

## ACTICHROME® Heparin LMWH Calibrator Set

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

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

### INTENDED USE

The ACTICHROME® Heparin LMWH Calibrator Set is intended for the creation of a reference curve for 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 Calibrator Set consists of lyophilized preparations of buffered human plasma spiked with five individual levels of low molecular weight heparin.

### PRECAUTIONS

- Do not ingest.
- Avoid contact with skin, eyes or clothing.
- 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

- Reconstitute each vial of the ACTICHROME Heparin LMWH Calibrator Set with 1.0 mL of purified water.
- 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 calibrator set is stable until the expiration date stated on the vial when stored unopened at 2°C to 8°C. Reconstituted calibrators are stable for 8 hours when stored at room temperature in the original container.

### PROCEDURE

The reconstituted ACTICHROME Heparin LMWH Calibrator Set are assayed to generate a reference curve for LMWH. Refer to the appropriate Instructions For Use or Instrument Application for the assay specific instructions.

It is not recommended to use different lots of individual calibrator levels when generating the reference curve.

### LIMITATIONS






The ACTICHROME Heparin LMWH Calibrator Set, when properly used, is subject to the limitations of the assay system employed. Results outside of the performance range may indicate product deterioration or problems with one or more components of the test system.

### VALUE ASSIGNMENT

The ACTICHROME Heparin LMWH Calibrator Set has been assigned values for low molecular weight heparin by direct comparison with World Health Organization International Standards. The assigned values are lot specific; therefore, refer to the certificate of analysis accompanying each lot to obtain the lot specific values.

### 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
<b>IVD</b>	In Vitro Diagnostic Medical Device
<b>LOT</b>	Lot Number
	Expiration Date (YYYY.MM)
	Temperature Limitations
<b>REF</b>	Catalogue Number
<b>CON</b>	Contents
<b>REC</b>	Reconstitution Volume
	Biological Risks

