

CITOSPRAY

CITOSPRAY SOLUTION

CE IVD *In vitro* diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - **Class A** device

Solution for fixation of cytological smears

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30705FIXAQX		
EMDN code	W01030705		
REF	Catalog number	Volume	UDI-DI number
	CS-100	100 mL	03858888821548
	CS-1L	1000 mL	03858888821555



Intended use and test principle

Impeccable sample fixation is a prerequisite for a correct cytological diagnosis. Tissue samples must be immersed in an optimally chosen fixative immediately after sampling, while they are still moist. Imminent fixation of the sample prevents drying and cell shape change, in turn enabling clear staining and a correct diagnosis. If the sample was fixed later than it had been recommended, brownish grainy structures will form on cytological samples stained according to Papanicolaou, and that has a negative effect on the further diagnostic procedure. Used for fixation of Pap smears.

Product description

- **CITOSPRAY** - Solution for fixation of cytological smears in a spray bottle. Contains an optimal concentration of alcohol and polyglycols.
- **CITOSPRAY SOLUTION** - Solution for fixation of cytological smears in a bottle, for refilling CitoSpray bottle with atomizer.

Other materials that can be used along with CitoSpray

- VitroGnost slides and coverslips for use in histopathology and cytology
- Dehydrating/rehydrating agent such as BioGnost's alcohol solution Histanol 95 (95% ethyl alcohol)

CitoSpray use – cytological smear fixation

Spread the cytological smear on a glass slide (VitroGnost) after sampling, immediately fixate it using BioGnost's fixative in a spray bottle (CitoSpray). Spray it three times equally over still moist cytological smear from the distance of approximately 20 cm in order to avoid rinsing and losing cells because of a too intense jet. Alcohol from CitoSpray will evaporate, and polyglycol will form a protective layer. Cytological smear will be dry after approximately 10 min and ready for staining. A dried sample can be stored or processed further. Samples prepared using this technique remain stable for a period of a few weeks.

Prior to staining, the slide must be immersed into a 95% alcohol solution (Histanol 95) for 10 min. This removes polyglycols from the CitoSpray fixative.

NOTE

Cytological smears staining procedure using BioGnost's fixative in a spray bottle (CitoSpray) is described in BioGnost's Cytology reagents instructions for use (such as IFUs for Hematoxylin HP, Papa 1A, OG-6 reagent, Papa 2A, EA 31 reagent, Papa 3A).

Usability

100 mL of CitoSpray fixative is sufficient for approximately 250 applications.

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the fixation procedure described in BioGnost's Instruction for use can cause biological degradation of the sample.

Preparing the sample and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. Be sure to follow the manufacturer's handling instructions. To avoid errors, fixation, staining, and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards. In order to avoid an incorrect result, it is advised to use positive and negative control.

If a serious incident occurs during use of this product or as a result of its use, please report it to the manufacturer or authorized representative and competent authority.

Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. It is mandatory to read and act according to the information and warning signs printed on the product label and in the Safety Data Sheet, which is available on request.

Storage, stability, and shelf life

Upon receipt, store the product in a dry place and well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or expose to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The expiration date is printed on the product label.

Reference

1. Danos, M.L. (1974): *Fixatives for Cytologic Use*, 3rd ed., Chicago.
2. Keebler, C., Reagen J. (1983): *A Manual for Cytotechnology*, American Society of Clinical Pathologists Press, Chicago.
3. Conn, J. (1977): *Biological Stains*, 9th ed., Baltimore: Williams and Wilkens Co.

Warnings and precautions regarding the materials contained in the product:

	H225	Highly flammable liquid and vapor.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
	P233	Keep container tightly closed.

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 Manufacturer	 Batch code	 Consult instructions for use	 European conformity
 Date of manufacture	 Catalogue number	 Caution	 Unique device identifier
 Use-by date	 Temperature limit	 <i>In vitro</i> diagnostic medical device	

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Version	Description / reason for change	Date
7	Revised in acc to Regulation (EU) 2017/746 - IVDR	13.01.2026.