

Sodium Chromate Cr 51 Injection

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Diagnostic—For Intravenous Use

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DESCRIPTION

Sodium Chromate Cr 51 ($\text{Na}_2^{51}\text{CrO}_4$) Injection is available for diagnostic use as a sterile, non-pyrogenic solution. Each milliliter contains 3.7 megabecquerels (100 microcuries) chromium Cr51 on the calibration date, and 0.5 milligrams sodium bicarbonate as a buffer. The pH is adjusted to between 7.5 and 8.5 with hydrochloric acid or sodium hydroxide. The specific activity is at least 370 megabecquerels (10 millicuries) per milligram of sodium chromate.

PHYSICAL CHARACTERISTICS

Chromium-51 decays by electron capture with a physical half-life of 27.7 days.¹ The principal photon useful for detection is listed in Table 1.

Table 1: Principal Radiation Emission Data¹

Radiation	Mean Percent Per Disintegration	Energy (keV)
Gamma-1	9.83	320.1

EXTERNAL RADIATION

The specific gamma ray constant for chromium Cr51 is 0.18 R/mCi-hr at 1 cm. The first half-value thickness is 0.17 cm 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 1.68 cm thickness of Pb will decrease the external radiation exposure by a factor of about 1,000.

Table 2: Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.17	0.5
0.56	10^{-1}
1.12	10^{-2}
1.68	10^{-3}
2.25	10^{-4}

To correct for radioactive decay of chromium-51, the fractions that remain at selected time intervals after the date of calibration are shown in Table 3.

Table 3. Physical Decay Chart; Chromium Cr51,
Half-Life 27.7 Days

Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	17	0.654
1	0.975	18	0.637
2	0.951	19	0.622
3	0.928	20	0.606
4	0.905	21	0.591
5	0.882	22	0.577
6	0.861	23	0.562
7	0.839	24	0.549
8	0.819	25	0.535
9	0.798	26	0.522
10	0.779	27	0.509
11	0.759	28	0.496
12	0.741	29	0.484
13	0.722	30	0.472
14	0.704	60	0.223
15	0.687	90	0.105
16	0.670		

*Calibration Time

CLINICAL PHARMACOLOGY

Chromium is present in the hexavalent (plus 6) state, in which form it readily penetrates the red blood cell, attaches to the hemoglobin, and is reduced to the trivalent (plus 3) state. This state is maintained until the red blood cell is sequestered by the spleen, at which time the chromium is released to the plasma and is readily excreted in the urine. In the trivalent state, chromium Cr51 is not re-utilized for tagging of additional red blood cells. Since the product has a high specific activity, adequate red blood cell tagging is secured in minimum time without demonstrable effect on cell life.

INDICATIONS AND USAGE

Sodium Chromate Cr 51 Injection may be used in the determination of red blood cell volume or mass, the study of red blood cell survival time, and evaluation of blood loss.

CONTRAINDICATIONS

None known.

WARNINGS

None known.

PRECAUTIONS

General

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.

In order to preclude or minimize the possibility of contamination and increased fragility of the tagged red blood cells, sterile techniques must be employed throughout the collection, tagging, rinsing, suspending, and injection of red blood cells. Also, the number of washes and transfers should be kept to a minimum, and only sterile, pyrogen-free isotonic diluent should be employed throughout the tagging procedure.

Specific activity should be not less than 370 megabecquerels (10 millicuries) per milligram of sodium chromate at the time of use. Do not use after expiration date stated on label.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis,
Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential, or whether this drug affects fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Sodium Chromate Cr 51. It is also not known whether Sodium Chromate Cr 51 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chromate Cr 51 should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Since Chromium-51 is excreted in human milk during lactation, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

No adverse reactions specifically attributable to the use of this drug have been reported.

DOSAGE AND ADMINISTRATION

The usual dosages in the average adult patient (70 kg) are as follows:

The determination of red blood cell volume or mass: 0.37 to 1.11 megabecquerels (10 to 30 microcuries).

The determination of red blood cell survival time: 5.55 megabecquerels (150 microcuries).

