

BIOTECHNOLOGY MADE IN GREECE

LIQUID BASED CYTOLOGY



WORLD CANCER DAY

Inhale Courage Exhale Fear

www.menidimeditica.gr



1

SOLUTIONS

2

KaryoPrep Solution for Fixation - Box of 20 vials 10 mL

KaryoPrep Solution for Fixation - 1 Lt.

KaryoPrep Solution for Fixation - 5 Lt.

KaryoPrep General Preservative - 100 mL

KaryoPrep General Preservative - 200 mL

KaryoPrep General Preservative - 500 mL

KaryoPrep General Preservative - 1000 mL

KaryoPrep Fixative - 100 mL

KaryoPrep Fixative - 200 mL

KaryoPrep Fixative - 500 mL

KaryoPrep Fixative - 1000 mL

KaryoPrep RBC Lytic Reagent - 100 mL

KaryoPrep RBC Lytic Reagent - 200 mL

KaryoPrep RBC Lytic Reagent - 500 mL

KaryoPrep RBC Lytic Reagent - 1000 mL

KaryoPrep Cell Whole - 100 mL

KaryoPrep Cell Whole - 200 mL

KaryoPrep Cell Whole - 500 mL

KaryoPrep Cell Whole - 1000 mL



KaryoPrep Solution for Fixation

KaryoPrep Solution for Fixation is the fixative liquid specially dedicated to the preservation of cytological samples. It is designed, developed and produced by MenidiMedica Greece and it can be used with all kinds of biological samples. KaryoPrep Solution for Fixation is designed for use with the manual method introduced by MenidiMedica or with MenidiMedica LBC system or other commercial processors. It serves as a transport, preservative, and antibacterial medium for the processed biological samples, including certain tests for Human Papilloma Virus (HPV) and other sexually transmitted infections.

It has no haemolytic activity in order to ensure conservation of red blood cells, eventually present in urinary samples, to make them visible and diagnosable by the pathologist during the specimen analysis. In case the user wishes elimination of mucus or red blood cells (absence of artifacts), KaryoPrep RBC Lytic Reagent must be applied to the KaryoPrep Solution for Fixation.

KaryoPrep Solution for Fixation is a saline solution based on ethanol, which ensures the perfect cytological material fixation and a safe operator's handling at the same time. It guarantees the morphological preservation of cytological samples for at least 5 years at room temperature. The genetic material of the collected samples is stored and available for molecular biology in-depth analysis, up until 5 years after collection .

For optimal samples fixation, it is recommended to use unexpired vials of KaryoPrep Solution for Fixation. The vials are ready-to-use and are stable for 60 months at room temperature.

Karyoprep Solution for fixation is supplied in different packaging, ranging from 10 mL pre-filled collection vials, to 1 or 5 Lt. - bottles approved for air transport.

The vials are made of a special transparent plastic material, characterized by peculiar optical transmittance technical specifications, allowing them to be used with the MenidiMedica LBC fitting system and with various other platform systems.

The 1 Lt - formats are supplied in HDPE plastic material bottles. HDPE material, certified by the provider, is free of BPA, phthalates and latex and does not contain or contains less than the 0.1% of substances that can be defined as "high concern", identified as SVHC and listed in the candidates list in the XIV REACH annex.

The 5 Lt - formats are provided in stackable plastic tanks, UN/ADR approved for land, air and sea transport of dangerous liquid products, according to UN Legislation.





KaryoPrep Solution for Fixation



Ref: 65000 - 10

Ref: 65000 - 20x10

Ref: 65000 - 1

Ref: 65000 - 5

KaryoPrep Fixative

KaryoPrep Fixative is the protective alcoholic solution designed to protect cells from air contact during the drying phase of the slides prepared with MenidiMedica cytology processors, or with the manual method.

Compatible with the reagents of other liquid based cytology technology methods, it can be implemented, as a universal fixative, into the sample processing of competition. It is supplied in various volumes in HDPE plastic material. The HDPE material, certified by the provider, is free of BPA, phthalates and latex and does not contain or contains less than the 0.1% of substances that can be defined as "high concern", identified as SVHC and listed in the candidates list in the XIV REACH annex.



KaryoPrep Fixative

Ref: 65020 - 100

Ref: 65020 - 200

Ref: 65020 - 500

Ref: 65020 - 1000

KaryoPrep RBC Lytic Reagent

KaryoPrep RBC Lytic Reagent combines the properties of 2 activities in one reagent. It has mucolytic activity used in the sample purification procedures. The aim of this reagent is to remove a part of mucus eventually present in some samples. Depending on the biological specimen and the appropriate procedure, the user can evaluate whether or not to use KaryoPrep RBC Lytic Reagent.

