

HB110, HB110S

## HbF + HbA<sub>2</sub> Bilevel Control with and without HbS in level 2 (lyophilised)

**Description** These lyophilized controls are prepared from human adult haemolysate, fetal cord lysate and purified HbA<sub>2</sub>. The source material for these standards is from healthy blood donors and has tested negative for Hepatitis B surface antigen, Anti-HCV, Anti-HIV 1 & 2, HIV-1Ag and RPR. Production has been in keeping with Current Good Manufacturing Practice requirements.

**Precautions** **Warning: Potentially Biohazardous Material.**  
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 care as patient specimens.  
**For In Vitro Diagnostic Use.**

**Reconstitution** Each vial is reconstituted by the addition of 200 µL (5 drops) of Reconstitution Fluid, 0.09% sodium azide solution. 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:** 4 weeks from time of reconstitution.

**HbF & A<sub>2</sub> Levels** The levels below have been determined using the BioRad Variant Beta Thalassaemia Short Program. 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				
		Hb F %		Hb A <sub>2</sub> %		Hb F %,		Hb A <sub>2</sub> %		Hb S%
		Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean
1013	2009-03	2.1	1.7-2.5	2.6	2.1-3.1	6.6	5.3-7.9	6.1	4.9-7.3	
1014	2010-01	2.2	1.8-2.6	3.0	2.4-3.6	6.3	5.0-7.6	6.2	5.0-7.4	31.0