BRACCO DIAGNOSTICS

ACD-P00

BRACCO A-C-D SOLUTION MODIFIED™

Anticoagulant Citrate Dextrose Solution Modified

DESCRIPTION

Bracco A-C-D Solution Modified (Anticoagulant Citrate Dextrose Solution Modified) is for use in the radioisotopic labeling of red blood cells with chromium 51 for intravenous administration. Each reaction vial contains 80 mg citric acid, 224 mg anhydrous sodium citrate, and 120 mg anhydrous dextrose in a sterile, nonpyrogenic aqueous 10 mL solution; pH has been adjusted between 4.5 to 5.5. The formula differs from Anticoagulant Citrate Dextrose Solution USP in the ratio of ingredients.

CLINICAL PHARMACOLOGY

In vitro, citrate ions combine with ionic calcium in the blood; the resulting lack of ionic calcium prevents coagulation.

Blood treated with citrate anticoagulants is nontoxic to the body when injected in small amounts intravenously. After injection, citrate ions are rapidly removed from the blood by the liver, polymerized into glucose, and then metabolized in the usual manner.

INDICATIONS AND USAGE

Bracco A-C-D Solution Modified is indicated for use with Chromitope® Sodium (Sodium Chromate Cr 51 Injection) in the labeling of red blood cells for intravenous administration and *in vitro* diagnostic tests.

CONTRAINDICATIONS

None known.

PRECAUTIONS

General

In order to obviate or minimize the possibility of contamination and of increased fragility of the labeled red blood cells, sterile techniques should be employed throughout the collection, labeling, rinsing, suspending, and injection of red blood cells. In addition, the number of washes and transfers should be kept to a minimum and only sterile, nonpyrogenic isotonic diluent should be employed throughout the labeling procedure.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential, or whether this anticoagulant solution may impair fertility in males or females.

Pregnancy: Teratogenic Effects

Category C. Animal reproduction studies have not been conducted with Anticoagulant Citrate Dextrose Solution Modified. It is also not known whether this anticoagulant solution can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. A suspension of chromium 51-labeled red blood cells containing Sodium Chromate Cr 51 Injection and Bracco A-C-D Solution Modified (Anticoagulant Citrate Dextrose Solution Modified) should be administered to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether the components of this anticoagulant are excreted in human milk. Since this anticoagulant may be a component of a chromium 51-labeled red blood cell suspension, caution should be exercised when Bracco A-C-D Solution Modified is administered to a nursing woman. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety of the chromium 51-labeled suspension of red blood cells in children has not been established.

ADVERSE REACTIONS
None known.

DOSAGE AND ADMINISTRATION
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

It is essential that the user adhere to strict aseptic procedures during the preparation, withdrawal and administration of the labeled red blood cells. Waterproof gloves are to be worn during the labeling procedure to prevent the possibility of radioactive contamination of the hands. Shielded syringes should be used when adding the Chromitope Sodium (Sodium Chromate Cr 51 Injection USP) to the reaction vial and for the withdrawal and administration of the labeled red blood cells. To maintain adequate shielding during the life of the labeled preparation, a lead vial shield and lead cover must remain in place on the reaction vial.

Red Blood Cell Labeling Procedure
Labeling may be performed without washing or centrifugation steps directly in the silicone-coated reaction vial.

A 30 to 50 mL sample of whole blood is withdrawn from the patient and added aseptically to a vial of Bracco A-C-D Solution Modified (Anticoagulant Citrate Dextrose Solution Modified). 50 to 150 microcuries of Chromitope Sodium is then injected into the reaction vial using a shielded syringe. The amount of radioactivity added to the vial will depend on the intended use of the labeled red blood cells. The suspension is incubated for 30 to 60 minutes at room temperature with frequent gentle agitation. After incubation, 100 mg Ascorbic Acid Injection USP is injected into the vial. The ascorbic acid reduces any remaining unbound dianionic chromium 51 to the anionic state which does not penetrate red blood cells; thus *in vivo* labeling of red blood cells is prevented.

The extent of chromium 51 labeling is influenced by hematocrit values; hematocrits below 35 percent will result in a higher degree of labeling; whereas hematocrits exceeding 45 percent will produce the opposite result. Although the rate of labeling is initially more rapid at 37°C, samples incubated at 37°C and room temperature will show the same degree of Chromium 51 labeling after a 30-minute period.

Labeling may also be accomplished by centrifugation and washing techniques which are described in the literature.

The admixture of Bracco A-C-D Solution Modified with Chromitope Sodium (Sodium Chromate Cr 51 Injection) for use as a stock solution is not recommended. For best results, the whole blood sample should be combined with Bracco A-C-D Solution Modified prior to labeling.

The uses of red blood cells labeled with chromium 51 are described in the package insert accompanying Chromitope Sodium (Sodium Chromate Cr 51 Injection).

HOW SUPPLIED

Bracco A-C-D Solution Modified (Anticoagulant Citrate Dextrose Solution Modified) is supplied in packages of ten 75 mL capacity silicone-coated reaction vials each containing 10 mL anticoagulant solution.

Storage

Store the product as supplied at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F) [See USP Controlled Room Temperature].

Disposal

Any unused portion of the labeled preparation must be stored and disposed of in accordance with the conditions of NRC radioactive material license pursuant to Agreement State Regulation.

Rx only

Manufactured for:
Bracco Diagnostics Inc.
Princeton, NJ 08543

Manufactured by:
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Bedford, OH 44146

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