

BIOCLEAR NEW

CE IVD *In vitro* diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - **Class A** device

Aliphatic hydrocarbons-based xylene substitute

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30799PROCYU		
EMDN code	W01030799		
REF	Catalog number	Volume	UDI-DI number
	BCN-1L	1000 mL	03859891237920
	BCN-2.5L	2500 mL	03858890007879
	BCN-5L	5000 mL	03858890005813
	BCN-10L	10000 mL	03858890006681



Intended use and test principle

BioClear New is xylene substitute used as clearing agent. Clearing agents are completely miscible with alcohol and paraffin which makes them an ideal intermedium between alcohol and embedding paraffin (BioWax), as well as alcohol and section mounting agent. Beside xylene, the standard clearing agent, aliphatic hydrocarbons-based xylene substitutes are more and more frequently used (such as BioClear New); they are weakly reactive and of low toxicity. They are not irritable and do not cause hypersensitivity. Results of clearing using them are comparable to results of using xylene. BioClear New can be used with every tissue processing device and automated slide stainers. Adequately dehydrated and cleared tissue sample becomes transparent and appropriate for microscopic analysis of the slide. During histological sample processing, the sample is exposed to BioClear New, which mixes with the alcohol and gradually displaces it from the sample until BioClear New remains in the sample. The sample is then treated with paraffin, which in the same manner gradually displaces BioClear New and infiltrates the sample.

During the staining procedure of the slides, BioClear New at the beginning of the staining process serves to remove paraffin from the slides (deparaffinization) and infiltrates the slides with alcoholic solutions. At the end of the staining procedure, BioClear New serves as a replacement for alcoholic solutions and clears the slides so that they can be covered with a mounting medium for the purpose of preparing permanent slides..

Product description

- **BIOCLEAR NEW** – aliphatic hydrocarbons-based reagent, xylene substitute used in clearing process.

Additional reagents and materials that can be used in this method

- Fixatives such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydrating/rehydrating agent, such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95 and Histanol 100
- Clearing agent, such as BioClear xylene or its aliphatic hydrocarbon substitutes, such as BioClear New
- Infiltration and embedding agent, such as BioGnost's granulated paraffin BioWax Plus 56/58, BioWax 56/68, BioWax Blue
- Covering agents for microscopic sections and mounting cover glass, such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology
- BioGnost's immersion oils, such as Immersion oil, Cedarwood oil, Immersion oils types A and C, FF, 37 or Tropical Grade

Recommended procedure for processing routine 3-5 mm histological sections

Note: Fix the tissue sample before processing (Formaldehyde NB 4%, Formaldehyde NB 10%) for at least 24 hours.

STEP	REAGENT	TIME / min	TEMPERATURA	PRESSURE/VACUUM
1	Dehydrate in 70% alcohol (Histanol 70)	60	room temperature	vacuum
2	Dehydrate in 95% alcohol (Histanol 95)	60	room temperature	vacuum
3	Dehydrate in 100% alcohol (Histanol 100)	60	room temperature	vacuum
4	Dehydrate in 100% alcohol (Histanol 100)	60	room temperature	vacuum
5	Dehydrate in 100% alcohol (Histanol 100)	90	room temperature	vacuum
6	Clear in xylene substitute (BioClear New)	90	room temperature	vacuum
7	Clear in xylene substitute (BioClear New)	90	+35 °C	vacuum
8	Clear in xylene substitute (BioClear New)	90	+45 °C	vacuum
9	Infiltrate with paraffin (BioWax)	60	+62 °C	vacuum
10	Infiltrate with paraffin (BioWax)	60	+62 °C	vacuum
11	Infiltrate with paraffin (BioWax)	60	+62 °C	vacuum

- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 4-6 μ m thin slices and mount on a VitroGnost microscope slide

An example of deparaffinization and clearing of histological sample during staining

1.	Deparaffinization in 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.	Staining procedure	
6.	Dehydrate in 70% alcohol (Histanol 70)	10 dips for 1 sec
7.	Dehydrate in 95% alcohol (Histanol 95)	10 dips for 1 sec
8.	Dehydrate in 100% alcohol (Histanol 100)	10 dips for 1 sec
9.	Clear in xylene substitute (BioClear New)	2 exchanges, 2 min each

Immediately after clearing, apply BioGnost's xylene substitute – based mounting agent (BioMount New).

Result

The result of clearing the tissue sample (through processing) is high-quality and complete infiltration/permeation of the sample with paraffin, which enables easy and simple sectioning of the sample on a microtome.

The result of clearing the slides (through the staining procedure) is high-quality dehydration of the sample with a series of alcohols of increasing concentrations and a clear visualization of tissue and cellular structures after coverslipping the preparation with a mounting medium.

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Major deviations from the procedure of processing, deparaffinization and dehydration during staining procedure described in this Instruction for use may cause an inadequate visualization of cellular structures and prevent diagnosis.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. Be sure to follow the manufacturer's handling instructions. To avoid errors, histological processing of samples, staining and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards.

If a serious incident occurs during use of this product 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, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. 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 expiration date is printed on the product label.

References

1. Carson, F. L. (2007), Histotechnology, 2nd ed. Singapore
2. Cook, D. J. (2006): Cellular pathology, 2nd ed. Banbury: Scion Publishing Ltd.
3. Kiernan J. A. (2008) Histological and histochemical methods, 4th ed. Bloxham: Scion Publishing Ltd.

Warnings and precautions regarding the materials contained in the product:	
	<p>H304 EUH066</p> <p>May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking.</p> <p>P280 P301 + P310 P331 P405 P501</p> <p>Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: immediately call a POISON CENTER/doctor. Do NOT induce vomiting. The product must be stored in a secure location. Dispose of the container contents in accordance with local regulations.</p>

BCN-IFU_ENV10, 02.02.2026., IŠP

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

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Version	Description / reason for change	Date
10	Revised in acc. to Regulation (EU) 2017/746 - IVDR	02.02.2026.