

KLESSIDRA 2.0



CODE	PACKAGING
05-01V15PKF	27 prefilled containers with 10 ml of formalin and 27 prefilled containers with 20 ml of buffer



In Vitro Diagnostic – Medical Device



Manufacturer: Bio-Optica Milano S.p.A.

TECHNICAL FEATURES

Code	Unit size	Container capacity	Filling volume	Container dimensions (cm)	Box dimensions (cm)
05-01V15PKF	27 x 10 ml formalin container 27 x 20 ml buffer container	35 ml 55 ml	10 ml of formalin 20 ml of buffer	∅ 3,4 x h 4,5 ∅ 3,4 x h 6,7	24 x 38 x 7,2

PRODUCT DETAILS

Klessidra is a special closed-circuit system that prevents the contact between formaldehyde and the user in compliance with the European Regulation 605/2014. It is ideal for the fixation and the transport of small histologic specimens.

The device consists of two containers in neutral PP:

- one, with the yellow lid, prefilled with a buffered solution where the biopsy can be released;
- one, with a special double blue lid prefilled with concentrated formalin, to be screwed on the container with the biopsy.

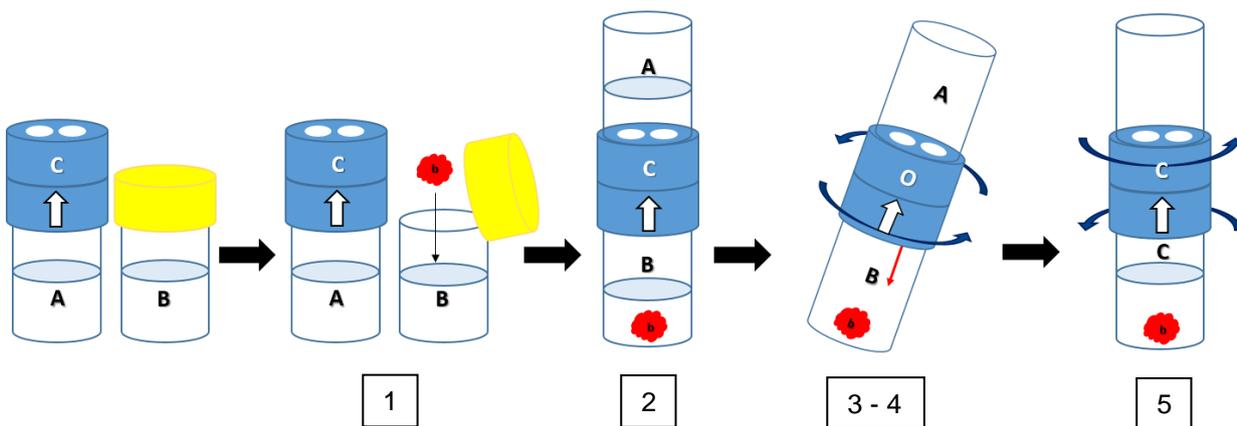
A special double screw lid in blue PE connects the two containers.

The formalin flow between the two containers is possible thanks to two holes on the double lid that are aligned after rotating the two parts of it.

- The seal is guaranteed by two silicon spheres for the occlusion of the holes;
- The device is provided by a mechanism which prevents the reflux of formalin into the previous container in order to avoid ipofixation problems and the loss of the biopsies;
- The final formalin concentration is 10%.

MODE OF USE

- Open the container with the yellow lid containing the buffer (solution B) and release the biopsy;
- Screw the container prefilled with formalin (solution A) on the container with the biopsy;
- Rotate the two lids in open position (until the arrow is aligned with the "O");
- Tilt the dispositive and let the formalin flow in the lower container;
- Rotate the two lids again in close position (until the arrow is aligned with the "C").



Solution A: neutral buffered formalin 30%
 Solution B: phosphate buffer
 Solution C (A+B): neutral buffered formalin 10%

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 Rev. 01

Technical details

Specifications	Expected aim	Product for the preparation of cyto-histological samples for optical microscopy. Safety fixation and transport with 10% neutral buffered formalin (equivalent to an aqueous solution of 4% formaldehyde).		
	Principle	Interaction between formaldehyde and functional groups in tissue macromolecules (proteins and nucleic acids) occurs as follow: - The formaldehyde molecule in water gives the following equilibrium $CH_2O + H_2O = CH_2(OH)_2$ with the formation of methylene glycol. - Methylene glycol interacts primarily with functional groups in the side chains of proteins and with acids stabilizing the nuclear structure. - Formaldehyde form crosslinks between the free amino groups present in the side chains of amino acids.		
	pH	Density	7,2 ± 0,2	
		Buffer molarity	1,003	
			0,05 M	
	Specimen / fixative ratio	Specimen thickness	1:50 (volume)	
			1 cm	
		Fixation time at room temperature	For specimens up to 5 mm 5 hours For greater thickness 1-2 days	
	Packaging	Primary container: container in neutral PP with blue screw cap in PE and container in neutral PP with yellow screw cap in PE. Secondary container: carton box, white colour. Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.		
	Formaldehyde 12% p/v	Methanol 0,1% v/v	CAS: 50-00-0	CE: 200-001-8
Sodium phosphate monobasic monohydrate 0,15-0,2% p/v		CAS: 67-56-1	CE: 200-659-6	Index: 603-001-00-X
Sodium phosphate dibasic dihydrate 0,7-0,8% p/v		CAS: 7558-80-7	CE: 231-449-2	-
Deionized water		CAS: 10028-24-7	CE: 231-448-7	-
		-	-	-
Storage	Storage	Store the preparation at 15-25°C. Keep the containers tightly closed.		
	Storage temperature	15-25°C		
	Stability	After opening, it is usable until the expiry date, if correctly stored.		
	Validity	2 years		
Product classification	Product classification	The product must be used by specialized technical operators. Carefully read the information on the classification of dangerous substances on the label. Always refer to the safety data sheet for information on the risks of the mixture, the precautionary measures during use, and the measures first aid and in case of accidental release. Do not use if the primary container is damaged.		
	Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.		