BIOMEDICA DIAGNOSTICS

QuikCoag™ Control Level 1 Normal

CE IVD For *In Vitro* Diagnostic Use

REF	Catalog Number	Quantity
	C.BMD.CON1-01ML-8A	10 x 1mL

INTENDED USE

The **QuikCoag Control Level 1 Normal** is intended for use in quality assurance of *in vitro* diagnostic coagulation tests [1-3]. The reagent is suitable for use as a ***normal coagulation time*** control in the one-stage prothrombin time (PT) assay and in the activated partial thromboplastin time (APTT) assay.

REAGENT

The **QuikCoag Control Level 1 Normal** is a lyophilized preparation of human plasma containing buffers and stabilizers.

PRECAUTIONS

1. Do not ingest.
2. Avoid contact with skin, eyes or clothing.
3. **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

1. Reconstitute the **QuikCoag Control Level 1 Normal** with 1.0 mL of purified water.
2. 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

The reconstituted **QuikCoag Control Level 1 Normal** 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

The **QuikCoag Control Level 1 Normal**, when properly used, is subject to the limitations of the assay system employed. Results outside of the reference range may indicate product deterioration or problems with one or more components of the test system.

PERFORMANCE CHARACTERISTICS

Influences such as reagent type, ISI value of the PT reagent, methodology, instrumentation and technique contribute to variation in test results. Each laboratory should establish its own acceptance ranges with each new lot of plasma control. The **QuikCoag Control Level 1 Normal** will typically yield results within the range specified in the following table, for most PT and APTT assays.

Coagulation Test	Expected Result
PT-HS ISI 0.9 – 1.5	10 – 16 seconds
PT-LS ISI 1.6 – 2.2	9 – 14 seconds
APTT-EA	24 – 39 seconds

The coefficient of variation (CV) for prothrombin time PT and activated partial thromboplastin time APTT tests performed on the **QuikCoag Control Level 1 Normal** 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

REFERENCES

1. Miale JB, Laboratory Medicine, Hematology, CN Mosbey Co., St Louis (1977)
2. Sirridge MS, Laboratory Evaluation of Hemostasis, Lea & Febiger, Philadelphia (1967)
3. Loeliger EA, Hemker HA, Thromb Diathes Haemo 40 p359 (1969)

WARRANTY

This product is warranted to perform in accordance with its labeling and literature. **BioMedica Diagnostics Inc.** disclaims any implied warranty of merchantability or fitness for any other purpose. Purchaser must calibrate and determine the suitability of **BioMedica**'s products for their specific applications. In no event will **BioMedica Diagnostics Inc.** be liable for any consequential damages arising out of aforesaid express warranty.

Symbols Key	
	Manufactured By
	Consult Instructions For Use
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
	Expiration Date (YYYY.MM)
°C	Temperature Limitations
REF	Catalogue Number
CON	Contents
REC	Reconstitution Volume
	Biological Risks
EC REP	European Authorized Representative

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