

## Anexa 7 la Specificatia Tehnica

### Coagulometru semi-automat

| Coagulometru semiautomat |                                                                                                                                             |                                                                           |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Descriere                | Coagulometru semiautomat destinat pentru testarea mostrelor preluate de la pacienti pentru determinarea factorilor de coagulare a sangelui. |                                                                           |
| Parametrul               | Specificatia                                                                                                                                | Specificatia tehnica oferita<br>C-2 (Helena Biosciences / Marea Britanie) |
| Configuratia             | Capacitatea sistemului $\geq 2$ probe simultan                                                                                              | 2 probe simultan                                                          |
| Tip proba                | plasma                                                                                                                                      | da                                                                        |
| Teste                    | APTT                                                                                                                                        | da                                                                        |
|                          | FIB                                                                                                                                         | da                                                                        |
|                          | PT                                                                                                                                          | da                                                                        |
|                          | TT                                                                                                                                          | da                                                                        |
| Data management          | Display LCD sau LED                                                                                                                         | LCD                                                                       |
|                          | Imprimanta                                                                                                                                  | da                                                                        |
|                          | Interfață PC                                                                                                                                |                                                                           |
|                          | Interfață LIS                                                                                                                               | da                                                                        |
|                          | Cititor bar cod                                                                                                                             | da                                                                        |

# Technical Specifications



|                                  | Helena C-1                                                                                            | Helena C-2        | Helena C-4        |
|----------------------------------|-------------------------------------------------------------------------------------------------------|-------------------|-------------------|
| Optical measurement channels     | 1                                                                                                     | 2                 | 4                 |
| Optical wavelength               | 405 nM (UV)                                                                                           |                   |                   |
| Automatic light level adjustment | Y                                                                                                     |                   |                   |
| Reagent/optic warming            | Y                                                                                                     |                   |                   |
| Cuvette pre-warm                 | 10×                                                                                                   | 20×               | 20×               |
| Reagent pre-warm, 24mm           | 1×                                                                                                    | 1×                | 1×                |
| Reagent pre-warm, 22mm           | 2×                                                                                                    | 2×                | 2×                |
| Microtubes pre-warm              | 2×                                                                                                    | 2×                | 2×                |
| Reagent stirrer                  | N                                                                                                     | 1×                | 1×                |
| Cuvettes                         | Single, 75 µL; activated via <a href="http://www.c-series.com">www.c-series.com</a> or TECAM software |                   |                   |
| Auto-start                       | Yes, on reagent addition                                                                              |                   |                   |
| Samples                          |                                                                                                       |                   |                   |
| Patient ID                       | No                                                                                                    | Y                 | Y                 |
| Double determination             | No                                                                                                    | Up to 200 results | Up to 200 results |
| Whole-blood testing              | N                                                                                                     |                   |                   |
| Assays                           |                                                                                                       |                   |                   |
| Dual reagent lots                | No                                                                                                    | Y                 | Y                 |
| Global clotting assays           | PT, aPTT, Fibrinogen, TT                                                                              |                   |                   |
| Special clotting assays          | Intrinsic and Extrinsic Factors                                                                       |                   |                   |
| Chromogenic assays               | AT, Protein C                                                                                         |                   |                   |
| Latex-enhanced assays            | Auto D-Dimer (Blue)                                                                                   |                   |                   |
| Hardware Specifications          |                                                                                                       |                   |                   |
| Display                          | 4.3" (480×272 pixels) with capacitive touchscreen control                                             |                   |                   |
| Multi-language                   | Y                                                                                                     |                   |                   |
| Printer                          | Optional external printer (RS232)                                                                     |                   |                   |
| Barcode scanner                  | Optional external 1D barcode scanner (RS232)                                                          |                   |                   |
| LIMS connectivity                | Yes, via TECAM software                                                                               |                   |                   |
| Dimensions                       | 225 mm × 150 mm × 90 mm (L × W × H)                                                                   |                   |                   |
| Power supply                     | Input 110–240V at 50–60 Hz; output 5V, 3.3A                                                           |                   |                   |

# Quality and reliability from the reagent experts.

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C-Series is the ideal platform to use Helena's reliable, market-tested portfolio of reagents. Our flexible range of kit formats provide unbeatable quality and value regardless of throughput.

## Routine Assays

- PT
- aPTT
- Clauss Fibrinogen
- Thrombin Time

## Factor Deficient Plasmas (Immunodepleted)

- Factor II Deficient Plasma
- Factor V Deficient Plasma
- Factor VII Deficient Plasma
- Factor VIII Deficient Plasma
- Factor IX Deficient Plasma
- Factor X Deficient Plasma
- Factor XI Deficient Plasma
- Factor XII Deficient Plasma

## Specialist Assays

- Auto Blue D-Dimer 400
- DRVVT Screen
- DRVVT Confirm

## Chromogenic Assays

- Antithrombin Xa (Chromogenic)
- Protein C (Chromogenic)

## Calibrators and Controls

- Calibration Plasmas
- Routine Controls
- Speciality Assayed Controls



**Contact Helena for more information**

Email [sales@helena-biosciences.com](mailto:sales@helena-biosciences.com)



By Royal Charter

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Queensway South  
Team Valley Trading Estate  
Gateshead  
Tyne and Wear  
NE11 0SD  
United Kingdom

Holds Certificate Number:

**MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: **MD 69326**

Location

Registered Activities

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Sunderland Enterprise Park  
Colima Avenue  
Sunderland  
SR5 3XB  
United Kingdom

The design, manufacture, supply, servicing and repair of  
in-vitro diagnostic devices, molecular biology products,  
immunochemistry products and medical laboratory equipment  
and consumables.

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# Training certificate

helena  
Biosciences Europe

This is to certify that

**Sergeu Sorokovice**

from

**IM Global Biomarketing Group**

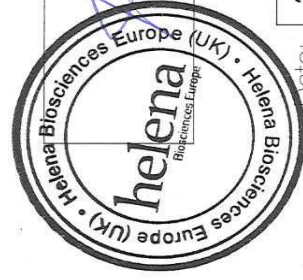
has received training on the following:

Electrophoresis products: SAS-1/2

Haemostasis products: C-series, AC-4, AggRAM and reagents

Service training: AC-4

Signed:



Date: 31st October - 4th November 2011

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