

CONGO RED, C.I. 22120

CE IVD In vitro diagnostic medical device

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

For staining of amyloids acc. to Highman and Puchtler

Congo red, Direct Red 28, Congorot

INSTRUCTIONS FOR USE

Basic UDI-DI	385889212HPC30707PDYETD		
EMDN code	W01030707		
REF	Catalog number	Mass	UDI-DI
CR-P-25		25 g	03858888820664



Intended use and test principle

Histology, cytology, and other related scientific disciplines study the microscopic anatomy of tissues and cells. Proper staining is required to achieve good visualization of tissue and cellular structures. Congo Red is a diazo dye used primarily for the demonstration of amyloid in histological samples based on its ability to bind specifically to the β -pleated sheet structure of amyloid fibrils. Congo Red molecules are elongated and linear, whereas amyloid fibrils consist of protein chains arranged in a characteristic β -pleated sheet structure.

Congo Red molecules align parallel to the amyloid fibrils and bind to the amyloid structure through a combination of hydrogen bonding, hydrophobic interactions, and electrostatic interactions. Under a light microscope, amyloid is stained red to orange-red, whereas under a polarized light microscope it exhibits a characteristic apple-green birefringence, which is its most important diagnostic feature. When Congo Red molecules are properly aligned along the amyloid fibrils, an ordered anisotropic structure is formed that refracts polarized light differently, resulting in a characteristic green birefringence under a polarized light microscope.

Product description

- **CONGO RED, C.I. 22120** - powder stain for preparation of a staining solution for microscopic identification of amyloid

Example of using Congo Red powder dye in the staining method according to Highman

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
- A clearing agent such as BioClear xylene or a substitute such as BioClear New, an aliphatic hydrocarbon-based agent
- Infiltration and embedding agents such as BioGnost's granulated paraffins BioWax 52/54, BioWax Plus 56/58, BioWax 56/58, BioWax Blue
- Microscopic slide covering agents and cover glass mountants such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount New Low, BioMount DPX, BioMount DPX High, BioMount DPX Low, 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
- Remaining components for Congo Red staining according to Highman: Potassium hydroxide solution (Cat. No. KHO-OT-100) and Hematoxylin G2 (Cat. No. HEMG2-OT-100)

Preparation of the staining solution

Congo Red powder dye solution (for staining according to Highman):

- 1% Congo Red powder dye solution (100 mL):
Dissolve 0.5 g of Congo Red powder dye in 50 mL of distilled/demineralized water with stirring. Add 50 mL of 100% ethanol (Histanol 100). Filter before use.

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** micrometer thin sections and mount on VitroGnost microscope slides (mount sections on VitroGnost adhesive microscope slides)

Example of the staining procedure for histological sections according to Congo Red Highman method

Pour the reagents into glass staining jars (type Coplin, Hellendahl or Schifferdecker) and return them to the original bottles after staining. Close well. If necessary, filter the reagents.

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 min
4.	Rehydrate in distilled/demineralized water	2 min
5.	Immerse in Congo Red dye solution	5 min
6.	Pour off the reagent from the section without rinsing	
7.	Immerse in Potassium hydroxide solution	15 sec
8.	Rinse with tap water	5 dips
9.	Immerse in Hematoxylin G2 reagent	3 min
	Note: If precipitation occurs in the solution or metallic sheen forms on the surface, the reagent must be filtered before use	
10.	Rinse with tap water	3 min
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 min
14.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing, apply an appropriate BioMount covering/mounting medium. 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

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the method of preparing the dye solution or from the staining procedure may cause variations in the staining results shown in this Instructions for Use.

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, staining solution preparation, staining procedure and diagnosis may only be performed by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards.
 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. Conn, J. (1977): Biological Stains, 9th ed., Baltimore: Williams and Wilkins Co.
2. Gurr, E. (1971): Synthetic dyes in biology, medicine and chemistry, London: Academic Press

Warnings and precautions regarding the materials contained in the product:	
	<p>H319 Causes serious eye irritation. H350 May cause cancer. H361d Suspected of damaging the unborn child.</p> <p>P280 Wear protective gloves/protective clothing/eye protection/face protection. P308 + P313 IF exposed or concerned: Get medical advice/attention. P305+P351+P338 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.</p>

CR-P-IFU_ENV3, 13.04.2026.

 Manufacturer	 Batch code	 Consult Instructions for use	 <i>In vitro</i> 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
3	Revised acc. to Regulation (EU) 2017/746 - IVDR	13.04.2026.