RF CONTROL

Lot xxxxxxxx

EN

CE IVD

Cat. No.:	Pack name:	Packaging (Content):
BLT20039	RF CON	1 x 1 ml

Intended Use

Accuracy control for the determination of Rheumatoid Factor (RF) in human serum by turbidimetry and nephelometry.

Composition

A dilution of human plasma containing a high level of RF with saline. The dilution is liquid stabilised and contains 0.095 g % sodium azide as preservative.
Ready for use.

Storage and Stability

The expiry date of the product at 2-8 °C is listed on the label.
After first opening the container, the control can be used for 6 weeks if stored tightly closed at 2-8 °C after use.
Do not freeze.

Precautions and Warnings

1. For in Vitro Diagnostic use.
2. Each individual donation intended for use in manufacture of protein control serum was tested for hepatitis B surface antigen (HBsAg), anti-hepatitis C virus (anti-HCV) and anti-HIV1 and HIV 2 by FDA required test. Only donations with negative findings were used for its manufacture. Nevertheless every product obtained from human body fluids should be handled with appropriate care in accordance with recommended procedures for biohazardous materials since absence of infectious agents can never be proven.
3. Reagents containing sodium azide must be handled with due caution: Do not ingest or allow to contact skin or mucous membranes! Sodium azide can form explosive azides when contacting heavy metals such as copper or lead.

Assigned Values

Titrated value for RF is based on WHO standardisation:

RF: xyz (xyz – xyz) IU/ml

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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SYMBOLS:
The following symbols are used in the labeling of ERBA kits:

REF Catalogue No	CE Mark - Device comply with the Directive 98/79/EC
LOT Batch Code	**IVD** In Vitro Diagnostics
Expiry Date (Last day of the month)	Consult Instruction for Use
Manufactured by	Storage temperature
RF CONTROL Product Name	**CONT** Content

Date of Revision: 11.7.2013

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