gernon

HEMOTROL N
Normal Control Plasma

	Manufacturer: RAL, TÉCNICA PARA EL LABORATORIO, S.A. **Av. Mare de Déu de Montserrat 51** **08970 Sant Joan Despí – Barcelona (SPAIN)**
IVD	**FOR IN VITRO DIAGNOSTIC**
	STORE AT 2-8°
	READ INSTRUCTIONS

REF	Cont.
Reference:	Presentation:
GN 1100	6 x 1 ml

INTENDED USE:
HEMOTROL N control plasma is intended for use in quality assurance of in vitro diagnostic coagulation tests. The reagent is suitable for use as a normal coagulation control time in the one-stage prothrombin time (PT) assay and in the activated partial thromboplastin time (APTT) assay. The Fibrinogen concentration is also establish in the control.

REAGENT:
HEMOTROL N is a lyophilised preparation of human plasma containing buffers and stabilisers.

PRECAUTIONS:
Do not ingest
Avoid contact with skin, eyes or clothing.
WARNING: POTENTIAL BIOHAZARDOUS MATERIAL.
The source material for this product has been tested and found negative for the presence of HIV and HCV antibodies as well as Hepatitis B Surface Antigen by approved test methods. However, no known test method can offer assurance that products derived from human blood are free of infectious agents. Therefore, handle this material observing the same safety precautions employed when handling any potentially infectious material.

REAGENT PREPARATION:
Reconstitute HEMOTROL N with 1.0 ml of distilled water.
Replace the stopper and gently mix the vial to thoroughly disperse the contents. Let stand at room temperature for no less than 30 minutes before use to assure complete rehydration of the contents.

STORAGE AND STABILITY:
The reconstituted plasma control is stable for 6 hours when stored refrigerated (2 to 8°C) in the original container.

PROCEDURE:
HEMOTROL N is tested in the same manner as freshly drawn citrated patient plasma in prothrombin time test and activated partial thromboplastin times. Refer to the appropriate product inserts for test specific instructions.

LIMITATIONS:
HEMOTROL N, when properly used, is subject to the limitations of the assays system employed. Results outside of the reference range may indicate product deterioration or problems with one or more components of the test system.

RESULTS:
Influences such as reagent type, ISI value of the PT reagent, methodology, instrumentation and technique contribute to variation in test result. Each laboratory should establish its own acceptance ranges with each new lot of plasma control.
HEMOTROL N will typically yield results within the range specified in the following table, for most PT and APTT assays.

Coagulation test	Normal clotting time (seconds)
Prothrombin Time (PT) ISI 1.0 – 1.4	11 – 16
Prothrombin Time (PT) ISI 1.7 – 2.2	11 – 14
Activated Partial Thromboplastin Time (APTT)	24 - 39
Fibrinogen concentration	250-350 mg/dl

The coefficient of variation (CV) for prothrombin time (PT) and activated partial thromboplastin time (APTT) tests performed on the HEMOTROL N has been shown to be less than 5% in intra-laboratory studies. However, precision characteristics will vary depending on the instrumentation and reagent system used.

The results are shown in the following table:

	PT Precision	APTT Precision
Within-run (n=20)	± 1.1 % CV	±2.3 % CV
Day to day (5 days)	±1.5 % CV	±1.8 % CV

BIBLIOGRAPHY

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RAL Técnica para el laboratorio, S.A.

TÜV
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