

**CONTROL PLASMA NORMAL
CONTROL PLASMA – ABNORMAL LEVEL 1
CONTROL PLASMA – ABNORMAL LEVEL 2**



**COAGULATION CONTROL PLASMA
(LYOPHILISED)**

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| CONTROL PLASMA NORMAL | 10 x 1 ml | Cat. No K-100 |
| CONTROL PLASMA – ABNORMAL LEVEL 1 | 10 x 1 ml | Cat. No K-101 |
| CONTROL PLASMA – ABNORMAL LEVEL 2 | 10 x 1 ml | Cat. No K-102 |

Control plasmas are processed from human plasma collected with <0.4% sodium citrate anticoagulant.

They are intended for use as controls to monitor the performance of routine coagulation assays.

CONTROL PLASMA NORMAL LEVEL use as a control in PT, APTT, TT and fibrinogen determinations.

CONTROL PLASMA-ABNORMAL LEVEL 1 and LEVEL 2 use as a control in PT, APTT and fibrinogen determinations.

Control plasmas should be tested in conjunction with patient plasmas in accordance with instructions accompanying PT, APTT and fibrinogen assays.

RECONSTITUTION

Open the vial carefully and add exactly 1 ml of distilled water, close bottle and let stand undisturbed for 15 minutes at room temperature. Do not invert vial or mix vigorously. Use only after complete reconstitution.

STABILITY AND STORAGE

1. Lyophilised plasmas remains stable when stored at 2-8°C until expiry date given on the product label.
2. The reconstituted plasmas are stable for 8 hours when stored in capped vial at 2-8°C.

EXPECTED VALUES

Values for CONTROL PLASMANORMAL are expected to be normal (for APTT, PT, TT and fibrinogen assays).

Values for CONTROL PLASMA–ABNORMAL LEVEL 1 and LEVEL 2 are expected to be abnormal (for APTT, PT and fibrinogen assays).

Assay values are provided for each lot.

However, actual results depend largely on the standard, reagents, instrument, and individual laboratory protocols in use.

Each laboratory should evaluate these products with their reagent system and methodology to establish acceptable limits.

NOTES

- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Each unit of source material used in the preparation of this product has been tested and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. This product should be handled as potentially infectious biological material.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. NCCLS: One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline. NCCLS document H47-A. NCCLS, Wayne, PA, 1996.
2. NCCLS: Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays. 2nd edition. Approved guideline. NCCLS Document H21-A3. Wayne, PA, 1998.

MANUFACTURER

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