

MoL-DECALCIFIER



Ready to use solution.

1. Intended use

CATALOGUE NUMBER: 51413 MoL-DECALCIFIER, Tank of 5 liters

MoL-DECALCIFIER is a decalcification solution suitable for the preparation of histological specimens. Decalcification is a necessary step to prepare specimens for subsequent diagnostic phases.

MoL-DECALCIFIER is In-Vitro-Diagnostic medical device.

Example: decalcification of sensitive, hard tissues such as iliac crest biopsies and keratinized tissues such as blood vessels.



MM104-MoL-DECALCIFIER 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 intended for use by specialized technical personnel.

The product is ready to use.

Read carefully the information concerning Hazard Statements and Safety Advice stated on the label.

Consult the Safety Data Sheet for risks information, precautionary measures to be taken during use, first aid instructions and hazard information in case of accidental release.

Do not use if packaging is damaged.

The reagents are produced according to uniform and control methods according to Quality Control Specifications.

During and after the use, handle all the materials according to Good Laboratory Practice and remember always that the material to be analyzed must be considered as a potential biological risk.

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

MoL-DECALCIFIER is contained in tank for light protection, with a sealed cap; store tightly closed, away from light, in a cool and dry place.

Range of temperature recommended for storage: 15-25°C (59-77°F).

Range of temperature recommended for transport: 15-30°C (59 – 86°F).

Shelf life of the product is 2 years in undamaged packaging and correctly storage. After opening the container, the reagent can be used until its expiry, as shown on the package.

Close well the tank after the use.

4. Principle

Decalcification methods are necessary for optical microscopic examinations of hard tissue in routine histological procedures. The material to be decalcified is placed in an excess of decalcifying solution and demineralized (decalcified) in this. The decalcification time is dependent on the size and structural density of the respective tissue, while the composition of the decalcifying solution also exerts a decisive influence on the process. When decalcifying sensitive, calcium-containing tissue a solution such as MoL-DECALCIFIER is used, which contains complex- or chelate-forming agents that bind the calcium ions of the tissue. This type of decalcifying solution preserves the antigen structures in the tissue, with the result that immunological and molecular biology procedures can be conducted.

5. Use of MoL-DECALCIFIER



Sample material to be decalcified with MoL-DECALCIFIER must be fixed and rinsed in water before decalcification. Calcified specimens require more time for proper fixation; please refer to the following tables for guidelines on fixation with formalin.

Step 1: pre-soaking

Sample thickness	Room temperature
1mm	45min
2mm	1hr
3mm	1hr 15min
4mm	1hr 30min
5mm	2/3hr

Step 1: fixation with different times according to temperature

Sample thickness	Room temperature	Heated fixation	
		37°C	50°C
1mm	1hr	50min	25min
2mm	1hr 30min	1hr	30min
3mm	2hr	2hr	50min
4mm	4hr	2hr 30min	1hr
5mm	5hr	4hr 30min	2hr

Place the whole tissue to be descaled in a container (glass or plastic) containing an excess of MoL-DECALCIFIER solution and decalcify completely in the solution.

Heated decalcification with MoL-DECALCIFIER leads to satisfactory results for morphology, IHC, and molecular biology; however, it is of paramount importance not to over-decalcify the sample, which means that checks of the bones' status must be consistently performed.

When users decide to set their own protocols, temperatures above 50°C should be avoided.

Bone marrow biopsy 1.8 mm	
TEMPERATURE	TIME REQUIRED
37°C	18 hours
50°C	4 hours
Bone specimens 5 mm	
TEMPERATURE	TIME REQUIRED
37°C	10 days
50°C	5 days



Milestone decalcifiers 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@milestonemedsrl.com

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

It is recommended to replace the reagent (if used in Milestone decalcifiers) after processing 50 cassettes, if using the standard rack with two liters of reagent.



The maximum number of cassettes is merely 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.

6. Waste disposal



Handle with care and store in a cool dry space using a tightly closed container.

Vapors may collect in empty containers. Treat empty containers as hazardous.

Waste material should be disposed in an approved incinerator or in a designated landfill site, in compliance with all federal, 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



Warehouse storage temperature

STORAGE



Storage temperature for transport alone

TRANSPORT



Unique Device Identification



UK Conformity Assessed logo

EUH210 Security Data Card available on demand

issue date: 2024-04

