# pH=7.0 buffer Solution for Haematology

CE IVD

**REF. 330370**

Differential staining of cellular structures

**IFU014A-RAL**

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

## Table of contents



## Intended use

pH=7.0 buffer Solution for Haematology in combination with staining reagents is intended to be used for the differential staining of cellular structures 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

Quality and reproducibility of staining are obtained by using buffer solution.
Due to complex mode of action of stains, it is essential to set up standard staining conditions to assure a perfect staining quality and reproducibility. The use of buffer solution allows the controls of unpredictable variations and alter staining results noticeable with tap water or water mixing.
RAL buffers solutions for Haematology solution are specially formulated for Hematology. Safe for users, Buffer solutions for Haematology formulated with phosphates, are specially developed for hematology, and allow to guaranty a better products stability and rinsability.

## Device description

**pH=7.0 buffer solution for Haematology**

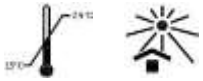
Clear colorless solution

| | |
|---|---|
| REF. 330370-1000 | 1 x 1.0 L |
| REF. 330370-5000 | 1 x 5.0 L |

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 the expiry date on the label.



## Active components

**pH=7.0 buffer solution for Haematology**

Potassic mono phosphate - CAS 7778-77-0: < 0.1%
Anhydrous disodic phosphate - CAS 7558-79-4: < 0.1%
A mixture of 5-chloro-2-methyl-2H-isothiazol-3-one [EC No 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC No 220-239-6] (3:1) – CAS 55965-84-9: ca0.005 %

## Hazard classification and safety information

**pH=7.0 buffer solution for Haematology**

Warning: H317 - May cause an allergic skin reaction H412 - Harmful to aquatic life with long lasting effects. P280 - Wear protective gloves, protective clothing, eye protection. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

| | |
|---|---|
| **CONT** | 5-chloro-2-methyl-2H-isothiazol-3-one/ 2-methyl-2H-isothiazol-3-one |

## 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

Please refer to the IFU of the staining reagent used.

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**
Please refer to the IFU of the staining reagent used.

**Reagents and instruments preparation**
If applicable use the pH=7.0 buffer solution for Haematology to dilute your staining product.

**Protocols**
Please refer to the IFU of the staining reagent used.

## Expected results

Please refer to the IFU of the staining reagent used.

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.

Please refer to the IFU of the staining reagent used.

## Other products

For more information, please 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.

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

Quality and reproducibility of staining are obtained by using buffer solution.
Due to complex mode of action of stains, it is essential to set up standard staining conditions to assure a perfect staining quality and reproducibility. The use of tap water or water mixing is not recommended because unpredictable variations may occur and alter staining results.
Quality and reproducibility of staining are obtained using Buffer solution specially formulated for Hematology. Safe for users, Buffer solutions for Haematology are formulated with phosphates, are specially developed for hematology, and allow to guaranty a better products stability and rinsability.

**Product 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**
Please refer to the IFU of the staining reagent used.

**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 |

| SYMBOL | INTERPRETATION |
|---|---|
| LOT | Batch code |
| SN | Serial number |
| REF | Catalogue reference |
|  | Date of manufacture |
|  | Use up to |
| UDI | Unique device identifier |
|  | Manufacturer |
|  | Importer |
|  | Entity distributing the medical advice in the region concerned |
| CE | CE marking device |
| IVD | In vitro diagnostic medical device |
|  | Authorised Representative in the European Community |
|  | Authorised Representative in Switzerland |
| UK CA | 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 | 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, 4 th ed., 1981, p.2-8. DEAN **J.A.**, *Lange's Handbook of chemistry*, Mc GRAW-HILL, 12 th ed., 1972, p.5-73 to 5-78.

## Changes tracking

| Date | Version | Changes |
|---|---|---|
| 05/2022 | IFU014A-RAL | IVDR (EU) 2017/746 compliance |

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