NORMAL CONTROL SERUM

Composition
The control serum is obtained from a pool of normal human sera. The serum is in a stabilized lyophilised form.

For \textit{in vitro} diagnostic use.

Intended use
This serum is designed for the quality control of electrophoretic quantification of human serum proteins, lipoproteins, cholesterol and apolipoproteins on HYDRAGEL and for serum proteins on CAPILLARYS & MINICAP.

It is used as a "marker" for identification of the different isoenzymes separated by electrophoretic methods.

The values obtained must fall within the mean \pm 2 SD confidence range provided with each batch of control serum.

Procedure
Reconstitute the lyophilised serum with 1 mL of distilled or deionized water.

\textit{NOTE} : The precision of the reconstitution volume to be maintained is \pm 1.0 \%.

Allow to stand for 30 minutes and mix gently (avoid formation of foam).

Store the lyophilised serum refrigerated (2 to 8 °C). It is stable until the expiration date indicated on the vial labels or the package. Store the reconstituted serum at 2 - 8 °C. Due to the risk of microbial contamination and denaturation, use within one week. The reconstituted serum may also be frozen (in aliquots) and stored at -18 / -22 °C for maximum 6 months. Before use, store thawed control serum at 2 - 8 °C and use it within the day.

For optimal use of the Control Serum with the CAPILLARYS & MINICAP system, it is recommended to split it into aliquots in microtubes before freezing.

\textbf{IMPORTANT} : For optimal use of the Control Serum, it is necessary to use the bar code labels intended to identify hemolyzing tubes holding the microtubes which contain Serum Control aliquots (cut the cap of the microtube before using it).

\textit{NOTE} : During transportation, the control serum can be kept without refrigeration (15 to 30 °C) for 15 days without any adverse effects on performance.

\textbf{WARNING} : No test method can provide an absolute assurance of the absence of HIV, hepatitis B and C or other infectious agents. Therefore, handle the control serum as a hazardous biological material.

This lot of control serum was found negative on assays approved by FDA or EU equivalent regulatory agency :
- against hepatitis B surface antigen ;
- for antibody to HCV ;
- for antibody to HIV1 and HIV2.

\textit{NOTE} : The expected values are indicated in the package insert provided with the control vials.