Carbolic toluidine blue

CE IVD

REF. 320130

Dye for histological metachromatic staining

IFU104A

For professional use only
Please read all this information carefully before using this device.
IFU content may change, make sure you have the latest version available at my.ral-diagnostics.fr.

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Intended use

Carbolic toluidine blue is intended to be used as a dye for histological metachromatic staining prior to microscopic examination.

If applicable, CellaVision RAL Diagnostics recommends using the associated CellaVision RAL Diagnostics products and cannot guarantee that the expected results will be achieved if used in combination with products of other brands.

Principle

Carbolic toluidine blue is use for metachromatic staining of sections. Carbolic toluidine blue stain epithelium elements and the conjunctive stroma.
Toluidine blue, which is the reference stain for extemporaneous tests, selectively stain acid tissues components.

Device description

Carbolic toluidine blue
Clear blue solution

REF. 320130-0125	1 x 125 mL
REF. 320130-1000	1 x 1.0 L

For a specific batch, refer to the certificate of analysis for the batch available on my.ral-diagnostics.fr.

Storage

Storage and use temperature: 15-25°C.
Storage and use conditions: away from light and heat sources.
Bottle shelf life before opening: refer to expiry date on the label.
Bottle shelf life after opening : refer to expiry date on the label and if the "period after opening" symbol is present take it into account.

Active components

Carbolic toluidine blue
Phenol CAS 108-95-2: ca 1 %
Toluidine blue O CAS 92-31-9: < 1 %

Hazard classification and safety information

Carbolic toluidine blue
Warning:
H226 - Flammable liquid and vapour.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H341 - Suspected of causing genetic defects.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P264 - Wash hands thoroughly after handling.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.

CONT	C6H5OH

Personnel qualification

All samples and products must be handled by qualified and authorized personnel, with individual or collective protection, according to the national directives in force in the laboratories and be aware of the classification of hazardous materials indicated on the label and of the safety data sheet (available at my.ral-diagnostics.fr).

The diagnosis must be conducted by qualified and authorized personnel, in accordance with the procedures in force within the laboratory.

Specific equipment and reagents required but not provided

Microscope slides, methanol, formalin, Ultropak or Binocular magnifying glass, cryostat and this following RAL Diagnostics devices:
CryoRAL REF. 361405

This equipment may vary depending on the protocol. Please refer to the relevant protocol (see the section operating procedure) to ensure that you have the necessary equipment to carry out tests.

Operating procedure

The use of the material necessary for the sample must comply with the supplier's instructions for use.

Sample preparation
The specimen must be treated in accordance with procedures available in the laboratory and promulgated by national authorities.

Surface test (method on thin slices):
On a fresh section or rapidly fixed, sample a tissular slice as thin as possible, either by freehand or by quick freezing, and a section of the piece surface with a cryostat.

Test by transparency (method on mounted sections):
Make a thin section according to the frozen section technique.

Protocols
The staining steps of the protocols indicated below consist of a successive covering of the slides with the different staining reagents or dipping of the slides in the different staining baths. Please refer to the title to know which case you are in. For the covering method, place slide on a stand with fixed smear on top.
The processing time only considers the dipping time in the reagents.

Manual protocol on thin slices - Covering staining method - Manual microscopic analysis

Processing time [hh:mm:ss]: NA

Steps	Reagents	Time [mm:ss]	Indications
Fix	Methanol-formalin mixture	NA	NA
Stain	Carbolic toluidine blue	NA	NA

Manual protocol on mounted sections- Covering staining method - Manual microscopic analysis

Processing time [hh:mm:ss]: 00:02:36

Steps	Reagents	Time [mm:ss]	Indications
Fix	Methanol-formalin mixture	NA	NA
Rinse	Ethanol 90°	00: 01	Can be extend
Rinse	Absolute ethanol	00: 01	to 2 sec
Rinse	Xylene	00: 02	Dip in
Hydrate	Absolute ethanol	00: 01	Can be extend
Hydrate	Ethanol 90°	00: 01	to 2 sec
Stain	Carbolic toluidine blue 1%	00: 30	Can be extend to 1min
Rinse	Water	NA	Rapidly and dry carefully on filter paper
Rinse	Absolute ethanol	01: 00	NA
Dehydrate	Ethanol 90°	01: 00	NA
Dehydrate	Xylene	NA	Dip in *
Mount	Toluene or Xylene base mounting media	NA	NA

*Repeat this step until the preparation is perfectly clear before mounting

Expected results

Nuclei: violet
Lipoids: dull blue
Cytoplasm: blue
Fibrin: greenish blue
Mucus: purplish red
Elastic Fibres: pale green
Amyloid: purplish red
Starch: pale greenish blue
Colloid: strong Blue
Erythrocytes: Green

If observed results vary from those expected, please contact CellaVision RAL Diagnostics technical service through your usual supplier for assistance.

