Histoplast

Instructions for Use

For in vitro diagnostic use.

Histoplast is a mixture of purified paraffin wax formulated for use in routine histological techniques. **For use as an infiltration and embedding medium in histology.**

Description

Epredia Histoplast is specifically designed for tissue processing and embedding of histological specimens intended to be used by trained laboratory personnel. Histoplast is a paraffin product which is a white solid at room temperature and a clear, colorless liquid when molten. All kinds of paraffins are filtered to 0.25 µm. Histoplast can be used with both open and closed tissue processors. We highly recommend this product and suggest that each customer be encouraged to sample these waxes and validate based on internal procedures. It is also compatible with all embedding centers and manual embedding techniques. Store Histoplast in a dry, out of direct sunlight, cool, place with a temperature under 86° F (30 °C).

Epredia Histoplast Paraffin

Histoplast paraffin is offered in four versions (in pellet form) with varying polymer contents and additives to facilitate infiltration and sectioning. Histoplast LP is especially useful for delicate or heat-sensitive tissue types with its lower melting point.

Melting Points and Suggested Uses:

- Histoplast: 54-58ºC (for infiltration and embedding)
- Histoplast PE: 56-57ºC (for infiltration and embedding)
- Histoplast IM* 56-57ºC (for infiltration and embedding)
- Histoplast LP: 50-54ºC (for infiltration and embedding)

**Histoplast IM contains DMSO. Care should be taken in regards to personnel safety and equipment compatibility.*

Instructions For Use

It is not required that Histoplast be molten prior to placing on the tissue processor. However, allow for adequate melting time, as the paraffin must be completely molten prior to starting a tissue processing run. Histoplast can be pre-melted, such as in a paraffin pot, prior to placing on the tissue processor. The temperature of the paraffin pot, processor's paraffin chambers, and embedding center should be monitored regularly. Use in accordance with established tissue embedding and processing procedures.

Tissue Processing

Histoplast is used in tissue processing during the infiltration steps. The vacuum has been viewed as an asset during all phases of tissue processing, including infiltration. A typical tissue processing schedule would include two to four steps of molten paraffin, with the time varying according to tissue type and size.

Paraffins with lower polymer contents generally require less infiltration time than paraffin with higher polymer contents.

The following is an example tissue processing schedule that may require modification by the end user. All results should be tested and validated following normal laboratory procedure.

Station	Solution	Time
1	10% Neutral Buffered Formalin	Holding
2	10% Neutral Buffered Formalin	1 hour
3	Pen-Fix™ or 80% Denatured Ethyl Alcohol	40 minutes
4	95% Denatured Ethyl Alcohol	40 minutes
5	95% Denatured Ethyl Alcohol	40 minutes
6	100% Denatured Ethyl Alcohol	40 minutes
7	100% Denatured Ethyl Alcohol	40 minutes
8	100% Denatured Ethyl Alcohol	40 minutes
9	Clearing Reagent	1 hour
10	Clearing Reagent	1 hour
11	Paraffin	1 hour
12	Paraffin	1 hour

The following is an example tissue processing schedule for small biopsy specimens (less than 2 mm in thickness) that may require modification by the end user. Tissues are assumed to be fixed. If not, stations 1 and 2 should utilize 10% Neutral Buffered Formalin for a minimum of 30 minutes each. All results should be tested and validated following standard laboratory procedures.

Station	Solution	Time
1	10% Neutral Buffered Formalin	(30 minutes)
2	10% Neutral Buffered Formalin	(30 minutes)
3	Pen-Fix™ or 80% Denatured Ethyl Alcohol	10 minutes
4	95% Denatured Ethyl Alcohol	10 minutes
5	95% Denatured Ethyl Alcohol	10 minutes
6	100% Denatured Ethyl Alcohol	10 minutes
7	100% Denatured Ethyl Alcohol	10 minutes
8	100% Denatured Ethyl Alcohol	10 minutes
9	Clearing Reagent	15 minutes
10	Clearing Reagent	15 minutes
11	Paraffin	20 minutes
12	Paraffin	20 minutes

Histoplast

Instructions for Use

Embedding

The tissue processing sequence infiltrates tissues with molten paraffin. After processing, the tissue must additionally be embedded in paraffin, e.g. Histoplast. Add Histoplast, either solid or molten, to the paraffin reservoir in the embedding center. Set the temperature of the reservoir so that it is slightly higher than the melting point of the paraffin in use.

