

FineFIX

1. Intended use

CATALOGUE NUMBER: **70148 FineFIX, tank of 5 liters**
 70149 FineFIX, tank of 10 liters

FineFIX is a fixation solution suitable for the preparation of histological specimens. Fixation is a necessary step to prepare specimens for subsequent diagnostic phases.

FineFIX is In-Vitro-Diagnostic medical device.

FineFIX is formaldehyde-free.

FineFIX working solution is prepared as described in the chapter 5.

The ethanol concentration in the working solution of FineFIX is 72%. This concentration was found to produce good histology and to allow optimal recovery of DNA/RNA and proteins for several downstream molecular analyses.

When diluted with ethanol, its formulation of low toxicity additives overcomes the drawbacks commonly associated with the use of pure ethanol or ethanol-based fixatives, e.g., significant tissue shrinkage, vacuolization and pyknotic nuclei. FineFIX also provides optimal preservation of tissue antigens, nuclear and cytoplasmic morphology and reduced lysis of red blood cells with preservation of the cytoplasmic membranes.



MM190-FineFIX Technical Sheet in electronic format: www.milestonemedsrl.com/docs/reagents/
Contact your local distributor if you need the technical sheet in paper format.

2. Warnings and precautions for use



The product is concentrated and must be diluted to be used.

The device is intended for use by specialized technical personnel.

Read carefully the information related to the Hazard Indications and to the Safety Advice Phrases, as per the Safety Data Sheet and the label. Always consult the Safety Data Sheet, where you will find the information pertaining to the risks arising from the product, the precautionary measures to be adopted during use, the first aid and intervention measures in case of accidental release.

Do not use if the primary container is damaged. The reagents are produced with uniform and controlled methods as per Quality Control requirements.

Please pay particular attention to the handling of the biological samples to be treated, as they may be sources of biohazard.

Any other use of the product is considered improper and relieves the manufacturer of responsibility.

Medical devices and in vitro diagnostic medical devices are subject to surveillance by the National Competent Authority for their safety. In the event of a serious accident, it is therefore required to inform the competent Authority and Milestone by writing to the e-mail address: regulatory@milestonesrl.com

3. Storage and stability

The package must be stored closed well, away from light, in a cool and dry place.

Shelf life of the product is 2 years in undamaged packaging and correctly storage. After opening the tank, the reagent can be used until the expiry date, indicated on the package.

Close well the tank after the use.

Recommended Temperature Range for storage: 5-30°C (41°F-86°F)

Recommended Temperature Range for transport: 2-50°C (35.6°F-122°F)

4. Principle

Fixation is a process that aims at “locking” the structure of living matter into conditions as close to physiological as possible.

Through fixation, it is possible to delay/prevent the natural morpho-physiological modifications due to post-mortem degradation processes.

Fixation consists of two stages, both essential:

- Presoaking (pre-fixation): this takes place at a temperature below 37°C to allow the reagent to penetrate the tissue
- Fixation: molecular modification stage, which fixes the specimen and can be carried out up to a temperature of 50°C. FineFIX is a coagulant fixative which leads to a reversible denaturation of the proteins with the result that antigen retrieval, immunohistochemistry and molecular biology are better. Alcohol alone has these positive effects but altering the morphology and creating artifacts. FineFIX instead contains other additives in low percentage, which allow the fixation of solid and smear tissues, thus replacing the formalin and achieving excellent results even from morphological point of view.

Its major advantage is the absence of carcinogenicity than the formalin.

5. Use of FineFIX

The working solution must be prepared by adding 720ml of ETHANOL reagent pure/denatured to 280ml FineFIX Concentrate.

$$\begin{array}{c} \mathbf{280ml\ FineFIX\ Concentrate} \\ + \\ \mathbf{720ml\ Ethanol} \\ \\ = \\ \mathbf{1000ml\ Working\ Solution} \end{array}$$

The ethanol concentration in the working solution of FineFIX is 72%. This concentration produces good histology and allows optimal recovery of DNA/RNA and proteins.

