

REF: (1 Vial) 5 ml  
REF: (5 Vials) 5 ml each.

## Description:

BioMed-NORMOTROL is a lyophilized human-based control serum.

## Storage and stability:

Unopened bottles must be stored at 2–8 °C and are stable up to the expiration date printed on the labels. After reconstitution the serum can be used, stored at 2 – 8°C and protected from light, in between 5 days.  
Bilirubin is stable 1 day, refrigerated.  
The frozen serum is stable for at least 30 days at < -20°C .

## Warnings and Precautions:

Each individual blood donation used for this serum was found negative when tested with FDA-approved methods on HBsAg, anti-HIV 1+2 and anti-HCV. Nevertheless the serum should be treated for safety reasons always as a potentially infectious material.

## Preparation:

Reconstitute carefully by adding exactly 5 ml of distilled water. Allow the vial to stand for 30 minutes, swirling occasionally. Avoid foaming i.e. do not shake!  
For alkaline phosphatase the control serum should stand for 2 hours at + 25 °C before use.

## Procedure:

Refer to the package inserts of the reagent kits

## Assay Values and Ranges:

Assay values for analytes for which approved Reference methods are available were determined according to Guidelines of the German Federal Medical Council [Bundesaerztekammer] from 1987 (reference method values) [3]. Ranges of acceptance were calculated as assigned Value  $\pm$  three times the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council [4].

## Literature:

1. Röhle G, Siekmann L. Quality assurance of Quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).
3. Richtlinien der Bundesärztekammer zur Qualitätssicherung in medizinischen Laboratorien. Deutsches Ärzteblatt 1988;85: B519–B532.
4. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer Laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt 2002; 98: A 2747-59.



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