

CONGO RED REAGENT



IVD In vitro diagnostic medical device

Classification according to Regulation (EU) 2017/746 - **Class A** device

For use with Congo Red Highman kit

INSTRUCTIONS FOR USE

Basic UDI-DI	385889212HPC30708STARVF		
EMDN code	W01030708		
REF	Catalog number	Volume	UDI-DI
CR-OT-100		100 mL	03858888823559
CR-OT-1L		1000 mL	03858888823573



Intended use and test principle

Congo Red reagent is used as a component of the Congo Red Highman kit and is used for staining amyloid (amorphous deposits composed of protein fibrils) that accumulate within cells in cases of amyloidosis. The staining principle is based on the formation of hydrogen bonds between the Congo red dye and the carbohydrate component of the substrate. Congo red dye is an anionic dye that deposits in amyloid fibrils and shows birefringence under polarized light. Tissue stained with Congo red shows a red-orange color under a light microscope, while under a polarizing microscope amyloid deposits show the property of birefringence, producing a distinct green color on a dark background. Other structures that are also stained by Congo red (such as collagen) are not visible under a polarizing microscope.

Product description

- **CONGO RED REAGENT** – Reagent for staining amyloid deposits

Example of using Congo Red reagent as a component of the Congo Red Highman kit

Additional reagents and materials that can be used in the method:

- Fixatives, such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydration/rehydration agents such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95, and Histanol 100
- Clearing agents, such as BioClear xylene or BioClear New, an aliphatic hydrocarbon-based xylene substitute
- Infiltration and embedding agents such as BioGnost's granulated paraffins BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue
- Microscopic slide covering agents and cover glass mountants such as BioGnost's BioMount, BioMount High, BioMount M, BioMount DPX, BioMount New, BioMount New Low, BioMount DPX High, BioMount DPX Low, BioMount DPX New, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology
- Immersion oils such as BioGnost's Immersion Oil, Immersion Oils types A, C, FF, 37, or Immersion Oil Tropical Grade
- Other components of the Congo Red Highman kit: Potassium hydroxide, solution and Hematoxylin G2

Preparation of histological sections for staining

- Fix (Formaldehyde NB 4%, Formaldehyde NB 10%) and process the tissue sample
- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 8-10 µm thin sections and mount them on a VitroGnost slide (sections should be mounted on a VitroGnost adhesive slide)

NOTE

Pour the reagents into staining jars (Coplin, Hellendahl or Schifferdecker type) and return them to the original bottles after staining. Close well. Filter the reagents as needed.

Sample staining procedure

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 minutes
4.	Rehydrate in distilled/demineralized water	2 minutes
5.	Immerse in Congo Red reagent	5 minutes
6.	Drain the reagent from the slide without rinsing	
7.	Immerse in Potassium hydroxide, solution	10-15 seconds
8.	Rinse under tap water	5 dips
9.	Immerse in Hematoxylin G2 reagent	3 minutes
	Note: If sedimentation occurs in the solution or a metallic sheen forms on the surface, the reagent must be filtered before use	
10.	Rinse with tap water	3 minutes
11.	Dehydrate in 70% alcohol (Histanol 70)	5 dips
12.	Dehydrate in 95% alcohol (Histanol 95)	5 dips
13.	Dehydrate in 100% alcohol (Histanol 100)	2 minutes
14.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing, apply the appropriate type of BioMount coverslipping/mounting medium to the slide. If BioClear xylene was used, use one of BioGnost's xylene-based mountants (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate mountant is BioMount New. Cover the section with a VitroGnost cover glass.

Result

Amyloid deposits - pink to red, green under polarized light
Nuclei - blue

Note

When using a polarizing microscope, amyloid deposits show the property of birefringence (green color).

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instructions for Use may cause differences in staining results.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. It is necessary to follow the manufacturer's instructions for use. To avoid errors, the staining process and diagnosis can only be carried out by authorized and professionally qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards. To avoid a false result, it is recommended to use a positive and negative control.

If a serious incident occurs during use or as a result of its use, please report it to the manufacturer or authorized representative and competent authority.

Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, therefore it is necessary to implement human health protection measures in accordance with good laboratory practice guidelines. It is mandatory to read and act according to the information and warning signs printed on the product label and in the Safety Data Sheet, which is available on request.

Storage, stability, and shelf life

Upon receipt, store the product in a dry place and well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or expose to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The production date and expiration date are printed on the product label.

References

1. Bancroft, J.D., Gamble, M. (2002), Theory and practice of Histological Techniques, Churchill Livingstone, New York.
2. Highman, B., Improved methods for demonstrating amyloid in paraffin sections, Archives of Pathology, V 41, p. 559

Warnings and precautions regarding the materials contained in the product:		
 	H226 H350	Flammable liquid and vapour. May cause cancer.
	P210 P233 P280 P308 + P313	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Wear protective gloves/protective clothing/eye protection/face protection. IF exposed or concerned: Get medical advice/attention.

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	Manufacturer		Batch code		Consult Instructions for use		In vitro diagnostic medical device
	Date of manufacture		Catalogue number		Caution		European conformity
	Use-by date		Temperature limit		Contains hazardous substances		Unique device Identifier

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Version	Description / reason for change	Date
2	Revised acc. to Regulation (EU) 2017/746 - IVDR	14.09.2026.