

10% neutral buffered formalin (ready to use)



Contains Formaldehyde 4 %

IVD In-vitro diagnostic medical device
EMDN: W01030705
IVD in **Class A**, Reg. UE 2017/746

Catalog number	Unit size	UDI-DI	BASIC UDI
05-K01004	20 l	08033976234096	080339762W01030705X2
05-01004F	5 l – blue cap	08034120274753	080341202W01030705AJ
05-K01009	10 l	08033976234157	080339762W01030705X2
05-01005Q	2,5 l x 4	08033976231576	080339762W01030705X2
450001	5 l (for B-PRO 450 processor) – red cap	08034120278478	080341202W01030705AJ
05-I348	Tap in PE for an accurate dispensing dripless for 5l, 10l or 20l tank		

Packaging

05-K01004
Primary container: PE tank in neutral colour, capacity 20 liters, UN approved. Blue screwcap in PE with a seal. Watertight.
Secondary container: EUR pallet wood 80 x 120 cm. Protective coating: lateral film LLDPE, HDPE top.

05-01004F, 450001
Primary container: PE tank in neutral colour, capacity 5 liters, UN approved. Blue screwcap in PE with a seal. Watertight.

05-K01009
Primary container: PE tank in neutral colour, capacity 10 liters, UN approved. Blue screwcap in PE with a seal. Watertight.
Secondary container: EUR pallet wood 80 x 120 cm. Protective coating: lateral film LLDPE, HDPE top.

05-01005Q
Primary container: white bottle in polyethylene terephthalate (PET). Useful capacity 2.5 liters. HDPE cap. Tamper evident cap.
The polyethyleneterephthalate is a thermoplastic polymer of the polyester family. PET is an optimal oxygen, carbon dioxide and other gasses barrier. This material has a high resistance to ultraviolet radiation and an inertia toward the mainly chemical agents (solvents: xylene, limonene, liquid paraffines, alcohols, acids, bases etc.). It is biologically inert. It constitutes a good water and humidity barrier. It shows a great hardness and mechanical resistance.
The bottle has an optimal grip. The absence of the handles reduces space for storage. The anti-dropping cap permits a precise and clean use.

Secondary container: carton box.

Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.

Expected aim Product for the preparation of cyto-histological samples for optical microscopy.

Specifications
pH 7,0 -7,2 ± 0,2
Density 1.003
Buffer molarity 0.05 M

Application Universal fixative for histological specimens.

Principle The 10% formalin neutral buffered (equivalent to an aqueous solution of 4% formaldehyde) is the fixative most commonly used in the histopathological routine. The interaction between formaldehyde and functional groups present in tissue macromolecules (proteins and nucleic acids) occurs according to the following scheme:

- formation of methylene glycol: the molecule of formaldehyde in water gives rise to the following equilibrium:
 $\text{CH}_2\text{O} + \text{H}_2\text{O} = \text{CH}_2(\text{OH})_2$
- The methylene glycol is the chemical species that interacts primarily with the functional groups present in the side chains of the proteins and with acids stabilizing the nuclear structure.
- secondarily formaldehyde form crosslinks between the free amino groups present in the side chains of amino acids.

Fixation technique

- 1) Volume ratio specimen/ fixative 1 : 50
- 2) Specimen thickness 1 cm max
- 3) Fixation time at room temperature: for specimens up to 5 mm 5 hours, for greater thickness 1-2 days.

Components

Components	CAS	CE	Index
Sodium phosphate dibasic dihydrate 0,7- 0,8% p/v	10028-24-7	231-448-7	-
Sodium phosphate monobasic monohydrate 0,15-0,2% p/v	7558-80-7	231-449-2	-
Formaldehyde 4% p/v	50-00-0	200-001-8	605-001-00-5
Methanol 0.1% v/ v	67-56-1	200-659-6	603-001-00-X
Deionized water			

Warning and precaution

The product is intended for professional laboratory use for healthcare professionals. Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged. In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.

Storage

Store the preparation at 15-25°C. Keep the containers tightly closed.

Stability After the first opening, the product is reusable until the expiry date, if correctly stored.
Product validity: 2 years.

Disposal Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.

REVISION n°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022
002	New code entry	28/12/2022