**Use**

Normal control , for in vitro use, for monitoring the quality control of results obtained in the measuring of the antistreptolysin-0, C- reactive protein and rheumatoid factors in turbidimetry . Product from human origin.

**Calibration values**

The concentrations and activities of the components have been adjusted for a wide range of automatic analyzers and the assigned values are specific for each lot and they are listed below:

|  |  |  |
| --- | --- | --- |
|  | MEAN | RANGE |
| ASO UI/ml | 106 | 74.0-138 |
| CRP mg/l | 8.5 | 5.5-11.5 |
| RF UI/ml | 24.0 | 17.0-31.0 |

**Preparation**

Open one bottle of calibrator avoiding the loss of lyophilizate.

Reconstitute the lyophilized serum with exactly 1.0 ml of bi-distilled water.

Close the bottle and let it stand for 20 minutes out of bright light.

Before to use mix by inverting the vial.

Do not shake the vial as the formation of foam should avoid.

After reconstitution, stable for 10 days at 2-8°C or 6 months at -20°C.

**Storage and stability**

When stored at 2-8 °C, it is stable until the expire date.

**Note**

* In case of compliant or quality control request, refer to the lot number on the package or to the lot number of the single vial.
* Not properly storage and / or contamination can feed not correct results.

**Precaution in use**

The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.

 Product from human origin is obtained using only blood of donors tested by FDA method and found non-reactive for HbsAg and negative for antibodies to HIV-1/2 and HCV.However, no known test method can offer complete assurance that product derived from Human blood transmit infectious diseases, this product should be handled as potentially infectious biological material with caution according to good laboratory practice.

**Caution**: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

**Waste management**

Please refer to the local legal requirements.

**Bibliography**

Biosafety in Microbiological and Biomedical Laboratories. CDC/NIH manual, 4th edition,1999.

**Symbols**

|  |  |
| --- | --- |
| rischio biologico | Biological risk |
| CE | CE Mark (98/79 CE regulation) |
| IVD | in vitro medical device |
| LOT | Batch Code |
| SCADENZA | Use by |
| TEMPERATURA | Storage temperature limits |
| I | Read instruction for use |
| PRODOTTO DA | Gesan Production |