

Instructions For Use

Biological Control Base-1 (BCB-1)

REF HS201-007

Intended Use:

Biological Control Base-1 (BCB-1) is a defibrinated and non-lipid stripped human serum matrix manufacturing using CPD containing plasma donations. BCB-1 can be used as quality control materials in diagnostic assays for assessing the accuracy and precision of test results. It can be also used as a matrix for calibrator manufacturing for calibrating analytical instruments used in clinical laboratories. Calibration with human serum matrices helps maintain instrument accuracy and ensures consistent measurement of analytes in patient samples. Other usage areas include method validation and verification for clinical chemistry kits, developing/optimizing new assays.

Warnings and Precautions for Use



The used H. Plasma units of European origin have been tested by CE-marked test kits and found to be non-reactive for HBsAg, anti-HIV 1+2, anti-HCV, and Syphilis. In addition, HAV, HBV, HCV, HIV-1, and Parvo B19 have been tested by PCR. However, all human material should be considered potentially infectious. Since no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen.

Characteristics

BCB-1 is a frozen human serum matrix to make it more stable the biological molecules such as lipids and proteins. After thawing of the material, physical appearance is colloidal light yellow solution.

Disposal


Reagents must be disposed of in accordance with all Federal, Provincial, State, and local regulations.

Storage and Handling

The shelf life of the product is 2 years when stored at temperatures below -20°C. Refer to the Certificate of Analysis for the recommended re-testing date. To prevent microbial contamination, a 0.01% preservative has been added to the product. However, maintaining a clean working environment as much as possible helps to keep the product stable. Avoid subjecting the product to repeated freeze-thaw cycles.

Limitations

The product is shipped in a manner that preserves its frozen form. If, for some reason, the product was not received frozen, avoid refreezing it until use. Subjecting the product to additional freeze/thaw cycles cause the lipids to lose their intact state and their structure to deteriorate. If there will be a significant amount of time before use and refreezing is unavoidable, we recommend filtration using a 0.45 µm PES (polyethersulfone) material filter after thawing the product again.

	Manufacturer
IVD	In vitro diagnostic medical device
REF	Catalog Number



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