The fixation times of FineFIX, identical to those of Formalin, are linked to certain variables:

- The size of the specimens to be fixed;
- The number of samples;
- The type of tissue;

With specimens of reduced size, such as gastric biopsies, needle biopsies and similar, the times must be very short to avoid excessive drying and coarctation phenomena.

A more sustained fixation process will be necessary in the case bone tissues.

The methods and times, however, are determined mainly based on the experience of each laboratory; the product can help technicians obtain specimens that retain the features of the tissues and with cutting and staining conditions that meet the diagnostic requirements.

To use the reagent in the Milestone processors, please follow the instructions in the table:

Thickness of the sample	Pre-soaking (< 37°C)	Fixation		
		< 37°C	37°C	50°C
< 1mm	15min	30min	10min	5min
1mm	30min	1hr	40min	20min
2mm	45min	1hr 30min	50min	25min
3mm	1hr	2hr	1hr	30min
4mm	1hr 15min	4hr	2hr	50min
5mm	1 hr 30min	5hr	2hr 30min	1hr
5mm (adipose tissue)	2hr/3hr	10hr	4hr 30min	2hr

To use the reagent in Milestone processors in the case of bone tissues, please follow the instructions in the table:

Thickness of the sample	Pre-soaking (< 37°C)	Fixation		
		< 37°C	37°C	50°C
1mm	45min	1hr	50min	25min
2mm	1hr	1hr 30min	1hr	30min
3mm	1hr 15min	2hr	2hr	50min
4mm	1hr 30min	4hr	2hr 30min	1hr
5mm	2/3hr	5hr	4hr 30min	2hr



Milestone processors include specific protocols that are specifically developed to achieve the best result.

Before modifying a program in any way, please contact our Application Department at the e-mail address: application@milestonemedsr.com

We would like to emphasize the importance of replacing the fixation agent so that the tissues come into as much contact with the whole agent in its initial concentration.

We recommend that you replace the reagent (if used in the Milestone processors) after having processed six full racks.



The maximum number of racks is a guideline. The actual value is determined by a validation process, based on the capacity of the tanks and the type and size of the biopsies.

Mode of action of FineFIX avoids the deleterious affects associated with cross-linking fixatives, enabling antigenic unmasking to be performed without the requirement for aggressive retrieval methods. This allows for a more standardized approach to antigenic retrieval techniques with temperatures of up to 85°C.

The biocidal activity of FineFIX can be compared to that of Ethanol 70%. The antibacterial action of alcohols derives from their ability to denature proteins; this ability is expressed in presence of H₂O.

Below is a summary table of the bactericidal and virucidal efficacy of Ethanol 70% and therefore of FineFIX:

Spectrum of action	
Microorganisms	Effectiveness
Gram Positive Bacteria	+++
Gram Negative Bacteria	+++
Fungus	++
Idrophili Virus	+-
Virus HIV	+++
The Virus Epidemic	++
Microbacteria	+-
Spores	-

The minimum action time is 10 minutes for surface disinfection. In the case of biological samples, the reagent penetration time of 1mm per hour is required.

6. Waste disposal



Handle with care and store in a cool, dry space using a tightly closed container. There may be vapors in the empty containers. Treat empty vessels as hazardous. Waste material should be disposed of in an approved incinerator or in an approved landfill site, in compliance with all national, provincial and local government regulations.

For further information please refer to the Safety Data Sheet (SDS).

7. Symbols



Instructions with this symbol are quite important and require more attention



Biohazard: be careful when you execute the procedure marked with this symbol: danger of biohazard contamination



Reagent compliant with European Community directives



IVD medical device according to 2017/746 Regulation (EU)



Reference



Lot number



Manufacturer



Expiry date



STORAGE

Warehouse storage temperature



TRANSPORT

Storage temperature for transport alone



Unique Device Identification



UK Conformity Assessed logo

EUH210 Security Data Card available on demand

issue date: 2024-04

