

PLASMAREF ARL-2

ASSAYED REFERENCE CONTROL LEVEL-2



INTENDED USE

PlasmaRef ARL-2 is an assayed reference abnormal 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 ARL-2** is used as an abnormal plasma validator for such curves.

The coagulation factor activities of **PlasmaRef ARL-2** are assigned against a freeze dried assayed standard, a fresh frozen normal pool, and, for most analytes, a World Health Organization standard. **PlasmaRef ARL-2** 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 ARL-2 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 ARL-2** 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 ARL-2** is packaged as 10 x 1 mL vials.

WARNING: Potential Biohazard: The **PlasmaRef ARL-2** 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 ARL-2** 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 ARL-2** 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 ARL-2** directly on ice.

INSTRUMENTS

PlasmaRef ARL-2 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 ARL-2** 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 ARL-2** 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 ARL-2** to be used.

