Brilliant cresyl blue solution

REF. 310750-0125

Multi-application laboratory reagent

CE IVD

IFU100A-RAL

For professional use only.
Please read all information carefully before using this device.

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Intended use

Brilliant cresyl blue solution is intended for reticulocytes staining prior microscopic examination.

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

Principle

At high concentration, vital stains like Brilliant cresyl blue, spread into the reticulocyte and precipitate its internal elements, forming a kind of network, the reticulo-filamentous substance, from which the cell gets its name.

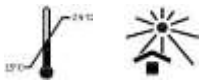
Device description

Brilliant cresyl blue solution
Clear dark blue solution
REF. 320550-0125 1 X 125 mL

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

Storage

Storage temperature: 15-25°C away from light.
Bottle shelf life before and after opening: refer to expiry date on label.



Hazard classification and safety information

Brilliant cresyl blue solution
No labelling applicable

Personnel qualification

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

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

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

Hemolysis tube and incubator

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 equipment used for sample processing must comply with the supplier's instructions for use.

Sample preparation
Specimen must treat in accordance with procedures available in the laboratory and promulgated by national authorities.

Reagents and instruments preparation
No preparation needed.

Protocols
The staining steps of the protocol are indicated in the table below.

Protocol for reticulocytes staining - Manual bath method - Manual microscopic analysis

Processing time: 15 min

Steps	Reagent	Time [mm: ss]	Indications
Stain	Brilliant cresyl blue solution	None	Mix 2 drops of blood with 2 drops of reagent in a hemolysis tube
Heat	None	15:00	37 °C in an incubator
Mix	None	None	After incubation
Smear	Drop of mixture	None	Let dry the smear prior to microscopic examination with a x100 immersion objective

Expected results

Reticular filaments: Deep blue
Background: Pale blue

If observed results vary from those expected, please contact 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.

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 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.
Filter Brilliant cresyl blue solution before use if deposits appear.

Products stability

Every 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.

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
	Compressed 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

CLARK G., *Staining Procedures,* Williams & Wilkins, 4th ed., 1981, p. 176-177.
LILLIE R.D., *H.J. Conn's Biological Stains,* Sigma Chemical Company, 9ème éd., 1990, p. 598-599.
LORD-DUBE H., L'ITALIEN R., *Hématologie,* éd. Décarie, 1983, p. 155-157

Change tracking

Date	Version	Changes
05/2022	IFU100A-RAL	IVDR (EU) 2017/746 compliance

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