The evaluation of blood loss: 7.4 megabecquerels (200 microcuries).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use if contents are turbid.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

RADIATION DOSIMETRY

The estimated absorbed radiation doses² to an average patient (70 kg) from an intravenous injection of a maximum dose of 7.4 megabecquerels (200 microcuries) of Sodium Chromate Cr 51 are shown in Table 4.

Table 4. Absorbed Radiation Doses

Tissue	Sodium Chromate Cr 51	
	mGy/7.4 MBq	rads/200 µCi
Blood	2.00	0.20
Spleen	26.4	2.64
Testes	0.66	0.066
Ovaries	0.66	0.066
Total Body	0.55	0.055

HOW SUPPLIED

Catalog Number

370 Sodium Chromate Cr 51 Injection is supplied at a concentration of approximately 3.7 megabecquerels (100 microcuries) per milliliter in vials containing approximately 9.25 megabecquerels (250 microcuries) as of the date of calibration. The specific activity is greater than 370 megabecquerels (10 millicuries) per milligram of sodium chromate within the expiration time of the product stated on the label.

372 A-C-D (Anticoagulant-Citrate-Dextrose) Solution (Modified) is supplied in 100-milliliter vials containing 10 milliliters of solution for tagging red blood cells with Sodium Chromate Cr 51. Each milliliter contains 8 milligrams of citric acid (anhydrous), 25 milligrams sodium citrate (dihydrate) and 12 milligrams dextrose (anhydrous). Ratio of ingredients differs from USP Formulas.

STORAGE AND HANDLING

Store at room temperature (below 86°F/30°C).

Storage, handling and disposal of Chromium-51 solutions should be controlled in a manner that is in compliance with the appropriate regulations of the governmental agency authorized to license the use of this radionuclide.

DIRECTIONS FOR USE (TEST PROCEDURE)

NOTE 1: Wear waterproof gloves during the entire red cell tagging procedure and during subsequent patient dose withdrawals.

NOTE 2: Make transfers of Chromium-51 solutions during the tagging procedure and during subsequent injections of radioIabeled blood cells with adequately shielded syringes.

NOTE 3: Maintain adequate shielding of the radioIabeled blood cells by using a lead vial shield and cover.

Various procedures may be employed in performing the diagnostic tests for which Sodium Chromate Cr 51 is indicated. The following outlines specific procedures which may be elected in performing these tests.

Red Cell Volume

The following procedure provides a direct measurement of the red blood cell component, and the whole blood volume is inferred from the venous hematocrit. The plasma chromium-51 radioactivity is excluded by calculation, thereby obviating the aseptic washing of the red blood cells.

Procedure

1. With A-C-D solution from the A-C-D tagging vial, wet a 20-mL syringe and then use the syringe to withdraw 15 mL of blood from the antecubital vein.
2. Slowly and gently (to prevent hemolysis) aseptically inject the contents of the syringe into the vial of A-C-D solution.
3. With a 10-mL syringe aseptically add approximately 3.7 MBq (100 μ Ci) of Sodium Chromate Cr 51 Injection to the blood-A-C-D mixture.
4. Gently mix the blood by intermittent swirling every 5 to 10 minutes. Allow to tag at room temperature for 30 minutes.
5. With a 1-mL syringe aseptically add 30 to 50 mg of suitable ascorbic acid injection to the vial, mix gently, and allow to stand for 5 minutes.
6. After gently mixing, withdraw exactly 10 mL of the tagged red blood cell (RBC) suspension, and inject intravenously into the patient.
7. Determine the hematocrit of the remaining Tagged RBC Suspension (A).
8. Pipet 1 mL of the tagged RBC suspension into a 100-mL volumetric flask and dilute to 100 mL with water. Mix thoroughly and pipet 4 mL into a counting vial. This is the Whole Blood Standard (B).
9. Centrifuge the remaining tagged RBC suspension, and pipet 1 mL of the plasma into a 100-mL volumetric flask, and dilute to 100 mL with water. Mix thoroughly, and pipet 4 mL into a counting vial. This is the Plasma Standard (C).
10. Ten to twenty minutes post-injection withdraw approximately 20 mL of blood from the patient with a sterile, evacuated container containing an anticoagulant.
11. Pipet 4 mL of the whole blood into a counting vial. This is the Patient Whole Blood Sample (D).
12. Remove a sample for a Patient Hematocrit (E) and centrifuge the remaining blood.
13. Pipet 4 mL of plasma into a counting vial. This is the Patient Plasma Sample (F).
14. Count the:
 - Whole Blood Standard (B)
 - Plasma Standard (C)
 - Patient Whole Blood Sample (D)
 - Patient Plasma Sample (F)
 - Background

