



**BRACCO  
DIAGNOSTICS**

43-8200

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# **CardioGen-82<sup>®</sup>**

## **Rubidium Rb 82 Generator**

**For Elution of Rubidium Chloride  
Rb 82 Injection**

**Diagnostic: Intravenous**

## DESCRIPTION

Cardiogen-82<sup>®</sup> (Rubidium Rb 82 Generator) contains accelerator produced strontium Sr 82 adsorbed on stannic oxide in a lead-shielded column and provides a means for obtaining sterile nonpyrogenic solutions of rubidium chloride Rb 82 injection. The chemical form of rubidium 82 is <sup>82</sup>RbCl.

The amount (millicuries) of Rb-82 obtained in each elution will depend on the potency of the generator.

When eluted at a rate of 50 mL/minute, each generator eluate at the end of elution should not contain more than 0.02 microcurie of strontium Sr 82 and not more than 0.2 microcurie of strontium Sr 85 per millicurie of rubidium chloride Rb 82 injection, and not more than 1 microgram of tin per mL of eluate.

## PHYSICAL CHARACTERISTICS

Rubidium Rb 82 decays by positron emission and associated gamma emission with a physical half-life of 75 seconds.<sup>1</sup> The annihilation photons released following positron emission which are useful for detection and imaging studies are shown in Table 1.

**TABLE 1**

Principal Radiation Emission Data		
Radiation	Mean Percent Per Disintegration	Mean Energy (keV)
Annihilation photons (2)	191.01	511 (each)

<sup>1</sup>Table of Isotopes, 7th Edition, M. Letterer and V. Shirley.

## External Radiation

The specific gamma ray constant for Rb-82 is 6.1 R/hour-millicurie at 1 centimeter. The first half-value layer is 0.7 centimeter of lead (Pb). A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of a 7.0 centimeter thickness of Pb will attenuate the radiation emitted by a factor of about 1,000.

**TABLE 2**

Radiation Attenuation by Lead Shielding	
Shield Thickness (Pb) cm	Attenuation Factor
0.7	0.5
2.3	10 <sup>-1</sup>
4.7	10 <sup>-2</sup>
7.0	10 <sup>-3</sup>
9.3	10 <sup>-4</sup>

Strontium Sr 82 decays to rubidium Rb 82 with a strontium Sr 82 half-life of 25 days (600 hrs). The Sr-82 is produced in an accelerator by proton spallation of molybdenum, Mo (p, spall) Sr-82 or by the reaction Rb-85 (p, 4n) Sr-82. The Sr-82 produced has no carrier added. To correct for physical decay of strontium Sr 82, the fractions that remain at selected intervals after the time of calibration are shown in Table 3.

**TABLE 3**

Physical Decay Chart: Sr-82 half-life 25 days					
Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	11	0.737	21	0.559
1	0.973	12	0.717	22	0.543
2	0.946	13	0.697	23	0.529
3	0.920	14	0.678	24	0.514
4	0.895	15	0.660	25	0.500
5	0.871	16	0.642	26	0.486
6	0.847	17	0.624	27	0.473
7	0.824	18	0.607	28	0.460
8	0.801	19	0.591	29	0.448
9	0.779	20	0.574	30	0.435
10	0.758				

\*Calibration time

To correct for physical decay of rubidium Rb 82, the fraction of rubidium chloride Rb 82 injection remaining in all 15 second intervals up to 300 seconds after time of calibration are shown in Table 4.

**TABLE 4**

Physical Decay Chart: Rb-82 half-life 75 seconds			
Seconds	Fraction Remaining	Seconds	Fraction Remaining
0*	1.000	165	.218
15	.871	180	.190
30	.758	195	.165
45	.660	210	.144
60	.574	225	.125
75	.500	240	.109
90	.435	255	.095
105	.379	270	.083
120	.330	285	.072
135	.287	300	.063
150	.250		

\*Elution time

### **CLINICAL PHARMACOLOGY**

Following intravenous administration, rubidium Rb 82 rapidly clears the blood and is extracted by myocardial tissue in a manner analogous to potassium. In human studies, myocardial activity was noted within the first minute after injection. When areas of myocardial infarction are detected with rubidium chloride Rb 82 injection, they are visualized within two to seven minutes after injection as photon-deficient or "cold areas" on the myocardial scan. Uptake is also observed in kidney, liver, spleen, and lung.

### **INDICATIONS AND USAGE**

Rubidium chloride Rb 82 injection is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction.

Cardiogen-82 (Rubidium Rb 82 Generator) must be used with an infusion system specifically labeled for use with the generator and capable of accurate measurement and delivery of doses of rubidium chloride Rb 82 injection not to exceed a single dose of 2220 MBq (60 mCi) and a cumulative dose of 4440 MBq (120 mCi) at a rate of 50 mL/min with a maximum volume per infusion of 100 mL and a cumulative volume not to exceed 200 mL. These performance characteristics reflect the conditions of use under which the drug development clinical trials were conducted.

Adequate data from clinical trials to determine precise localization of myocardial infarction or identification of stress-induced ischemia have not been collected.

Positron emission tomographic (PET) instrumentation is recommended for use with rubidium chloride Rb 82 injection.

## **CONTRAINDICATIONS**

None known.

## **WARNINGS**

Caution should be used during infusion as patients with congestive heart failure may experience a transitory increase in circulatory volume load. These patients should be observed for several hours following the Rb-82 procedure to detect delayed hemodynamic disturbances.

## **PRECAUTIONS**

### **General**

Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of rubidium chloride Rb 82 scans. Attention is directed to the fact that rubidium is physiologically similar to potassium, and since the transport of potassium is affected by these factors, the possibility exists that rubidium may likewise be affected.

Rubidium chloride Rb 82 injection must be administered only with an appropriate infusion system capable of meeting the performance characteristics previously described. (See **INDICATIONS AND USAGE**). The drug should be used only by those practitioners with a thorough understanding of the use and performance of the infusion system.

Repeat doses of Rubidium chloride Rb 82 injection may lead to an accumulation of the longer lived radioactive contaminants strontium Sr 82 and strontium Sr 85.

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