Performance

This medical device is state of the art. Its analytical performance, scientific validity and medical relevance are assessed in the CE marking review.

To ensure product performance, use clean and dry laboratory equipment.

The laboratory is responsible for notifying the manufacturer and state competent authority of any serious incident relating to the medical device uses.

User quality control

Users are responsible for determining the appropriate quality control procedures for their laboratory and complying with applicable laboratory regulations.

CellaVision RAL Diagnostics recommends quality control at reagents renewal and for the first staining cycle of each day. Slides stained for quality control purposes should be checked to ensure that they are satisfactory for intended test (properly stained and free of precipitate). Staining results for each cell type must also be compliant with this manual expected results.

These quality control procedures should only be performed by qualified personnel.

Other products

For more information contact your usual supplier.

Recommendations, notes, and troubleshooting

Products appearance
If the appearance of the products differs from the description above, do not use it and contact CellaVision RAL Diagnostics technical service through your usual supplier for assistance.

Procedures notes
To prevent products degradation, please comply with the storage and handling recommendations specified in this manual.

Products stability
Every CellaVision RAL Diagnostics product can be used until the expiry date indicated on, in its original packaging if it is still hermetically sealed.

Staining stability
Staining quality and reproducibility depend on the correct use of the products. CellaVision RAL Diagnostics recommends mounting the stained slides with a coverslip using a suitable mounting liquid and to store them in a light and dustproof container.

Instructions for cleaning and waste disposal
All biological samples, effluents and used consumables should be considered potentially hazardous.

To avoid any risk, apply the following instructions: dispose of samples, effluents and consumables in accordance with laboratory standards and applicable national and local standards and regulations.

Chemical and biological waste must be collected and processed by specialized, registered companies.

Table of symbols and abbreviations

Depending on the product, you may find the following symbols on the device or the packaging material.

GHS Pictograms	Interpretation
	Explosive
	Flammable
	Oxidizer
	Compresses gas
	Corrosive
	Toxic
	Harmful
	Health Hazard
	Environmental Hazard
	No labelling applicable

Symbols	Interpretation
	Batch code
	Serial number
	Catalogue reference
	Date of manufacture
	Use up to
	Unique device identifier
	Manufacturer
	Importer
	Entity distributing the medical advice in the region concerned
	CE marking device
	In vitro diagnostic medical device
	Authorised Representative in the European Community
	Authorised Representative in Switzerland
	Complies with UK guidelines
	Do not use if packaging is damaged
	Keep away from light
	Temperature limit: 15-25°C
	Temperature limit: 15-30°C
	Keep dry
	Box: handling upwards
	Fragile
	Sterilised by irradiation
	Single sterile barrier system with outer protective packaging
	Sterile and radiation-sterilised barrier suit
	Do not reuse
	Do not resterilize
	Contents sufficient for n tests
	Hazardous material contained
	Consult instructions for use
	Use
	After opening, use within XX months
	The product must not be used in conjunction with an automatic colouring machine
	Indicates a medical device that contains potentially carcinogenic, mutagenic or reprotoxic (CMR) substances, or substances classified as endocrine disruptors

Bibliography

GANTER P., JOLLES G., *Histochimie normale et pathologique,* ed. GAUTHIER-VILLARS, vol. 2, 1970, p. 1478-1479.

Change tracking

Date	Version	Modifications
03/2023	IFU104A	IVDR (EU) 2017/746 compliance

Legal representatives

Countries	Address
United Kingdom	QAvis UK Ltd, company N° SC679796, 56-66 Frederick Street Edinburgh, EH21LS, United Kingdom
Switzerland (CH-REP)	MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug Switzerland