

HbA₂ Trilevel control (Lyophilized)

Description

These lyophilized controls are prepared from a stabilised human haemolysate containing defined proportions of HbA₂ defined by analysis on an HPLC (BioRad Variant) procedure. The source material is from healthy blood donors and has tested negative for Hepatitis B surface antigen, Hepatitis B core antibody, Anti-Hepatitis C, Anti-HIV 1 & 2 and HIV-1 antigen. The haemolysates are stabilized and freeze dried in the presence of a cryoprotectant. Production has been in keeping with current Good Manufacturing Practice rules.

Precautions

WARNING! POTENTIALLY BIOHAZARDOUS MATERIAL.

Human sourced materials were used in the manufacturing of this product. Although all the source material for this product has tested negative for all the serological tests, the product should nevertheless be handled with the same precautions used with patient specimens.

For *In Vitro* Diagnostic Use.

Reconstitution

Each vial is reconstituted by the addition of 250 µL of Reconstitution Fluid, 0.09% sodium azide solution. This is done by **adding six (6) drops of reconstitution fluid** to the control, replacing the cap and swirling the vial several times. The control should be allowed to **stand at room temperature for 15 minutes** with intermittent swirling prior to use. This gives a stable haemolysate solution of approximately 10 g/dL.

Storage

Store both lyophilized and reconstituted vials at 4°C.

Expiry Date

Lyophilized Material: 3 years from production date as per table below

Reconstituted Sample: 6 weeks from time of reconstitution.

HbA₂ Levels

The levels below have been determined using the BioRad Variant HPLC Assay system. Because other assay systems may produce different values it is necessary to establish a mean value and range about the mean for each assay system.

Lot #	Expiry Date	Level 1		Level 2		Level 3	
		Mean	Range	Mean	Range	Mean	Range
3002	January 2008	2.4%	2.0 – 2.8	3.8%	3.2 – 4.4	5.8%	4.9 – 6.7