pH=7.0 Buffer Powder (6 doses)

REF. 361600-0000

Multi-application laboratory reagent

CE IVD

IFU040A-RAL

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

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Intended use

pH=7.0 Buffer Powder is intended to be used to buffer biological or chemical reactions.

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

A large number of biological reactions can take place only at specific pH values. Buffers solution help maintain a stable pH. During the staining process, pH values have a significant role on staining affinities.
In hematology, May-Grünwald, Giemsa and Laveran Panchrome stains are neutral mixtures. They are not active in an alcoholic medium and only act selectively when released in a buffered aqueous solution. Buffered solutions are used as diluting and possibly rinsing solutions.

Device description

pH=7.0 Buffer Powder (6 doses)
White powder
REF. 361600-0000 6 x 10 g

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.
Keep dry.
Shelf life before and after opening: refer to the expiry date on the label.

Hazard classification and safety information

pH=7.0 Buffer Powder (6 doses)
Warning: H319 - Causes serious eye irritation.
P280 - Wear protective gloves, protective clothing, eye protection. P337+P313 - If eye irritation persists: Get medical advice/attention.

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

A hermetic bottle of 1 L capacity, distilled or demineralized water.

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
Please refer to the IFU of the staining reagent used.

Protocols
Pour 1 dose pH=7.0 Buffer Powder in 1 L of distilled or demineralized water and mix until complete dissolution.
1 L of pH=7.0 Buffer Solution prepared as described above remains stable for 4 weeks, if packed in an airtight clean bottle.

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.

1L of pH=7.0 Buffer Solution prepared as described above remains stable for 4 weeks, if packed in an airtight clean bottle.

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

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