

HEMOGLOBIN A₂ (HbA₂) abnormal CONTROL

REF HbA₂02

LOT



HELLABIO Hemoglobin Control A₂02 is an assayed quality control material intended to be used in Hemoglobin electrophoresis in alkali and in acid. It is packaged in bottles, each containing 0.25 ml of control solution.

Active Ingredients: HELLABIO HbA₂02 control contains a solution of unfixed stabilized human erythrocytes and preservatives.

PRECAUTIONS:

This product contains human source materials that have tested non-reactive for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), hepatitis C virus (HCV), anti-HIV-1, anti-HIV-2, and human T-cell lymphotropic virus type 1 (HTLV-1).

Since no known test method can offer complete assurance that specimens of human origin will not transmit infectious disease, this control should be handled as a potentially biohazardous material. Follow the recommended "Universal Precautions" when handling this and any blood product.

Disposal of this product should be according to the practices of your institution for infectious medical waste. Discard all materials in a safe and acceptable manner and in compliance with all federal, state and local requirements.

STORAGE

The expiration date stated on the bottle is for product stored in freezing conditions (**under -8 °C**).

Bottles should be tightly closed after each use. Avoid exposing the bottle to temperatures greater than 8 °C. The solution is **ready to use**.

INSTRUCTIONS FOR USE

For the proper use of Hemoglobin control, follow the steps below:

- a) Place the vial on the laboratory workbench.
- b) Thoroughly mix by gently inverting the bottle and rolling between the palms until all cellular components are completely suspended. Do not shake or use a mechanical mixer.
- c) Twist open the cap.

d) Apply the control sample (**Ready to Use**) on the electrophoresis gel according to the instructions for use, (**user's Manual** kit HELLABIO HE, MHE, GHE, MGHE), for **30 seconds**.

e) Return the opened bottle to the chosen open-bottle storage temperature immediately after use. Do not use control solutions after the expiration date printed on the bottles and box.

For HEELECS-1 instrument:

- a) Place the vial on the laboratory workbench.
- b) Thoroughly mix by gently inverting the bottle and rolling between the palms until all cellular components are completely suspended. Do not shake or use a mechanical mixer.
- c) Twist open the cap.
- d) Transfer 20µl of the sample control (**Ready to Use**) to one hole of the sample holder. Follow IFU (HEA13) for electrophoresis procedure.
- e) Return the opened bottle to the chosen open-bottle storage temperature immediately after use. Do not use control solutions after the expiration date printed on the bottles.

LIMITATIONS

This product is intended for use as a quality control material in Hemoglobin electrophoresis in alkali and in acid. It is not for use as a calibration standard. Exposure to temperatures greater than 25 °C may affect product performance.

NORMAL (NV %)

Fractions	NV %
HbA	96.7 – 98.5
HbA ₂	1.5 – 3.5

EXPECTED VALUES

The levels have been determined using replicate analyses using HELLABIO electrophoresis procedures listed in the following table and are specific for this lot of control. **The mean value and SD (n=30) were calculated for each zone with HellabioScan software.**

HellabioScan software measurement:

Fraction	Mean value %	SD	Range
HbA	95.28	0.41	94.94 – 95.86
HbA ₂	4.72	0.41	4.14 – 5.06

Important: In order to improve accuracy of densitometric quantitation on gels of poorly defined hemoglobin fractions, it is recommended to mark each peak at the feet of its sharply rising sides nearest to the peak.

HEELECS-1 software measurement:

Fraction	Mean value %	SD	Range
HbA	N/A	N/A	N/A
HbA ₂	N/A	N/A	N/A

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