Subtract background from B, C, D, F. Counting times should be equal and of sufficient length to provide a minimum of 10,000 counts.

Calculations

- A = Hematocrit of Tagged RBC Suspension (step 7)
- B = Net Whole Blood Standard Count
- C = Net Plasma Standard Count
- D = Net Patient Whole Blood Sample Count
- E = Patient Hematocrit (step 12)

F = Net Patient Plasma Sample Count

$$\text{Red Cell Volume (mL)} = \frac{[B - C(1 - A)]E}{D - F(1 - E)} \times 1000$$

$$\text{Whole Blood Volume (mL)} = \frac{\text{Red Cell Volume (mL)}}{\text{Patient Hematocrit}}$$

$$\text{Plasma Volume (mL)} = \text{Whole Blood Volume (mL)} - \text{Red Cell Volume (mL)}$$

Red Cell Survival

Procedure:

1. With A-C-D solution from the A-C-D tagging vial, wet a 20-mL syringe and then use the syringe to withdraw 15 mL of blood from the antecubital vein.
2. Slowly and gently (to prevent hemolysis) aseptically inject the contents of the syringe into the vial of A-C-D solution.
3. With a 10-mL syringe aseptically add approximately 7.4 MBq (200 μ Ci) of Sodium Chromate Cr 51 Injection to the blood-A-C-D mixture.
4. Gently mix the blood by intermittent swirling every 5 to 10 minutes. Allow to tag at room temperature for 30 minutes.
5. Withdraw 20 mL of the tagged RBC suspension and inject intravenously into the patient.
6. At 24 hours post injection and every 2 to 3 days thereafter for a minimum of 30 days or until a half-time is reached, withdraw 10 mL of blood into a sterile, evacuated container containing an anticoagulant. Determine the hematocrit of each sample.

NOTE: Each sample should be labeled with the date and time of withdrawal. Each withdrawal should be at approximately the same time each day. Frequency of sampling depends primarily on convenience. For statistical accuracy a minimum of 10 samples should be obtained.

7. Pipet 4 mL of each sample into a counting vial and label accordingly.
8. Count all samples at the same time to negate the effect of radioactive decay. Count and subtract background.

Calculations

The calculations are based on using the 24-hour sample as 100% and making it the starting point. All other samples are calculated as a percent of the 24-hour sample, and indicate the percent remaining. If later samples have hematocrits different from the 24-hour sample, the correction below should be made.

$$\% \text{Remaining} = \frac{\text{Net Whole Blood Count (each sample)}}{\text{Net Whole Blood Count (at 24 Hours)}} \times \frac{\text{Hematocrit (at 24 hours)}}{\text{Hematocrit (each sample)}} \times 100$$

As indicated, the above calculation should be made on each sample individually. Upon completion of the calculation, the percent remaining should be plotted on the logarithmic scale against time on semi-logarithm paper. Draw a best-fit straight line through the points. The red cell survival time is determined from the graph by finding the time at which the straight line reached 50 percent.

Normal Range: Normal 28 to 40 days
Abnormal Less than 28 days

The U.S. Nuclear Regulatory Commission has approved distribution of this radiopharmaceutical to persons licensed to use byproduct material listed in Section 35.100, and to persons who hold an equivalent license issued by an Agreement State.

¹ Kocher, David C., "Radioactive Decay Tables," DOE/TIC-11026, page 74 (1981).

² Method of Calculation: "S" Absorbed Dose per Unit Cumulated Activity for Selected Radionuclides and Organs, MIRD Pamphlet No. 11 (1975).

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