

Drew Scientific Limited HbA ₂ Quality Control Kit (Part Number 014-165)	Control Kit Lot Number M-0170584 HbA ₂ Level 1 Lot Number MO-00172098 HbA ₂ Level 2 Lot Number MO-00172099 HbA ₂ Diluent Lot Number MO-00172100 Expiry Date 30 June 2008
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Intended Use

For in vitro diagnostic use only.

These controls are intended for use in a quality control procedure for determining imprecision and accuracy of haemoglobin A₂ + F measurements.

Summary and Principle

The routine use of Control Materials is recommended for the long term monitoring of imprecision of analytical methods and is a requirement of Good Laboratory Practice.

Contents

The kit contains three vials of each of the two levels which are preparations of freeze dried whole blood and one vial of A₂ diluent.

Storage

Store unopened at 2 – 8 °C. The expiration date is given at the top of this page.

After reconstitution, the material is stable for 3 days at 2 – 8 °C.

Procedure

Remove the screw cap carefully. Carefully add three drops of A₂ diluent to the vial to reconstitute the control. Replace the screw cap firmly and mix gently. Allow to stand for 30 minutes.

Visually inspect that all the material has dissolved before use.

Treat the reconstituted control as whole blood for the purpose of preparing samples for your analysis method.

The A₂ diluent contains 0.09 % (w/v) sodium azide.

Limitations

Do not use time-expired material.

Do not use incompletely dissolved material.

Do not use material that has not been stored in accordance with the recommendations above.

Safety Information

All the individual blood donor lots used to prepare this material were tested by FDA approved methods and found to be non-reactive for hepatitis B surface antigen (HbsAG), hepatitis C (HCV), HIV-1 and HIV-2.

No test methods can offer complete assurance that these materials are free from infective agents. Handle, use and dispose of these control materials as if they were human specimens and potentially infective.

Assigned values

Methods	Level 1				Level 2			
	HbF		HbA ₂		HbF		HbA ₂	
	Value	Acceptable Limits	Value	Acceptable Limits	Value	Acceptable Limits	Value	Acceptable Limits
Drew Scientific HbGold HbA ₂	2.5	1.3 – 3.8	2.6	2.0 – 3.3	7.2	6.1 – 8.3	4.5	3.6 – 5.4



014IL165 (08/05-B)

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