Remove one cassette from the cassette holding station of the embedding center. Open the cassette and examine the tissue (best practice during embedding is to open one cassette at a time). Choose an embedding mold of an appropriate size that best accommodates the tissue. Fill the base mold with the desired embedding medium. Orientate the tissue in the embedding medium and cool until the embedding medium begins to solidify. Place the tissue cassette on the base mold and fill it to the top with embedding medium. Cool until the block is easily removed from the base mold.

Note: The laboratory should develop a temperature monitoring schedule and product rotation/change-out schedule that adheres to the department's tissue processing and embedding policies.

Note: Paraffin pellets and flakes are still suitable for use even where media pellets and or flakes have fused together. Should this occur, gently tap the closed bag on a flat surface to obtain appropriate-sized pieces of paraffin.

Warnings and Precautions

- To avoid brittleness and inconsistency in tissue appearance, ensure that wax melt temperature is compatible with tissue.
- If using separate embedding and infiltration media, ensure compatibility prior to use.
- Product disposal: Always follow local guidelines to dispose of Histoplast.

Note: See Safety Data Sheets for warnings and precautions, as well as EUH code definitions. See container label for warnings and precautions.

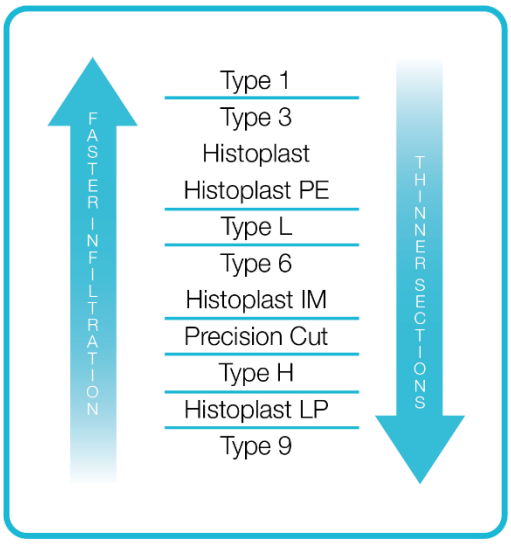
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user/or the patient is established.

Order Information

Product	Size	Qty.	REF
Histoplast	2.5 kg	1	6774006
Histoplast	10 kg	1	6774060
Histoplast PE	2.2 lb. (1 kg)	8 bags/cs.	8330
Histoplast PE	2.2 lb (1kg)	Kit	8330K
Histoplast IM	2.2 lb. (1 kg)	8 bags/cs.	8331
Histoplast LP	2.2 lb. (1 kg)	8 bags/cs.	8332
Histoplast LP	2.2 lb. (1 kg)	Kit	8332K

Other paraffin products available at Epredia (see document II8000R02):

Product	Size	Qty.	REF
Type 1 Paraffin	2 lb. (0.9 kg) bag	10 bags/cs.	8334
Type 3 Paraffin	2 lb. (0.9 kg) bag	10 bags/cs.	8335
Type 6 Paraffin	2 lb. (0.9 kg) bag	10 bags/cs.	8336
Type 9 Paraffin	2 lb. (0.9 kg) bag	10 bags/cs.	8337
Paraffin Type H	2 lb. (0.9 kg) bag	10 bags/cs.	8338
Paraffin Type L	2 lb. (0.9 kg) bag	10 bags/cs.	8339
Precision Cut Paraffin	2.2 lb. (1 kg)	10 bags/cs.	B1002490
Precision Cut Paraffin	2.2 lb. (1 kg)	Kit	B1002490K



Shandon Diagnostics Limited
A subsidiary of Epredia
Tudor Road, Manor Park, Runcorn,
Cheshire, WA7 1TA, UK

Tel: +44(0) 1928 534 000
Fax: +44(0) 1928 534 001
Web: www.epredia.com

Epredia Netherlands B.V.
Essendonk 30
4824 DA Breda Netherlands

IVD

30°C (86°F)
15°C (59°F)

A677-1001 Issue 1 June 2022