

READS COAGULATION CONTROL 2

READS Coagulation Control 2 (CC-2) is an assayed control plasma for *in vitro* diagnostic use in coagulation studies.

PRINCIPLE OF THE PROCEDURE

Coagulation Control 2 is tested in the same manner as citrated patient plasma samples to assess the performance of each assay run, for the parameters listed on the reverse side. Testing variables in each laboratory, including equipment, reagents, and technique may influence control recovery. Although an expected range is provided for each parameter, laboratories should establish their own expected range for their particular instrument-reagent system.

REAGENT

Contents: lyophilized pool of citrated human plasma from healthy donors, with stabilizers, to be reconstituted with 1.0 mL deionized water.

Precautions:

- CC-2 has been tested and found negative for HBsAg, HIV-I/II, and HCV antibodies. However, all human blood derivatives, including patient samples, should be treated as potentially infectious.
- Signs of deterioration: the unreconstituted material should appear as a light yellow, dry plug or straw-colored pieces. Notify manufacturer before use if appearance of product has changed.

Instructions for use:

Reagent preparation: reconstitute with 1.0 mL of deionized water. Swirl gently to mix. Allow to stand 10 minutes before use for complete dissolution.

Storage and stability: lyophilized product is stable until expiration date printed on the vial, when stored at 2 - 8°C; reconstituted product is stable for 4 hours when maintained at 2 - 8°C.

PERFORMANCE CHARACTERISTICS:

Assayed values for the various coagulation parameters should be used as a guideline. Reagents from Corgenix, Inc. or Helena Laboratories were used to assign values, against World Health Organization standards, where available. For best results, each laboratory should establish mean values and expected ranges for their own particular coagulation system.

manufactured for:



12061 Tejon Street
Westminster, Colorado 80234 USA

manufactured by:
Helena Laboratories
Beaumont, Texas 77704 USA

READS COAGULATION CONTROL 2

PRODUCT NO: 702-001

LOT:

EXP:

| Test | Procedure | Control value (mean) | Range |
|----------------------------------|------------------------------------|-------------------------|-------|
| Protein C | READS ELISA | | |
| Protein S, Total | READS ELISA | | |
| Protein S, Free | READS ELISA / PEG method | | |
| Protein S, Free Monoclonal | READS Monoclonal ELISA | | |
| von Willebrand Factor Antigen | READS ELISA | | |
| Prothrombin Time | One-stage method | | |
| Partial Thromboplastin | One-stage method | | |
| Fibrinogen | Functional (Clauss) | | |
| Factor II | One-stage method | | |
| Factor V | One-stage method | | |
| Factor VII | One-stage method | | |
| Factor VIII | One-stage method | | |
| Factor VIII | Kinetic / endpoint | | |
| Factor IX | One-stage method | | |
| Factor X | One-stage method | | |
| Factor X | Kinetic / endpoint | | |
| Factor XI | One-stage method | | |
| Factor XII | One-stage method | | |
| Plasminogen | Immunological - RID | | |
| Plasminogen | Kinetic / endpoint | | |
| Antithrombin III | Immunological - RID | | |
| Antithrombin III | Kinetic / endpoint | | |
| Ristocetin Cofactor | Helena PACKS-4 aggregometer | | |
| von Willebrand Factor Antigen | Laurell Rocket EID | | |
| Protein C | Laurell Rocket EID | | |
| Protein C | Kinetic / endpoint | | |
| Protein S, Total | Laurell Rocket EID | | |
| Protein S, Free | Laurell Rocket EID / precipitation | | |
| α_2 -Antiplasmin | Kinetic / endpoint | | |

