

## HbFASC Lyophilized Control

### Description

These lyophilized controls are prepared from human adult haemolysate and foetal cord lysate. 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 1.0 mL 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 4.0 to 5.0 g/dL total hemoglobin.

### 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.

### Hb FASC 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	HbF %	HbA %	HbS %	HbC %
6004	2010-02	21.9	47.3	18.5	5.7