MIELODEC
Fixative and decalcifier for bone marrow biopsy
04 - 230827

[IVD] In-vitro diagnostic medical device
CND Code: W01030799

- number of tests ..............................................
- Volumetric ratio:
  - specimen volume/fixative volume 1:50
  - specimen volume/decalcifying solution volume 1:50
- procedure time ........................................... 3 hours and 15 minutes
- product validity .......................................... 2 years
- storage temperature .................................... 15-25 °C
- complementary equipment ......................... not requested

Expected aim
Product for the preparation of cyto-histological samples for optical microscopy.

Application
Decalcifying fixative for bone marrow biopsy in the study of hematologic diseases.

Principle
The kit includes 2 reagents: fixative and decalcifier.
- B5 fixative is recommended for hematopoietic tissues; it contains formalin and mercury in a buffer solution. Concentration of mercury chloride has been chosen so that no mercury will precipitate on section during decalcifying process, provided that suggested procedure times are followed.
- Decalcifier contains E.D.T.A. (ethylenediaminetetracetic acid) in acid buffer. Decalcifying process takes place through chelation in acid environment and preserves tissue morphology in a remarkably short time for histopathological routine.

Method
1) Put bone marrow immediately after drawing in reagent A (fixative): leave to act 90 minutes.
2) Extract the fragment from solution A and put it in 70° ethanol for 15 minutes (the fragment can be left for an indefinite time)
3) Put the biopsy in reagent B (decal cifier) : leave to act 90 minutes.
4) Dehydrate through ascending alcohols, clear in xylene and embed in paraffin

ATTENTION:
Suggested procedure times have been tested on cylinders of bone marrow biopsy 3 mm thick, taken from crista iliaca and sternum. Decalcification times should be prolonged for compact bone and larger fragments. We recommend to avoid fragments thicker than 5 mm.

Reagents
A) B5 modified..............................................................5 x 100 ml
B) E.D.T.A. in acid buffer......................................................5 x 100 ml

Warning and precaution
The product must be used exclusively by specialized technical operators.
The product is classified as hazardous.
Read with attention the information written on the label (dangerous symbols, risks and safety phrases).
Consult always the safety data sheet where the information about the risks of the preparation, precautionary measures during use, first aid and disposal are available. Do not use if primary packaging is damaged.

Storage
Store the preparation at room temperature. Keep the containers tightly closed.

Stability
After the first opening, the product is usable until the expiry date, if correctly stored.

Disposal
Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.
References


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