

**Serum control multicomponent for clinical chemistry assays
IVD**

Store at 2 – 8°C.

PRODUCT CHARACTERISTICS

Control serum NORMAL or PATHOLOGIC is a human lyophilised serum.

With most constituent concentrations and activities in the normal or pathologic range.

Is intended for control of accuracy for use with manual and automated analytical procedures.

REAGENTS

Human serum. Biological additives. Bacteriostatics agents. The concentration / activities of the components are lot-specific. The exact values and ranges valid for reagents are given informational purpose in the value sheet.

PRECAUTIONS

Components from human origin have been tested and found negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious.

CALIBRATION

Information available on request.

PREPARATION

- Reconstitute (→) with 5.0 mL of distilled water.
 - Mix thoroughly, avoiding foam forming.
 - Bring to room temperature for about 30 min. before use.
- Improper handling and/or storage can affect results.
Inaccurate reconstitution and errors in assay technique can cause erroneous results.

STORAGE AND STABILITY

The Control serum is stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date or if there is visible evidence of microbial growth.

Store tightly capped when not use.

- After reconstitution is stable for:

At 15°C to 25°C 12 hours

At 2°C to 8°C 5 days

At -25°C to -15°C 1 month


- Bilirubin (stored protected from light):


At 15°C to 25°C 2 hours

At 2°C to 8°C 6 hours

At -25°C to -15°C 2 weeks


The following symbols are used on labels

 For in vitro diagnostic use

 Use by (last day of the month)

 Temperature limitation

 Batch Code of the kit

 Code

 Biological risk

 Contents of the kit