Q Buffer Citrate EDTA, pH 7.5 (RTU)

In Vitro Diagnostic Use (IVD)

Product identification

BU-001-1000	1 l
BU-001-5000	5 l

Intended use

Buffers are intended for immunohistochemical (IHC) applications. They are used as wash and rinse solutions, as dilution solutions and for antigen unmasking. The products may be used manually or with any automated staining platform.
Authorized and skilled personnel may only use the product. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results

Summary and explanation

The buffer is used for rinsing and as a liquid for wash baths in immunohistochemical and histochemical staining techniques. Citrate buffer with additional EDTA (Ethylenediaminetetraacetic acid) and pH 7.5 is used to improve tissue decalcification.

Principle of the procedure

Each step in IHC is incubated for a precise time and temperature and requires interposed washing steps.

Materials provided

BU-001-1000: 1 bottle of 1 l EDTA Citric acid buffer
BU-001-5000: 1 canister of 5 l EDTA Citric acid buffer
Product label shows the specific lot number.

The buffer contains the chemical ingredients EDTA and citric acid.

Materials required but not provided

Primary antibodies and further reagents for IHC application.

Storage and handling

Store at 2 - 8 °C.

The product is stable until the expiry date printed on the vial if stored correctly. Do not use the reagent after the expiration date.
To maintain proper delivery of reagents and stability of the product, the cap must be put on after each use and the vial must be refrigerated immediately in an upright position.

Reagent preparation

The buffer is a ready-to-use solution. The EDTA citric acid buffer should be at room temperature before opening the bottle. Check the pH value, if necessary, adjust to pH 7.5 with NaOH or HCl.

Warnings and precautions

1. Authorized and skilled personnel may only use the product.
2. There are no estimated health risks, if the product is used as directed. MSDS is available on request.
3. Do not use reagents after expiration date.
4. Take reasonable precautions when handling reagents. Use protective clothing and gloves.
5. All hazardous materials should be disposed according to guidelines for hazardous waste disposal.
6. Avoid microbial contamination of reagents as it may cause incorrect results.

Application

The slides with the tissue sections are rinsed with the buffer and placed in a washing bath with this buffer solution for 2 or 5 minutes.
The time in the wash bath depends on the immunohistochemical staining technique.

Quality control procedures

Please refer to the data sheet of the primary antibody when used in IHC applications.

Interpretation of results

Please refer to the data sheet of the primary antibody when used in IHC applications.

Performance characteristics

Please refer to the data sheet of the primary antibody when used in IHC applications.

Limitations

1. Errors excepted. This data sheet contains general information.
2. For *in vitro* diagnostic use.
3. For laboratory use only.
4. This reagent is "for professional use only" as immunohistochemistry is a multiple step process that requires specialized training in the selection of the appropriate reagents, tissues, fixation and processing, preparation of the immunohistochemistry slide, choice of detection system, and interpretation of the staining results.
5. Tissue staining is dependent on the handling, processing and storage of the tissue prior to staining. Improper fixation, freezing, thawing, washing, drying, heating, sectioning, or contamination with other tissues or fluids may produce artifacts, antibody trapping, or incorrect results. Optimal performance requires adequate specimen quality as well as appropriate sample preparation.
6. Excessive or incomplete counterstaining may compromise proper interpretation of results.
7. Unexpected results may occur due to biological variability of antigen expression in neoplasms or other pathological tissues.
8. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results. Staining must be performed in a certified, licensed laboratory under the supervision of a qualified pathologist who is responsible for evaluation and assuring the adequacy of positive and negative controls. Manufacturer is not liable for incorrect results due to visual evaluation.
9. Prediluted antibodies are ready-to-use and optimized for staining. Further dilution may lead to incorrect results.
10. After successful validation users may dilute antibody concentrates according to requirements. Appropriate controls must be employed and documented.
11. The performance of the product was established using the procedures provided in this package insert

only and modifications to these procedures may lead to changes in efficiency. Non-application as prescribed in this data sheet leads to loss of all liability. Any changes in product, composition, implementation, as well as use in combination with any reagents other than recommended herein is not allowed; users are responsible themselves for those changes and have to perform prior validation.

12. Application in combination with diagnostic devices requires prior validation.
13. We do not take responsibility for any possible damage including personal injury, time or effort on economic loss caused by this product. Our warranty is limited to the price paid for the product.

Troubleshooting

1. Only intact cells should be used for interpretation of staining results, as degenerated cells show non-specific staining.
2. If no staining occurs, control application order of reagents. Follow all indications given in the instructions for use.
3. Do not allow the sections to dry out.
4. If weak staining occurs, pay attention during staining steps to freshly prepared chromogen, incubation times and temperatures, as well as accurate draining off of reagents.
5. Avoid surplus background staining by optimal removal of paraffin, washing of slides and dilution of primary antibody. If excessive background staining occurs, high levels of endogenous biotin may be present (unless a biotin-free detection system is being used). A biotin blocking step should be included.
6. Sodium azide inactivates HRP, which may lead to false results. Wash sections in sodium azide free buffer.
7. Contact quartett customer service in case of any uncertainties.

Literature

1. Bancroft JD, Survana SK & Layton C (2013): Bancroft's Theory and Practice of Histological Techniques. 8th Edition, Elsevier.
2. Dabbs DJ (2021): Diagnostic Immunohistochemistry: Theranostic And Genomic Applications, Sixth Edition, Elsevier.
3. NCCLS Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline—Second Edition Volume 31 Number 4, January 2011.

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In the event that the user experiences any technical or performance-related issues with the product, please consult the manufacturer or a competent authority.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.

Date of publication or revision

2023-08-30
Change(s) made: Catalog numbers

Explanation of the symbols

REF	Bestellnummer Catalog number		Verwendbar bis Use by
LOT	Chargenbezeichnung Batch code	2 °C 8 °C	Temperaturbegrenzung Temperature limitation
IVD	In Vitro Diagnostika In vitro diagnostic agent		Bei beschädigter Verpackung nicht verwenden Do not use if package damaged
	Hersteller Manufacturer		Gebrauchsanweisung beachten Consult instructions for use
⚠	Achtung Caution		