Store at controlled room temperature 20-25°C (68-77°F).

INDICATIONS AND USAGE
Sodium Chromate Cr 51 Injection may be used in the determination of red blood cell volume or mass, and evaluation 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, mixing, suspending, and injection of red blood cells. Also, the number of washes and transfers should be kept to a minimum, and only sterile, non-pyrogenic isotonic diluent should be employed throughout the tagging procedure.

Nuclear medicine procedures involving withdrawal and reinjection of blood have the potential for transmission of blood borne pathogens. Procedures should be implemented to avoid administration errors and viral contamination of personnel during blood product labeling. A system of checks similar to the ones used for administering blood transfusions should be routine.

Specific activity should not be less than 370 megabecquerels (10 milligrams) 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 personnel who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and who have experience and training have been approved by the appropriate governmental 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 Cr 51 is excreted in human milk during lactation, formula feedings should be substituted for breast feedings.

Pediatric Use
Safety and effectiveness in pediatric patients has not been established.

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

DOSEAGE 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 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 dose 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.

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 milli- curies) per milligram of sodium chromate within the expiration time of the product stated on the label.

372 A-C-D (Anticoagulant-Citrates-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 (anthyrox), 25 milligrams sodium citrate (dihydrate) and 12 milligrams dextrose (anhydrous). Ratio of ingredients differs from USP Formulas.

STORAGE AND HANDLING
Store at controlled room temperature 20-25°C (68-77°F).

Storage, handling and disposal of Chromium Cr 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 Cr 51 solutions during the tagging procedure and during subsequent injections of radiolabeled blood cells with adequately shielded syringes.

NOTE 3: Maintain adequate shielding of the radiolabeled 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.


Table 1: Principal Radiation Emission Data

Table 2: Shield Attenuation by Lead Shielding

Table 3: Physical Decay Chart; Chromium Cr 51, Half-Life 27.7 Days

Table 4. Absorbed Radiation Doses

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Sodium Chromate Cr 51</th>
</tr>
</thead>
<tbody>
<tr>
<td>mGy/7.4 MBq</td>
<td>rad/200 μCi</td>
</tr>
<tr>
<td>Blood</td>
<td>2.00</td>
</tr>
<tr>
<td>Spleen</td>
<td>29.4</td>
</tr>
<tr>
<td>Testes</td>
<td>0.66</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.66</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.55</td>
</tr>
</tbody>
</table>

To correct for radioactive decay of chromium Cr 51, the fractions that remain at selected time intervals after the date of calibration are shown in Table 3.
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 Cr 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 syringes into the vial of A-C-D solution.

3. With a 10-mL syringe aseptically add approximately 3.7 MBq (100 μCi) 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.

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

Hematocrit (each sample)

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-logarithmic 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.

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Mallinckrodt Inc.

St. Louis, MO 63134

MALLINCKRODT

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

Red Cell Volume (mL) = Patient Hematocrit

Whole Blood Volume (mL) = Patient Hematocrit

Plasma Volume (mL) = Whole Blood Volume (mL) - Red Cell Volume (mL)