ACTICHROME® Heparin LMWH Control Set

REF **832CONLMWH** **5 x 2 x 1.0 mL**

CE IVD **For *In Vitro* Diagnostic Use**

INTENDED USE

The ACTICHROME® Heparin LMWH Control Set is intended for use as controls for monitoring the performance of assays that measure low molecular weight heparin (LMWH) activity via a manual method, or via semi-automated or automated coagulation analysers in a clinical setting.

REAGENT

The ACTICHROME Heparin LMWH Control Set consists of lyophilized preparations of buffered human plasma spiked with two levels of unfractionated heparin.

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.

   Dispose of discarded material and packing in accordance with all applicable local regulations.

REAGENT PREPARATION

1. Reconstitute the ACTICHROME® Heparin LMWH Control Set with 1.0 mL of purified water per vial.
2. Replace the stoppers and gently invert each 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

This lyophilized control set is stable until the expiration date stated on the vial when stored unopened at 2°C to 8°C. Reconstituted controls are stable for 8 hours when stored at room temperature in the original container.

PROCEDURE

The reconstituted ACTICHROME Heparin LMWH controls are assayed in the same manner as freshly drawn citrated patient plasma. Refer to the appropriate Instructions For Use or Instrument Application for the assay specific instructions.

LIMITATIONS

The ACTICHROME Heparin LMWH Control Set, 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, methodology, instrumentation and technique contribute to variation in test results. Each laboratory should establish its own acceptance ranges with each new lot of controls. The ACTICHROME Heparin LMWH controls will typically yield results within the range specified on the lot specific certificate of analysis provided in each kit.

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 Diagnostics' 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
YYYY.MM	Expiration Date (YYYY.MM)
°C	Temperature Limitations
REF	Catalogue Number
CON	Contents
REC	Reconstitution Volume
	Biological Risks

BioMedica Diagnostics Inc.
P.O. Box 1030, 94 Wentworth Road
Windsor, NS, Canada B0N 2T0
Tel: 1-902-798-5105 | Fax: 1-902-798-1025
info@biomedicadiagnostics.com | www.biomedicadiagnostics.com

EC REP
Obelis s.a.
Boulevard Général Wahis 53
1030 Brussels, Belgium
Tel: +(32) 2 732-59-54 | Fax: +(32) 2 732-60-03
email: mail@obelis.net