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: 1L260A and should not be used to prepare doses for any other batch.

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Date :	2021 DE21	Date: 2021 D ∈ 21