Instructions for Use (IFU)
Hemoglobin Reference Controls
REF.: HbA201, HbA202, HbF01, HbS01

This document represents the full Instructions for Use. A short paper (version) containing essential information for safe use may be supplied with the product.
Regulatory Framework: Regulation (EU) 2017/746 on in-vitro diagnostic medical devices (IVDR) Annex I, Chapter III §20.4/ Annex II §2.
CE Mark: In conformity with Annex V of the IVDR 2017/746

IDENTIFICATION	
Basic UDI-DI	521301229CONTROLSMX
UDI-DI HbA201	5213012290184
UDI-DI HbA202	5213012290191
UDI-DI HbF01	5213012290207
UDI-DI HbS01	5213012290214

1. Intended Purpose
HELLABIO Hemoglobin Reference Controls are assayed quality control materials intended for use in the quality control of Hemoglobin Electrophoresis procedures (alkaline and acid) on Hellabio Agarose Gels. They are designed to monitor the analytical performance of the electrophoresis system, including the migration and quantification of Hemoglobin A, A2, F, and S fractions. *For In Vitro Diagnostic Use only, by laboratory professionals.*

2. Summary and Principle
Electrophoretic separation of hemoglobin variants is a critical diagnostic tool for hemoglobinopathies. The use of reference controls allows the laboratory to:
1. Verify the resolution (separation) of hemoglobin bands.
2. Confirm the accuracy of the quantification (percentage) of HbA2 and HbF.
3. Validate the integrity of the reagents and the electrophoresis equipment settings.

3. Reagent Composition
- **Source:** Stabilized human erythrocytes in a buffered preservative solution.
- **Preservatives:** Contains <0.1% Sodium Azide.
- **Format:** Concentrated solution (requiring dilution as per kit instructions), except if noted as Ready-to-Use on the vial (typically HbS01).
- **Disposal**: Dispose of according to local environmental regulations for infectious waste.

4. Warnings and Precautions
- **Biohazard:** Each donor unit used in the preparation of this product has been tested and found non-reactive for HBsAg, anti-HIV 1/2, and anti-HCV.
- **Caution:** No test method can offer complete assurance that infectious agents are absent. Handle as potentially infectious material following "Universal Precautions".
- **Chemical Safety:** Contains Sodium Azide. Do not ingest. Dispose of according to local regulations for medical waste.

5. Additional Materials Required but Not Provided

- Electrophoresis tank and power supply (capable of providing a constant 100 -220 Volts)
- Staining and destaining baths
- Precision pipettes
- Densitometer or Gel Analyzer (e.g., HellabioScan) with a 520-600 nm filter
- Quality control sera (normal and abnormal levels)
- Hot air oven or dryer (up to 90°C)
- Distilled or deionized water

6. Storage and Stability

- **Unopened:** Stable until the expiration date printed on the vial and box when stored at 2-8°C.
- **Opened / In-use:**
  - 7 days when stored tightly capped at 2-8°C.
  - 3 months when stored at -18°C or lower (aliquoted).
- **Note:** Avoid repeated freeze-thaw cycles. Do not use if there are signs of microbial contamination or excessive hemolysis (turbidity).

7. Procedure

1. **Mixing:** Before use, gently invert the vial and roll it between your palms until all cellular components are completely and uniformly suspended. **Do not shake vigorously.**
2. **Dilution:** Follow the dilution ratio specified in the Hellabio Hemoglobin Electrophoresis Kit IFU (typically 1 part control to 5 or 10 parts Hemolyzing Solution).
3. **Application:** Apply the hemolysate to the agarose gel using the Hellabio Applicator.
4. **Electrophoresis:** Perform the run using the Hellabio HET and Power Supply according to the kit's technical specifications.

8. Assigned Values

The values are lot-specific and established through replicate analyses (n=30) using the HellabioScan system.

Example Lot-Specific Table **LOT: XXXX**

Control REF	Hb Fraction	Mean Value (%)	Expected Range (±2 SD)
HbA201	HbA2 (Normal)	[X.X]	[X.X – X.X]
HbA202	HbA2 (Abnormal)	[X.X]	[X.X – X.X]
HbF01	HbF (Fetal)	[XX.X]	[XX.X – XX.X]
HbS01	HbS (Variant)	[XX.X]	[XX.X – XX.X]

9. Interpretation of Results

- **Qualitative:** The control should show clear and distinct bands in the expected migration positions.
- **Quantitative:** The calculated percentage of each fraction must fall within the range defined in Section 7.

- If results fall outside the range, verify the hemolyzing step, the application technique, and the equipment calibration.

10. Limitations

- This product is a control material and should not be used as a primary calibrator.
- Performance is only guaranteed when used in conjunction with Hellabio reagents and equipment.

11. Troubleshooting

For any deviation from expected results or technical issues, please contact your local distributor or Hellabio directly.

12. Classification Statement

This device is classified as **Class B** according to **Annex VIII, Rule 1.6** of Regulation (EU) 2017/746 (IVDR).
It meets the applicable requirements of **Annex I (General Safety and Performance)** and **Annex II (Technical Documentation)**.

13. Manufacturer Information

DIMITRIADIS IOANNIS AND SON PC
Production of electrophoresis products
Business Incubator Thermi
Steliou Kazantzidi 47, 57001, Thermi, Greece
E-mail: hellabio@hellabio.com
Phone: + 30 2311 999911
www.hellabio.com

Symbol Panel

Symbol	Meaning
IVD	In Vitro Diagnostic Medical Device
REF	Catalogue Number
LOT	Lot Number
	Use Until/ Expiration Date
	Temperature Limit
	Keep Away from Sunlight
	Manufacturer
	Date Of Manufacture
	Consult Instructions for Use
	Non-Sterile
	Do Not Reuse
	Unique device identifier

Symbol	Meaning
CE	CE Marking

Human Serum Reference Control - Instructions for Use (IFU)

Code	IFU/HEMOGLOBIN_V31_EN	**Syntax**	Quality Manager
Edition	31	**Approval**	CEO
Manufacturer	Dimitriadis Ioannis and SON PC	**Address**	Steliou Kazantzidi 47, 57001 Thermi, Greece

SYNTAX (NAME-TITLE-SIGNATURE)	APPROVAL (NAME-TITLE-SIGNATURE)
Quality Manager **Gavriilidou Maria**	CEO **Dimitriadis Ioannis**

LIST OF MODIFICATIONS

Revised edition	Date	Description	Adopted by
31	26/05/2026	Update to align better to IVDR Requirements	CEO

The Quality Management Department is responsible for making the process available.

The procedure does not apply if it is not signed by the CEO and the Quality Manage