# BioMed- PLASMATROL H-I/II

**REF:** QC205010 ( 1ml )

## INTENDED FOR USE:
Normal and Abnormal Control Plasmas for Coagulation Assays

## PRINCIPLE:
The properties of the control plasma are similar to those of pooled fresh plasmas. Since the plasma controls have assigned values, when substituted in place of a sample, in clot based coagulation assays, they can be used Laboratory Quality Assurance.

## SPECIMEN COLLECTION:
BioMed-**PLASMATROL H-I** and BioMed-**PLASMATROL H-II** are two level human plasma controls that are suitable for use as normal and abnormal control plasma for **PT, APTT** and Fibrinogen testing using clot based methods. Coagulation controls provide a means of day to day quality control in the hemostasis for accuracy and precision

## REAGENT COMPOSITIONS :
BioMed-**PLASMATROL** is a stabilized and freeze dried preparation of selected human plasma with values determined and assigned for specific clot based tests, which are lot specific. The plasma controls are assayed using coagulation reagents.

## PACKAGE: Collection and storage.
Unopened vials should be stored at 2-8°C and are stable up to the expiry date mentioned on the vial labels.
After reconstitution the shelf life of the control plasma is 3 hours at 25-30°C and 8 hours when stored at 2-8°C.

## PRECAUTIONS & WARNING :
Avoid pipetting with mouth.
The preparation, according to current regulation, is classified as not dangerous.
The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.
Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes.
The samples must be handle as potentially infected from HIV or Hepatitis

## REAGENT PREPARATION & STABILITY :
- Reconstitute the control plasma with exactly 1 ml of bi distilled water. Avoid using water containing preservatives.
- Re-stopper the vial and allow to stand until, the hydration is complete (usually 5-7 minutes).
- Mix by gently swirling and inversion, avoiding froth formation. Do not shake.
- Allow to stand and equilibrate for a further 15 minutes before use.
- Use the reconstituted plasma within 3 hours of reconstitution.

## REQUIRED MATERIALS NOT PROVIDED:
General Laboratory Equipment and instrumentations.

## PROCEDURE:
1. Use the reconstituted BioMed **PLASMATROL** control in the same manner as freshly prepared citrated Platelet Poor Plasma from a patient.
2. Use the procedure as laid out in the Liquiplastin, Liquicelin-E, Fibrinogen, **FDP** pack inserts.

## EXPECTED VALUE:
1. The expected value of specific assays are provided on the assay value sheet accompanying each kit, and are lot specific.
2. The expected values are obtained using replicate assay of each manufactured lot of BioMed-**PLASMATROL**, manually and using mechanical coagulometers
3. The individual laboratory values should fall within the expected values.

## WASTE DISPOSAL:
The disposal of the product must be in accordance with local regulation concerning waste disposal.

## QUALITY CONTROL:

| BioMed-PLASMATROL H-I | LOT: 309608 | EXP: 9/2018 |
|---|---|---|

| Prothrombin Time Test | | | | |
|---|---|---|---|---|
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **LIQUIPLASTIN** | **Seconds** | **12.9** | **10.35-15.45** |
| **(c)** | **Liquiplastin-S** | **Seconds** | **12.25** | **9.8-14.7** |

| Activated Partial Thromboplastin Time Test | | | | |
|---|---|---|---|---|
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **Liquicellin -E** | **Seconds** | **41** | **31.0 - 51.0** |
| **Fibrinogen Assay** | | | | |
| **I** | **Thrombin Time Test** | | | |
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **Fibroscreen** | **Seconds** | **7.25** | **5.5-9.0** |
| **II** | **Fibrinogen Quantification Assay** | | | |
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **Fibroquant** | **mg/dl** | **275** | **206.5-343.5** |

| BioMed-PLASMATROL H-II | LOT: 310609 | EXP9/2018 |
|---|---|---|

| Prothrombin Time Test | | | | |
|---|---|---|---|---|
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **LIQUIPLASTIN** | **Seconds** | **22.5** | **17.5-27.5** |
| **(c)** | **Liquiplastin-S** | **Seconds** | **20.5** | **16.0-25.0** |

| Activated Partial Thromboplastin Time Test | | | | |
|---|---|---|---|---|
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **Liquicellin -E** | **Seconds** | **70.5** | **56.0-85.0** |
| **Fibrinogen Assay** | | | | |
| **I** | **Thrombin Time Test** | | | |
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **Fibroscreen** | **Seconds** | **8.0** | **6.3-9.7** |
| **II** | **Fibrinogen Quantification Assay** | | | |
| **Sr. No** | **Reagent** | **UNIT** | **MEAN** | **RANGE** |
| **(a)** | **Fibroquant** | **mg/dl** | **175** | **131-219** |

## PERFORMANCE:

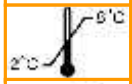

1. W.H.O. Technical Series, 687, 1983.
2. Human Blood Coagulation, Hemostasis and Thrombosis; Edited by Rosemary Biggs, Blackwell Scientific Publications,1972


## LIMITATIONS :

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The source material used for preparation of the reagent is screened by third generation assays for HBsAg, HCV and HIV antibodies and is found to be non-reactive. However handle the material as if it is infectious, as no known test method can assure that infectious agents are absent.

## REFERENCES:

1. When used appropriately, BioMed-PLASMATROL controls are subjected to the limitations of the assay system deployed.
2. If proper values are not obtained it may indicate problems with one or more variables of the assay system.
3. Stability of the reagent is dependent on storage and handling conditions. Since these can vary between laboratories, each laboratory should determine the stability of the reagent under usual operating conditions.
4. Incorrect mixing of control plasma and reagent, insufficient preparation of plasma/reagent, contaminated reagents and glassware etc. are a potential source of error.
5. Due to inter laboratory variations in techniques, standardization of test procedures and calibration of equipments, some variation from assigned mean values may be expected.

| | |
|---|---|
|  | Consult Instructions for Use |
|  | Caution, Consult accompanying Documents |
| IVD | In Vitro Diagnostic Medical Device |
|  | Temperature Limitation |
|  | Manufacturer |
| EC REP | Authorized Representative in the European Community |
| REF | Catalogue Number |
| LOT | Batch Code |
|  | Use by |


**EGY- CHEM** for lab technology
Badr City, Industrial Area Piece 170
250 Fadan In East of Elrubaki, Cairo, EGYPT
Tel: +202 26236727 / +202 26236598
Fax: +202 26240986
www.egy-chem.com

CE
EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany