Key Code TSMX7985B

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Thrombo-Wellcotest

REF R30852301..... Σ 20 **EN**

1. INTENDED USE

Thrombo-Wellcotest™ latex suspension is intended for use with the reagents and components supplied in the Thrombo-Wellcotest Kit (HA13/R30852601). The latex is provided as a replacement item in instances where multiple testing has exhausted this component before the other contents of the Kit. **For complete information the user is referred to the Instructions for Use which accompany the Thrombo-Wellcotest Kit (HA13/R30852601).** Thrombo-Wellcotest has been categorised as moderately complex under the Clinical Laboratory Improvement Act (CLIA88).

2. REAGENTS DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

See also **Warnings and Precautions**.

The Thrombo-Wellcotest latex suspension should be stored at 2 to 8°C where it will retain its potency at least until the date shown on the bottle label.

LATEX **Thrombo-Wellcotest Latex Suspension**

3.0 ml of 0.75% suspension of polystyrene latex particles coated with sheep anti-FDP globulin in glycine saline buffer containing 0.1% sodium azide, and 0.4% Micr-o-protect®.

3. WARNINGS AND PRECAUTIONS

IVD

For *in vitro* diagnostic use only.

For professional use only.

Please refer to the manufacturer's safety data sheet and product labelling for information on potentially hazardous components.

HEALTH AND SAFETY INFORMATION

1. Each latex reagent and positive control reagent contains 0.1% sodium azide. Note that azides can react with copper and lead used in some plumbing systems to form explosive salts. The quantities used in this kit are small, nevertheless when disposing of azide containing materials they should be flushed away with relatively large quantities of water.
2. Wear disposable gloves and eye protection while handling samples and performing the assay. Wash hands thoroughly when finished.
3. Please note the presence of natural rubber or dry natural rubber latex as a material of construction within the bulb of this medical device.

4. PACKAGING

REF HA08/R30852301..... Σ 20

5. SYMBOL LEGEND

REF	Catalogue Number
IVD	In Vitro Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
Σ N	Contains sufficient for <N> tests
LATEX	Contains or prescence of natural rubber latex
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

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Remel Europe Ltd.
Clipper Boulevard West, Crossways
Dartford, Kent, DA2 6PT
UK

For technical assistance please contact your local distributor.