Coagulation Controls IVD
Level I & II

PRODUCT CODE
CR004
CR005
CR006

INTENDED USE
Bio Research Coagulation Controls Level I and II are lyophilized human plasma, used to evaluate the precision, and the accuracy of PT, APTT and Fibrinogen determination in human plasma.

PRINCIPLE
The properties of control plasma are similar to those of pooled fresh plasma. Since the plasma controls have assigned values, when substituted in place of sample, in clot based coagulation assays, they can be used for day to day Laboratory quality assurance.

REAGENT
Bio Research Coagulation Controls are stabilized and freeze dried preparation of selected human plasma with vale determined and assigned for specific clot based tests, which are lot specific. These controls are assayed using Bio Research Coagulation reagents.

REAGENT STORAGE AND STABILITY
Unopened vials of control should be stored at 2-8ºC and are stable upto the expiry date mentioned on the labels. After reconstitution the shelf life of the control plasma is 3 hours at 25-30ºC and 8 hours when stored at 2-8ºC.

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

PREPARATION OF THE REAGENT
1. Reconstitute control plasma with stated volume of distilled water. Avoid water containing preservative.
2. Re-stopper the vials and allow to stand until the hydration is complete (usual 5-8 minute)
3. Mix gently by swirling and inversion, avoiding forth formation. Do not shake.
4. Allow to stand and equilibrate for a further 20 minutes before use.
5. Use the reconstituted control plasma within 3 hours after reconstitution.

TEST PROCEDURE
1. Use the reconstituted control plasma in the same manners as freshly prepared citrated Platelet Poor Plasma from a patient.
2. Use the procedure detailed in the BioClot-PT and BioClot APTT pack inserts.

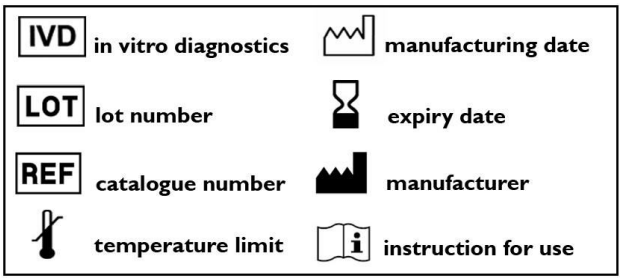
EXPECTED VALUE
1. The expected value of specific assays is provided on the assay value sheet accompanying with the kit, and are lot specific, instrument specific.
2. The expected values are obtained using replicate assay of each manufactured lot of Bio Research Coagulation Control manually.
3. The individual laboratory values should fall within the expected values.
4. It must however be noted that each laboratory should establish its own normal value and reference range according to GLP.

REMARKS
1. Stability of the reagent is depending on the storage and handling conditions. Since these can vary between laboratories, each laboratory should determine the stability of the reagent under usual operating conditions.
2. When used appropriate, Coagulation controls are subjected to limitations of the assay system deployed.
3. If proper value are not obtained it may indicate problems with one or more variables of the assay system.
4. Incorrect mixing of control and reagent, insufficient preparation of plasma reagent, contaminated reagents and glassware etc. are potential sources 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.

PERFORMANCE CHARACTERISTICS
Bio Research Coagulation Control I and II should give value within the range mentioned in the accompanying assay value sheet, under the described assay conditions with respective reagents. An internal evaluation demonstrated within run precision of less than 5% when coagulation Control I and II were tested with the reagents described in the assay value sheet. The test was performed on Coagulometer Hemostar-XF.

WARRANTY
This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

SYMBOL ON LABELS



BIBLIOGRAPHY

1. Dacie and Lewis, Practical Hematology, Ninth edition.
2. WHO Technical Series, 687. 1983
3. Human Blood Coagulation, Hemostasis & Thrombosis, Edited by Rosemary Biggs, Blackwell Scientific Publications 1972
4. Data on file: Bio Research for Medical Diagnostics

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235, Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,E-mail:info@bioresearch.com.jo