

# PLASMAREF ARN

ASSAYED REFERENCE NORMAL PLASMA



## INTENDED USE

**PlasmaRef ARN** is an assayed reference normal plasma for use in the quantitative determination of coagulation proteins.

## SUMMARY AND PRINCIPLES

Fresh pooled normal plasma or assayed reference normal plasma is necessary to construct the standard curve(s) in assay(s) that quantify the activity of coagulation factor(s) in patient plasmas. **PlasmaRef ARN** can be used to construct the standard curves of activity assays, or as a normal plasma validator for such curves.

The coagulation factor activities of **PlasmaRef ARN** are assigned against a freeze dried assayed standard, a fresh frozen normal pool, and, for most analytes, a World Health Organization standard. PlasmaRef ARN has assigned values for fibrinogen, FII, FV, FVII, FVIII, FIX, FX, FXI, FXII, AT-III (functional), Plasminogen (chromogenic and immunologic), Protein C (chromogenic, clotting, and immunologic), Protein S Total antigen (immunologic), Protein S Free antigen (immunologic), Protein S activity (clotting), and alpha-2 antiplasmin (chromogenic).

PlasmaRef ARN is used in factor assays and other tests in the same manner as a fresh plasma.

## REAGENTS

### FOR IN-VITRO DIAGNOSTIC USE ONLY

**Ingredients:** **PlasmaRef ARN** is prepared from a pool of frozen citrated normal plasmas from healthy donors. The pool is buffered and lyophilized to maximize stability of all plasma constituents. PlasmaRef ARN is packaged as 10 x 1 mL vials.

**WARNING: Potential Biohazard:** The **PlasmaRef ARN** has been found negative for Hepatitis B Antigen (HBsAg) and antibodies to HCV and HIV by FDA licensed tests. The control plasma should be handled with the same precaution observed when handling potentially infectious patient plasmas.

**Preparation for Use:** Reconstitute each vial of **PlasmaRef ARN** with 1.0 mL of distilled or deionized water. Swirl gently; do not shake. Allow product to stand for 15 minutes to insure complete dissolution.

**Storage and Stability:** Store unopened vials at -25C or below. The lyophilized **PlasmaRef ARN** is stable until the expiration date printed on the vial, the box and the certificate of analysis. After reconstitution, the product is stable for two hours when maintained at 2-8°C. Do not place reconstituted **PlasmaRef ARN** directly on ice.

## INSTRUMENTS

**PlasmaRef ARN** may be used for coagulation tests on any mechanical or photo-optical coagulation instrument in conjunction with suitable commercial reagents. Chromogenic assays may be performed on any suitable spectrophotometric instrument.

## LIMITATIONS

The results obtained with **PlasmaRef ARN** depend on several factors including instrumentation, types of reagents, factor deficient substrates and laboratory-to-laboratory variations. For optimum results, laboratories should establish mean values and expected reference ranges for their particular laboratory's coagulation system.

## REFERENCE VALUES AND PERFORMANCE CHARACTERISTICS

The assayed percent activities of the various coagulation factors should be taken from "Control Value" column as a guideline. It is recommended that **PlasmaRef ARN** be run daily in duplicate according to instructions given in a particular laboratory. The laboratory should establish an expected QC range for the particular instrument-reagent system used. If the product does not perform as expected, the patient results should be considered invalid. The lot number printed on the Certificate of Analysis should be the same as that on the vial of **PlasmaRef ARN** to be used.