It is provided in various volumes in HDPE plastic material. The HDPE material, certified by the provider, is free of BPA, phthalates and latex and does not contain, or contains less than the 0.1% of substances that can be defined as "high concern", identified as SVHC and listed in the candidates list in the XIV REACH annex.



KaryoPrep RBC Lytic Reagent

Ref: 65030 - 100

Ref: 65030 - 200

Ref: 65030 - 500

Ref: 65030 - 1000



KaryoPrep General Preservative

KaryoPrep General Preservative is designed for use with a variety of methods, including: the manual method introduced by MenidiMedica, MenidiMedica LBC system, other commercial processors. During the processing of various biological samples, the user can refill the vial of KaryoPrep Solution for Fixation with the same amount of volume collected for diagnosis. In this way, optimal preservation of the uncollected biological specimen is obtained.

It is provided in various volumes in HDPE plastic material. The HDPE material, certified by the provider, is free of BPA, phthalates and latex and does not contain, or contains less than the 0.1% of substances that can be defined as "high concern", identified as SVHC and listed in the candidates list in the XIV REACH annex.



KaryoPrep General Preservative

Ref: 65010 - 100

Ref: 65010 - 200

Ref: 65010 - 500

Ref: 65010 - 1000

KaryoPrep CellWhole Reagent

KaryoPrep CellWhole Reagent is designed and developed for urine biological samples which have few cells for examination. One drop from KaryoPrep Cell Whole Reagent on a glass slide is enough for stamping and processing of this kind of samples.

It is provided in various volumes in HDPE plastic material. The HDPE material, certified by the provider, is free of BPA, phthalates and latex and does not contain, or contains less than the 0.1% of substances that can be defined as "high concern", identified as SVHC and listed in the candidates list in the XIV REACH annex.



