DIAPATH

COMPANY WITH QUALITY SYSTEM CERTIFIED BY DNV =ISO 13485=

Containers pre-filled with 10% neutral buffered formalin, ready to use

CE IVD

Primary fixative containing formaldehyde 4%, ready to use, pH between 7.2 – 7.4

Manufacturer: Diapath S.p.A.

Use

Reagents for in vitro diagnostic use

Code	Container	Packaging	Container Volume	Filling Volume
Q01000	Plastic tube with conical bottom. Press-close lid. Non-serigraphied container. Label on the tray with formalin and bio-hazard symbols	1x12 pcs	10 ml	5 ml
Q01004	Polypropylene container with innovative screwcap for an excellent leak-resistant seal. Non-serigraphed container with label for formalin and bio-hazard symbols	1x60 pcs	25 ml	5 ml
Q01005		1x60 pcs	25 ml	10 ml
Q01006		1x60 pcs	25 ml	15 ml
Q01021		1x35 pcs	60 ml	20 ml
Q01022		1x35 pcs	60 ml	40 ml
Q01023		1x35 pcs	60 ml	30 ml
Q01011	Polypropylene container with screwcap. Non-serigraphed container with label for formalin and bio-hazard symbols	1x48 pcs	30 ml	10 ml
Q01012		1x48 pcs	30 ml	20 ml
Q01101		1x36 pcs	150 ml	90 ml
Q01102		1x36 pcs	150 ml	60 ml
Q01111		1x36 pcs	250 ml	150ml
Q01060	Polypropylene container with press-close lid. Serigraphed container with formalin and bio-hazard symbols	1 pc	600 ml	300 ml
Q01071		1 pc	1000 ml	600 ml
Q01082		1 pc	2500 ml	1200 ml
Q01081		1 pc	2500 ml	1500 ml
Q01091		1 pc	5000 ml	3000 ml

Description

- Disposable containers prefilled with formaldehyde 4% based fixative, used in histology and cytology as primary fixative
- The stability and the high quality of Diapath formalin guarantee an highly effective and reproducible fixation
- Wide range of available sizes according to specimens to be fixed

Composition

• Formaldehyde 4%	CAS No. 50-00-0	EC No. 200-001-8
• Methanol <0.1%	CAS No. 67-56-1	EC No. 200-659-6
• Sodium phosphate monobasic	CAS No. 10049-21-5	EC No. 231-449-2
• Sodium phosphate bibasic	CAS No. 231-448-7	EC No. 231-448-7
• Deionized water		

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Functional features

- pH between 7.2-7.4
- Density 1.003
- Buffer molarity: 0.05 M

- Fixation time:
  - For speciemens up to 5 mm thickness 5 hours
  - For speciemens pieces 1 to 2 days

- Volumetric relation specimen/fixative 1:50
- Maximum fragment thickness: 1 cm

Quality control

The products and the raw materials are entered and constantly monitored by computer systems that allow traceability between batch number of each single product and batches of their raw materials.

Instructions of use

To avoid mistakes, the product should be used by qualified and trained staff. Professional use product. The guidelines concerning safety on the workplace must be applied according to current regulations. The tools used for diagnosis must be suitable for diagnostic use in laboratory. The diagnosis should be performed only by authorized, trained and competent staff. Control sections should be used during each test to avoid incorrect results.

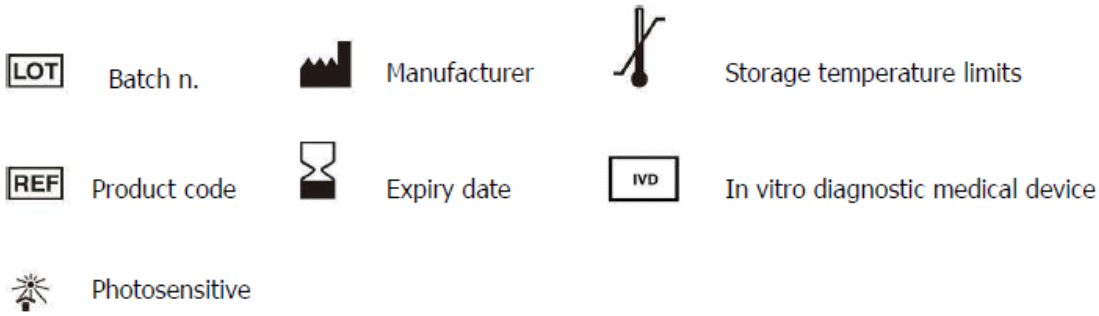
Storage

Store the product according to the specifications listed on the label. The product, if opportunely stored and integrally packed, is stable up to the expiry date reported on the label. Do not use after expiration date.
If the reagent is not stored as recommended, its performance may change and must be validated by the user. After opening, the reagent is stable up to expiration date but only if stored in its container and in accordance with the specifications listed on the label. It is recommended to close the container tightly after the use.

Disposal instruction

The expired and/or unused product must be disposed according to local waste regulations, based on danger classification on the label and after possible contaminations evaluation. In some cases it may be necessary an analytical evaluation to determine the correct waste classification and the danger features.

Labeling legend



For more information see the MSDS.

Diapath S.p.A. Via Savoldini, 71 - 24057 Martinengo (BG) Italy - Tel. (+39) 0363 986 411 - Fax (+39) 0363 948 000 - www.diapath.com - info@diapath.com

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