RHEUMATOID FACTOR STANDARD (RF CAL)

CAT. NO. RF 2301

PRESENTATION: Liquid

SIZE: 5 x 1 ml

EXPIRY: 2017-12-28

GTIN: 05055273205039

INTENDED USE

This product is intended for *in vitro* diagnostic use, in the calibration of RF on clinical chemistry analysers.

SAFETY PRECAUTIONS

The Calibration material is derived from human serum obtained from volunteer donors.
All donors have been found negative for Hepatitis B surface antigen, Hepatitis C Virus and Anti-HIV antibody. However, since no test method can offer complete assurance that products will not transmit infectious agents, it is recommended that this product is handled with the same precautions used for patient samples.

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

All reagents contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water.
In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Calibration of RF standards has been performed at Randox by latex enhanced immunoturbidimetry, with reference to material standardised against appropriate International Reference Preparation. The assigned values for the batch are listed below.

RECONSTITUTION AND STABILITY

The RF Standards are supplied ready for use, and are stable up to the expiry date when capped and stored at +2°C to +8°C in the absence of contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

VALUE ASSIGNMENT

Calibration has been carried out and values have been assigned using an immunoturbidimetric method standardised to the International Reference Preparation, WHO Standard 64/2. The assigned values for the RF Standards are listed below.

CAL. NO.	LOT NO.	CONCENTRATION
1	1292RF	9.9 IU/ml
2	1291RF	19.2 IU/ml
3	1290RF	39.2 IU/ml
4	1289RF	61.2 IU/ml
5	1288RF	106 IU/ml

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