HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 07 tháng 05 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

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DIAPATH

CE IVD

CytoPath® – Fixative solution

Prefilled Vial with fixative solution for the conservation and preparation of cytological liquid-based samples in thin layer

Manufacturer: Diapath S.p.A. via Savoldini 71 – 24057 Martinengo (BG) – Italy –
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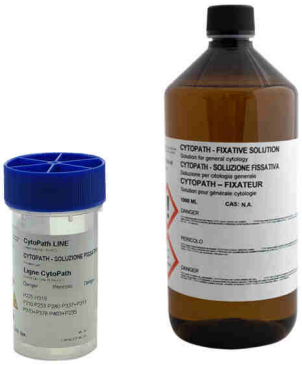
Intended use

Reagents for in vitro diagnostic use
Fixative for collecting, transporting, storing and preparing cytological liquid-based samples in thin layer



Code	Description	Vial volume	Filling volume	Packaging
CP204	CytoPath® – Fixative solution	60 ml	20 ml	25 pcs
CP306	CytoPath® – Fixative solution	1 lt	1 lt	1 bottle

Principles

60 ml container pre-filled with 20 ml of fixative, suitable for the collection of cytological liquid-based samples in liquid phase for the preparation of samples in a thin layer
The vials are equipped with frosted band useful to detect correct fluid level to perform thin layer preparation.
The Fixative solution is compatible with the protocols used in the laboratory and compatible with molecular testing.
The formulation of the fixative is ethanol based and formalin free in order to permit the highest safety in its usage

Composition

DS Ethanol

Characteristics

The CytoPath® - Fixative guarantees the perfect preservation of cytomorphological and cytochemical features of cells. It improves cells adhesion on the slide improving and standardizing preparation quality.
It improves cellular features in preparation area, providing an optimal thin layer. The vial is suitable for specimen preparation by automatic and semi-automatic devices. The fixative allows the preservation of the specimen for 6 weeks at room temperature.

Treatments before use

The product is a ready-to-use device for the collection, transportation, storage and preparation of cytological liquid-based samples in thin layer.

Instruction for use

Before starting the thin layer preparation, ensure that the liquid level inside the vial is included in the frosted band.
Once obtained the thin layer preparation, the residual specimens can be stored in the vial at room temperature for 6 weeks

To avoid mistakes, qualified and trained staff should use the product. 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.

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Quality control

All batches are under analytical controls useful to define their conformity.
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.

Storage

Store the product at room temperature. 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.

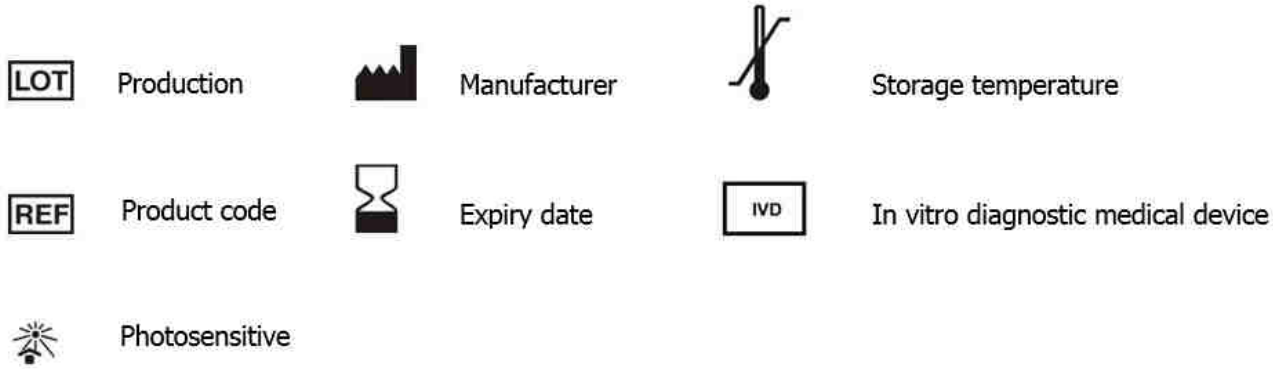
Disposal instructions

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 feature.

Warnings and precautions

Please refer both to the instructions of use and information concerning hazardous substances classification on the label.
Consult the Safety Data Sheet (MSDS) for the information concerning substances mixing risks, precautions of use and first aid procedures in case of accidental loss.
An amount of less than 2% of methanol and isopropanol is added to the formulation as denaturants of ethanol: below such concentration these substances do not induce risks to human health for any route of exposure.
The hazard classification of substances, which is expressed in MSDS by means of pictograms, and their limit concentrations, is achieved through a dedicated software on the basis of regulations and directives in the field of environmental safety, work and human health. [1][2]

Labeling legend



Bibliography

[1]: https://echa.europa.eu/it/information-on-chemicals/cl-inventory-database/-/discli/details/37212 - Specific Concentration limits
[2]: Annex I, 3.8.2.2 Classification criteria for Categories 1 and 2