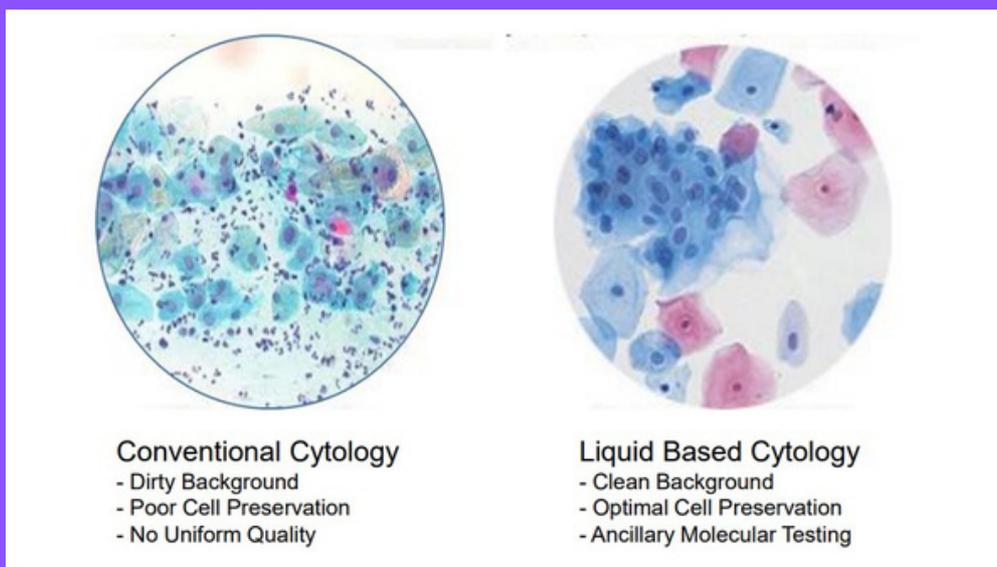
KaryoPrep CellWhole Reagent

Ref: 65040 - 100

Ref: 65040 - 200

Ref: 65040 - 500

Ref: 65040 - 1000



Application sheet of MenidiMedica manual LBC procedure

A. Non-bloody biopsy (in case of a specimen with mucus, we could use KaryoPrep RBC Lytic Reagent - see version B)

1. Collection of the specimen (biopsy) from the doctor into the KaryoPrep Solution for Fixation (After the collection, in the vial are contained up to 1000.000 cells).
2. Use of vortex for 20". Ensure that the cap of the KaryoPrep Solution for Fixation is tightly closed and secured for the homogenization of the solution.
3. Transport the insert of KARYOPREP SOLUTION FOR FIXATION INTO A CONICAL URINE TUBE
4. Centrifuge the conical urine tube at 800g for 10'.
5. Dispose of (throw away) the supernatant.
6. Collection of the mixture of cells which are gathered into the bottom of the conical urine tube with a Pasteur pipette (the mixture of cells contains 40.000-60.000 cells, so, the solution could be recentrifuged for future cross-exam).
7. Transfer the mixture of cells onto a glass slide and pass a second glass slide from the opposite side through the surface of the first glass slide, in order to obtain a homogenous layer of the cell mixture on the surface of the two glass slides.
8. Spray the two (2) glass slides with the KaryoPrep Fixative (you could use Mercifix as alternative, but it is much more expensive - the use of hair sprays is PROHIBITED and not recommended due to potential chemical reactions of the contents of the hair sprays with the cell mixture) from a distance suitable to ensure the positioning of the cells on the glass slide (15-20 cm away).
9. Dry the glass slide on air for 10'-15' or with a hair-dryer.
10. Fixation of the glass slides into a coplin jar with 95% ethanol for 20'.
11. Staining the glass slides according to Papanicolaou protocol (every histology laboratory uses its own Papanicolaou protocol as internal laboratory procedure).
12. Cover up the glass slide with 24x50 glass cover and dry from excess glue.
13. Use the microscope with 10x, 40x lenses.

* In case the laboratory wants to preserve the vial of KaryoPrep Solution for Fixation with the contained specimen (biopsy), the user MUST add 2 mL of KaryoPrep General Preservative into the vial.

B. BLOODY BIOPSY

The procedure is the same as in version A. for non-bloody specimens BUT before vortexing, we add 2 mL KaryoPrep RBC Lytic Reagent into KaryoPrep Solution for Fixation for 20'.



Product Comparison

KaryoPrep vs. Gynoprep vs. ThinPrep vs. Surepath

Country of origin

KaryoPrep - Greece (MenidiMedica)

GynoPrep - Germany (Tharmac)

ThinPrep - USA (Hologic)

SurePath - USA (BD)

Preparation device

KaryoPrep -

1. Manual method with normal centrifuges
2. Automated processor with MenidiMedica LBC system
3. Compatible with CytoCentrifuges and processors of competition

GynoPrep - CytoCentrifuge

ThinPrep - Processor

SurePath - Processor

Method

KaryoPrep -

(Manual) Centrifugation, stamping

(Automated) CytoCentrifuge, Aspiration, stamping

GynoPrep - CytoCentrifuge

ThinPrep - Aspiration, stamping

SurePath - Density gradient centrifugation

Outcome

KaryoPrep - 100% smear content transferred to slide

GynoPrep - 100% smear content transferred to slide

ThinPrep - Only cells with minimum size transferred to slide, smaller particles lost

SurePath - Particles in only small size range transferred to slide, bigger and smaller particles lost

Package content

KaryoPrep - Vial and consumables are sold individually

GynoPrep - Everything from taking a smear to prepared slides

ThinPrep - N/A

SurePath - Vial and consumables are sold individually



Advantages of KaryoPrep LBC method



The most economic method in the market, worldwide



The cells maintain their structural morphology



Quick method, totally modifiable application sheet



Use of KaryoPrep Solution for Fixation for all biological sample origins



Extended short life of the reagents -
5 years from the date of their production



Use of vortex and normal laboratory centrifuge
(for the manual method)



Compatible with molecular diagnostic procedures (e.g. HPV)



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2

INSTRUMENTS

MenidiMedica LBC System Generation 1



MenidiMedica LBC System Generation 1

(Automated method)

1. Fifty slides per hour
2. Filtration method
3. Improved preservative
4. Clean Background
5. Minimizes the obscuring effects of blood, inflammatory cells and mucus
6. Provides liquid based thin layer slide
7. "Dual filter" technology provides enhanced cellular enrichment
8. Processor with variable cycles for various sample types
9. Compact design
10. Circular Cell Deposit (20 mm)
11. Staining performed using traditional Papanicolaou Stain Procedure - ask for MenidiMedica Stains brochure

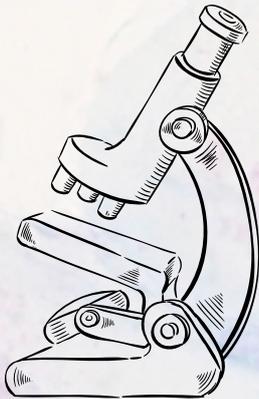




BIOTECHNOLOGY PRODUCTS

MenidiMedica

Medical Instruments,
Tools & Supplies



*Expertise in
Cytology*

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