IVD CE

Instructions for Use (IFU)
Human Serum Reference Controls
REF.: HSC01, HSC02

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

Catalogue Number (REF)	UDI-DI
HSC01 (Normal)	5213012290221
HSC02 (Abnormal)	5213012290238

1. Intended Purpose
HELLABIO Human Serum Controls are assayed, lyophilized or liquid quality control materials intended for use in the quality control of Serum Protein Electrophoresis (SPE) and Immunofixation (IFE) procedures on Hellabio Agarose Gels. They are used to monitor the precision and accuracy of the electrophoretic separation and quantification of human serum protein fractions.
*For **in vitro diagnostic use only**, by qualified laboratory professionals.*

2. Summary and Principle
The use of control materials is an essential part of good laboratory practice. By comparing the results of the control serum with the assigned values, the user can verify the integrity of the reagents, the functionality of the electrophoresis equipment (HET, Power Supply), and the accuracy of the densitometric scanning (HellabioScan).

3. Reagent Composition and Precautions
- **Source:** Prepared from human serum pools.
- **Preservatives:** Contains <0.1% Sodium Azide as a preservative.
- **Biohazard Warning:** * Each donor unit used in the preparation of this product has been tested by FDA-approved methods and found non-reactive for HBsAg, anti-HIV 1/2, and anti-HCV.
- **Precaution:** No test method can offer complete assurance that infectious agents are absent. Handle this product as potentially infectious, following "Universal Precautions" and ISO 15189 guidelines.
- **Disposal**: Dispose of according to local environmental regulations for infectious waste.

4. 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

5. Storage and Stability

- **Unopened:** Stable until the expiration date printed on the label when stored at 2-8°C.
- **Reconstituted/Opened:** * 7 days when stored tightly capped at 2-8°C.
    - For long-term storage, aliquot and store at -18°C or lower. Avoid repeated freeze-thaw cycles.
- **Indications of Instability:** Visible turbidity or microbial growth may indicate degradation.

6. Procedure

1. **Preparation:** (If lyophilized) Carefully reconstitute with exactly the volume of distilled water indicated on the vial label. Let it stand for 10 minutes and swirl gently to dissolve. (If liquid) Use directly.
2. **Application:** Apply the control serum to the Hellabio Agarose Gel following the same procedure as patient samples (refer to the Kit's IFU).
3. **Electrophoresis:** Perform the run using Hellabio HET and Power Supply.
4. **Quantification:** After staining and drying, scan the gel using HellabioScan software.

7. Assigned Values

The values provided are lot specific. The mean values and expected ranges are established by Hellabio using multiple replicates (n=30) and validated reference methods.
Example Lot-Specific Table **LOT: XXXX**

Fraction	Mean Value (%)	Range (±2 SD)
Albumin	[XX.X]	[XX.X – XX.X]
Alpha 1	[X.X]	[X.X – X.X]
Alpha 2	[XX.X]	[XX.X – XX.X]
Beta	[XX.X]	[XX.X – XX.X]
Gamma	[XX.X]	[XX.X – XX.X]

Note: Results may vary slightly depending on the densitometry software version used.

8. Limitations

- This control should not be used as a primary standard or calibrator.
- Performance is only guaranteed when used with Hellabio electrophoresis systems and reagents.

9. Troubleshooting

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

10. 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)**.

11. Manufacturer Information

DIMITRIADIS IOANNIS AND SON PC
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Business Incubator Thermi
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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
	CE Marking

Human Serum Reference Control - Instructions for Use (IFU)

Code	IFU/SERUM_V33_EN	**Syntax**	Quality Manager
Edition	33	**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
33	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