

Anexa nr. 54 la Formularul Specificații tehnice

Coagulometru semi-automat

Coagulometru semiautomat		
Descriere	Coagulometru semiautomat destinat pentru testarea mostrelor preluate de la pacienți pentru determinarea factorilor de coagulare a sîngelui.	
Parametrul	Specificatia	Specificatia tehnica oferita, model Helena C-2 (nr. cat. C-2X) (Helena Biosciences / Marea Britanie)
Configuratia	Capacitatea sistemului ≥ 2 probe simultan	2 probe simultan
Tip proba	plasma	plasma
Teste	APTT	APTT
	FIB	FIB
	PT	PT
	TT	TT
Data management	Display LCD sau LED	Coloured Touch Display
	Imprimanta	da
	Interfata PC	da
	Cititor bar code – optional	Da, optional

1.2 VIEWS OF THE DEVICE



FIGURE 1: TOP VIEW – HELENA C-1

Home Screen

Coloured Touch Display

Complete area is prewarmed to 37°C

1 x Reagent position \varnothing 24mm

2 x Reagent position \varnothing 22mm

(1 position will be stirred on Helena C-2 and Helena C-4)

2 x Reagent positions \varnothing 13mm

10 x Cuvette incubation positions

(x20 on Helena C-2 and Helena C-4)

1 x Cuvette measurement positions

(x2 for Helena C-2, x4 for Helena C-4)



FIGURE 2: REAR VIEW

5V:	Power in
PC:	LIS or PC
SERVICE:	Software update
PRINTER:	Serial printer
BARCODE:	Handheld barcode scanner (serial)



FIGURE 3: SIDE VIEW



1.3 CONSUMABLES / ACCESSORIES

Helena C-Series products available

REF	Product	Description
C-1X	Helena C-1	1 x single channel semi-automated coagulation analyser with starter kit.
C-2X	Helena C-2	1 x two channel semi-automated coagulation analyser with starter kit.
C-4X	Helena C-4	1 x four channel semi-automated coagulation analyser with starter kit.
C-101V	Single Cuvettes (Voucher)	500 x single use cuvettes with activation card.
AC4302	Stir Bars	4x stirring magnets. Required to mix Thromboplastin L reagent for PT testing.
AC4300	Reagent Container (22.5mm)	100x plastic containers for holding reagent.
C-104	Reagent Tube (11.0mm)	100x plastic containers for holding reagent.
C-011	Reagent Adapter 22.5 – 24.2mm	1x Reagent adapter Ø 24.5 – 22.5mm. Helps to place vials with different sizes.
C-013	Display Protection Foil	1x protection foil, to save glass from scratches. Kit includes, foil, clean tissues & remover tool.
C-02	TECAM Smart Software	A small local LIS and data management software package.
C-01	Thermal Printer	1x thermal printer, to print results, calibration data or system information. Supplied with UK power lead and C-015 interface cable.
C-016	Thermal Printer Paper	5 x rolls of paper for use with C-01
C-014	Barcode Scanner	1x external, handheld CCD-barcode reader. Reads 1D or QR codes for patient ID and cuvette vouchers.
2503600	Download cable	1x data cable for transfer of information between analyser and TECAM smart software.
C-015	Interface Cable	1 x Interface cable for Thermal Printer.

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

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Certificate No: **MD 69326**

Location

Registered Activities

Helena Laboratories (UK) Ltd
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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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1.4.2 TEST METHODS

The following tests are provided to detect defects of the human coagulation system, which can be bleeding or thrombosis and the monitoring of anti-coagulation drugs like Heparin or Warfarin.

Test	Name	Specimen	Method	Helena C-Series		
				Helena C-1	Helena C-2	Helena C-4
PT	Prothrombin Time	plasma	clot	Yes	Yes	Yes
APTT	Activated Partial Prothrombin Time	plasma	clot	Yes	Yes	Yes
FIB	Fibrinogen	plasma	clot	Yes	Yes	Yes
TT	Thrombin Time	plasma	clot	Yes	Yes	Yes
AT	Antithrombin	plasma	chromogen	No	Yes	Yes
DD	D-Dimer	plasma	immuno	Yes	Yes	Yes
Factors	Factors II, V, VII, VIII, IX, X, XI, XII	plasma	clot	No	Yes	Yes
PC	Protein C	plasma	chromogen	No	Yes	Yes
LA-S	Lupus Screen	plasma	clot	No	Yes	Yes
LA-C	Lupus Confirm	plasma	clot	No	Yes	Yes

1.4.3 SPECIMEN COLLECTION

Type:	Human citrated plasma
Collection:	Vein puncture, 1:10 mixed sodium citrate 3.2% (0.105M)
Centrifugation:	10min at 1500g
Storage:	Max 4h after collection at room temperature
Bilirubin:	< 50mg/dL
Haemoglobin:	< 9000mg/L
Triglyceride:	< 2500g/L



Always confirm specific specimen preparation and handling conditions for the test and reagent being used. This information can be found in the product specific IFU's or referenced in the Helena C-Series User Guide (HL-2-P-3429).