

10% neutral buffered formalin (ready to use)



Contains Formaldehyde 4 %



In-vitro diagnostic medical device

UDI-DI: 08033976231903

BASIC UDI: 080339762W01030705X2

IVD in Class A, Reg. UE 2017/746

Catalog number	Unit size	Container capacity	Volume contained	Container dimensions (cm)	Box dimensions (cm)
05-01V1000P	600 ml x 6	1.000 ml	600 ml	Ø 12 x h 13	45,5 x 30,5 x 14

Packaging	<p>Primary container: neutral container in PP. Pressure cap in PE with a seal, watertight. Secondary container: closed carton box, neutral colour.</p> <p>Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.</p>
Expected aim	Product for the preparation of cyto-histological samples for optical microscopy.
Specifications	<p>pH 7,0 -7,2 ± 0,2 Density 1.003 Buffer molarity 0.05 M</p>
Application	Universal fixative for histological specimens.
Principle	<p>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:</p> <ul style="list-style-type: none"> ▪ 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	<ol style="list-style-type: none"> 1) 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.

References

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REVISION n°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022