

CRP CONTROL

Lot xxxxxxx



Cat. No.:	Pack name:	Packaging (Content):
BLT20013	CRP CON H	1 x 1 ml
BLT20014	CRP CON L	1 x 1 ml

Intended Use

Accuracy control for the determination of C-Reactive Protein (CRP) in serum by turbidimetry and nephelometry.

Composition

A dilution of human sera containing high levels of CRP with phosphate buffered saline.

Liquid stabilised.

Preservative: 0.095 % sodium azide.

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 serum 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

The value for CRP has been assigned to ERM-DA472/IFCC

CRP: x.yz (x.yz – x.yz) mg/dl

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485



SYMBOLS:


The following symbols are used in the labelling of ERBA kits:

 Catalogue No


 CE Mark - Device comply with the Directive 98/79/EC


 Batch Code

 In Vitro Diagnostics

 Expiry Date
(Last day of the month)

 Consult Instruction for Use

 Manufactured by

 Storage temperature

 Product Name  Content

Date of Revision: 11.7.2013



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