

Human abnormal serum control



REF HSC02

LOT 919-XXXX

INTENDED USE

HELLABIO *Human abnormal serum control* is an assayed quality control material intended to be used in Protein or in Immuno-electrophoresis. This serum is designed for the quality control of electrophoretic quantification of human serum proteins on **HELLABIO** gels. It is packaged in bottles, each containing 0.5 ml of control serum.

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

Store the serum at $-18 / -22^{\circ}\text{C}$ for maximum 6 months. Bottles should be tightly closed after each use. Avoid exposing the bottle to temperatures greater than 8°C .

During transportation, the control serum can be kept without refrigeration (15 to 25°C) for 15 days without any adverse effects on performance.

INSTRUCTIONS FOR USE

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

For manual system:

- Place the vial on the laboratory workbench.
- 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.
- Twist open the cap.
- Dilute the control sample 1:4 with diluent solution (included in package)**
- Apply the control sample on the electrophoresis gel according to the instructions for use. (*User's Manual kit HELLABIO PE, MPE, IE*).

- 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:

- Place the vial on the laboratory workbench.
- 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.
- Twist open the cap.
- Transfer $20\mu\text{l}$ of the sample control (**undiluted**) to one hole of the sample holder. Follow IFU (PEA13, PEA26) for electrophoresis procedure.
- Return the opened bottle(s) 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 Protein electrophoresis. It is not for use as a calibration standard. Exposure to temperatures greater than 25°C may affect product performance.

Under advised electrophoresis conditions the control serum will be clearly separated into albumin, α_1 , α_2 , β (β_1 , β_2), and γ -globulin's.

Note that β -globulins are separated in β_1 , β_2 only in fresh serum and therefore in case of control serum the value refers as β - the sum of β_1 , β_2

NORMAL VALUES (NV %)

Fraction	Normal Values%
Albumin	52.0 – 65.0
α_1 -	2.0 – 5.5
α_2 -	6.0 – 11.7
β -globulins	8.2 – 14.5
γ -globulins	9.5 – 19.8

EXPECTED VALUES

Performance characteristics:

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.**

HellabioScan software measurement:

Fraction	Mean value %	SD	Range
Albumin	38.87	1.96	38.95 – 39.78
α_1 -	2.22	0.88	1.11 – 2.41
α_2 -	11.57	0.72	11.03 – 12.23
β -globulins	13.94	1.47	13.56 – 14.88
γ -globulins	33.40	3.28	32.80 - 35.14

HEELECS-1 software measurement:

Fraction	Mean value %	SD	Range
Albumin	41.51	2.34	41.22 – 42.67
α_1 -	2.27	0.71	1.98 – 3.01
α_2 -	11.14	0.23	10.86 – 11.55
β -globulins	13.39	0.49	13.02 – 14.11
γ -globulins	31.70	2.88	30.55 - 33.17



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