

Drew Scientific Limited HbA <sub>2</sub> Quality Control Kit (Part Number 014-165)	Control Kit Lot Number M-162934 HbA <sub>2</sub> Level 1 Lot Number MO-00168058 HbA <sub>2</sub> Level 2 Lot Number MO-00168059 HbA <sub>2</sub> Diluent Lot Number M-168437 Expiration Date 31 August 2007
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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 A<sub>2</sub> + 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 A<sub>2</sub> 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 two drops of A<sub>2</sub> 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 A<sub>2</sub> 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 <sub>2</sub>		HbF		HbA <sub>2</sub>		HbS	
	Value	Acceptable Limits	Value	Acceptable Limits	Value	Acceptable Limits	Value	Acceptable Limits	Value	Acceptable Limits
Drew Scientific HbGold HbA <sub>2</sub>	2.6	1.2 – 4.1	2.5	2.1 – 2.9	7.0	5.6 – 8.5	5.6	4.5 – 6.7	30.0	25 - 35



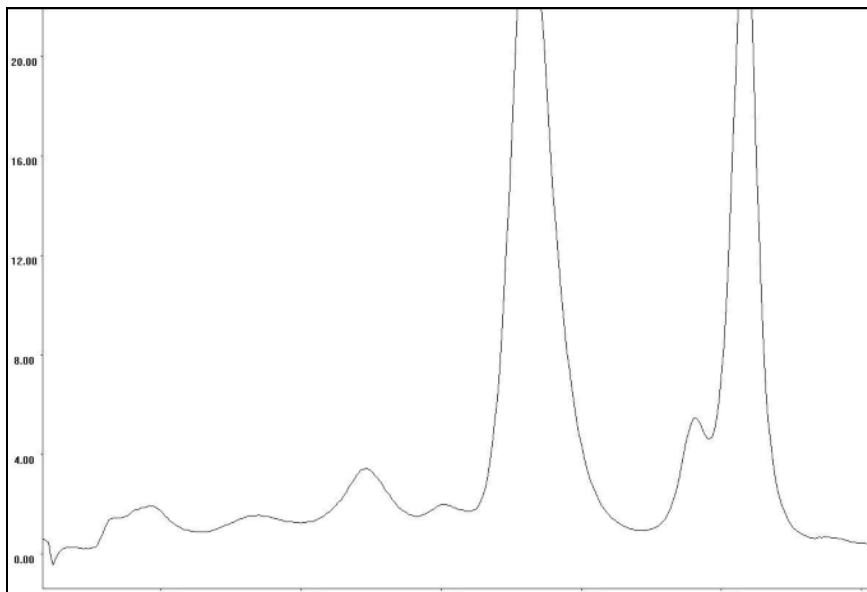
Manufactured By  
Drew Scientific Limited  
Sowerby Woods Industrial Estate  
Park Road  
Barrow-in-Furness  
Cumbria  
LA14 4QR United Kingdom

# CONCESSION NOTE

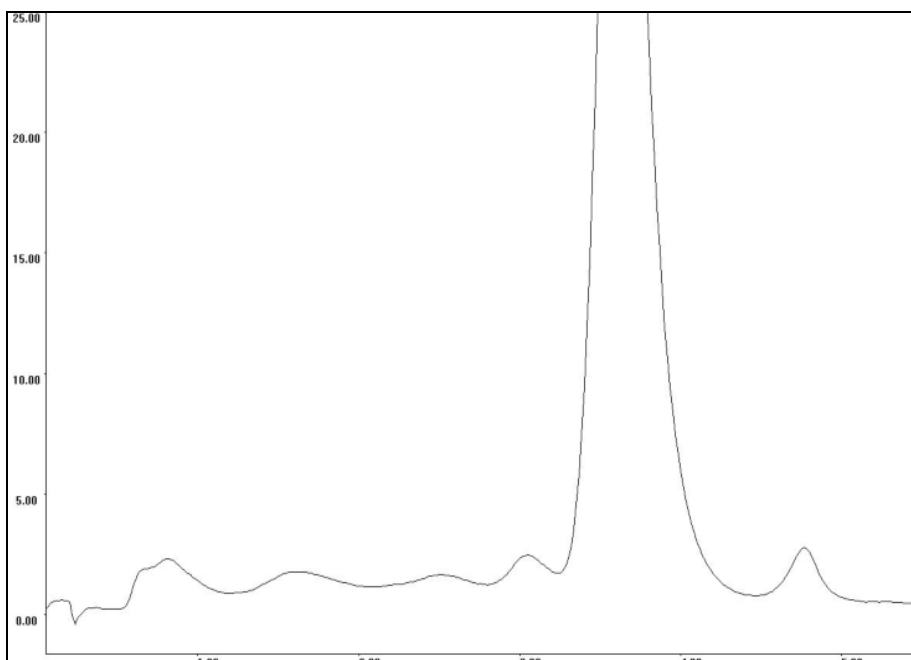
Date issued: 20 January 2005	Lot M-162934

Dear Customers,

On this Lot of HbA2 Control we have to change suppliers which has altered the Control in three very important regards. 1) Take notice that we are now reconstituting the control using only two drops of diluent. 2) Once the control has been reconstituted the open bottle life is 3 days. Keeping the control in the refrigerator when not in use will ensure the best performance from this product. 3) The High Control now contains an S Variant. The Low Control does not have this S Variant and will retain the chromatography you are familiar with. We expect this Control situation to remain this way for the foreseeable future. If you have questions regarding these changes, please contact your local distributor or Drew-Scientific.



Example of HbA2 High Control containing HbS



Example of HbA2 Low Control