Testing Protocol

- Immediately stop the patient infusion and permanently discontinue the use of the affected CardioGen-82 generator if the incorrect eluent is used.

- Use only additive free 0.9% Sodium Chloride Injection USP to dilute the rubidium Rb 82 chloride injection.

- Use the lowest dose necessary, consistent with the goal of as low as reasonably achievable (ALARA); to obtain adequate cardiac visualization.

- Follow the specific indications and restrictions in patient labeling and the CardioGen-82 Infusion System Model 510 Operator's Manual for performing all eluate testing as described.

- Use only additive free 0.9% Sodium Chloride Injection USP to dilute the rubidium Rb 82 chloride injection.

- If using the CardioGen-82 Infusion System Model 510, refer to the Eluate Testing Protocol in Section 2.6, Precautions (5.1), and Warnings and Precautions (5.1) for the appropriate testing.

- If the ratio is not within +/- 2% (0.98 to 1.02), the system requires another calibration elution (steps 1 through 4).

- The intravenous administration of the rubidium chloride solution must be performed only as a single dose.

- The rubidium chloride solution must be used only as a single dose.

- Before administering rubidium Rb 82 chloride injection, perform all necessary tests as described.

- The maximum activity (delivery limits) will decrease on the day of generation due to decay (see Dosage and Administration (2.6)).

- Use the lowest dose necessary, consistent with the goal of as low as reasonably achievable (ALARA); to obtain adequate cardiac visualization.

- Perform additional system calibration every 14 days.

- If the CardioGen-82 Infusion System Model 510 is used, discard the first 50 mL eluate each day the generator is eluted, and employ proper safety techniques.

- For example, 3D image acquisition may require doses at the lower end of the recommended range, compared to 2D imaging where higher doses may be necessary to achieve adequate visualization and lower radiation exposure.

- Use the lowest dose necessary, consistent with the goal of as low as reasonably achievable (ALARA); to obtain adequate cardiac visualization.

- If using the CardioGen-82 Infusion System Model 510, refer to the Eluate Testing Protocol in Section 2.6, Precautions (5.1), and Warnings and Precautions (5.1) for the appropriate testing.

- Use only additive free 0.9% Sodium Chloride Injection USP to dilute the rubidium Rb 82 chloride injection.
Use only additive free 0.9% Sodium Chloride Injection USP to elute the generator. [see Boxed Warning, Contraindications (4), and Warnings and Precautions (5.1)]. CardioGen-82 is contraindicated if a solution other than additive free 0.9% Sodium Chloride Injection USP has been used to elute the generator. [see Boxed Warning, Contraindications (4), and Warnings and Precautions (5.1)].

CardioGen-82 is a closed system used to produce rubidium Rb 82 chloride injection for intravenous use. CardioGen-82 consists of strontium Sr 82 chloride injection, strontium Sr 85 chloride injection, and a Sr 82 and Sr 85 generator. The Sr 82 and Sr 85 generator enables the production of Rb 82 and Rb 85 chloride injection.

1. USE IN SPECIFIC POPULATIONS
1.1 Pregnancy

1.1.1 Human Reproduction

1.1.2 Nursing Mothers

1.2 Pediatrics

1.3 Geriatrics

2. DESCRIPTION

2.1 Active Pharmaceutical Ingredient

2.2 Pharmaceutical Forms

2.3 Chemistry

2.4 Pharmacology

3. CLINICAL PHARMACOLOGY

3.1 Pharmacokinetics

3.2 Pharmacodynamics

3.3 Radiation Dosimetry

3.4 Radiation Exposure with Failure to Follow Eluate Testing Protocol

4. ADVERSE REACTIONS

5.1 Prematurity: Rubidium Rb 82 chloride injection is administered in a dose of 444 MBq (12 mCi) of rubidium Rb 82 chloride injection. The chemical form of Rb 82 is 82RbCl.

5.2 Excess Radiation Exposure with Failure to Follow Eluate Testing Protocol

6.7 Health Care Worker Protection

6.8 Pediatric Use

7. DRUG INTERACTIONS

8.1 Pregnancy

8.2 Lactation

8.3 Nursing Mothers

8.4 Pediatric Use

8.5 Geriatrics

9. INTERACTIONS

10. USE IN SPECIFIC POPULATIONS

11.1.1 Human Reproduction

11.1.2 Nursing Mothers

11.2 Pediatrics

11.3 Geriatrics

12. CLINICAL PHARMACOLOGY

12.1 Pharmacokinetics

12.2 Pharmacodynamics

12.3 Radiation Dosimetry

12.4 Radiation Exposure with Failure to Follow Eluate Testing Protocol

13. ADVERSE REACTIONS

13.1 Prematurity: Rubidium Rb 82 chloride injection is administered in a dose of 444 MBq (12 mCi) of rubidium Rb 82 chloride injection. The chemical form of Rb 82 is 82RbCl.

13.2 Pediatrics

13.3 Geriatrics

14. CLINICAL STUDIES

14.1 Clinical Studies

15. REFERENCES

16. HOW SUPPLIED/STORAGE AND HANDLING

17. PATIENT COUNSELING INFORMATION

18. IMPOTANT SAFETY INFORMATION

18.1 Indications and Methods of Administration and Use

18.2 Storage and Handling

18.3 Precautions for Safe Injection

18.4 Patient Information

18.5 Packet Withdrawal

18.6 Single Use/Single Dose Container

19. PATIENT COUNSELING INFORMATION

19.1 Precautions for Safe Injection

19.2 Special Instructions for Use

19.3 Special Instructions for Use

19.4 Patient Information

19.5 Patient Information

19.6 Packet Withdrawal

19.7 Single Use/Single Dose Container

20. PATIENT COUNSELING INFORMATION

21. HAULING INFORMATION

22. VIRAL AND MYCOBACTERIAL Fungi

23. INFLAMMATORY CONDITIONS

24. RENAL FAILURE

25. MALIGNANCIES

26. SEIZURE DISORDER

27. DIABETES MELLITUS

28. OBSTRUCTIVE HYPERVENTILATION SYNDROME

29. IMMUNE-MEDIATED DISORDERS

30. PULMONARY HYPERTENSION

31. LUNG DISEASES

32. VASCULAR DISEASES

33. CARDIOVASCULAR DISEASES

34. BURN Wounds

35. OTHER THERAPEUTIC AREAS