

Histolog[®]

Dip

English

Product name	Volume	Product catalog number (REF)
Histolog [®] Dip	250 mL	005

INTENDED USE

The Histolog[®] Dip is a fluorescent histological stain for imaging tissue specimens with the Histolog[®] Scanner.

PRINCIPLE

Histolog[®] Dip contains a fluorochromatic dye which binds to nucleic acids and some negatively charged proteins. This dye reveals the morphological microstructure of tissue specimens for imaging with Histolog[®] Scanner.

COMPOSITION

Histolog[®] Dip contains < 0.1% Acridine Orange in buffered saline.

WARNINGS AND PRECAUTIONS

This product is for In Vitro Diagnostic use by healthcare professionals.

The Histolog[®] Dip is non-sterile and is contraindicated for in vivo tissue examination.

Dispose after use, in accordance with local regulations for handling and disposing of infectious materials.

When handling Histolog[®] Dip solution avoid skin and eye contact by wearing appropriate protective equipment.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF ON SKIN: Wash with plenty of soap and water.

STORAGE

Store at 15-30 °C. The expiration date applies to the product in its intact container when stored as directed. Do not store after opening.

PRODUCT DETERIORATION

Do not use if evidence of leaking or damage to bottle.

Do not use if there is evidence of a precipitate or the solution shows other signs of deterioration.

SPECIMEN COLLECTION AND HANDLING

Tissue specimens should be collected and handled following local guidelines.

Tissue marking dyes, if any, should be applied on the tissue specimen only after the complete imaging procedure with Histolog[®] Scanner.

MATERIALS

Provided:

Histolog[®] Dip

Required but not provided:

Histolog[®] Scanner (REF 003), Histolog[®] Dish (REF 004), saline solution, 2 dipping containers

PROCEDURE

1. Stain specimen by immersing 10 seconds in dipping container filled with Histolog[®] Dip solution. One bottle of Histolog[®] Dip is intended for a single patient procedure.
2. Rinse specimen by immersing 2 to 5 seconds in dipping container filled with saline solution.
3. Image specimen with Histolog[®] Scanner.

INTERPRETATION

Distribution of the fluorochromatic dye in the tissue specimen reveals its morphological microstructure in images acquired with Histolog[®] Scanner.

USER QUALITY CONTROL

Examine the Histolog[®] Dip solution for color and clarity. The solution should be clear, orange and without evidence of a precipitate.

For additional control, measure the pH of the solution. The pH should be 7.0-7.4.

LIMITATIONS OF THE PROCEDURE

Specimen staining and image quality are negatively impacted by tissue marking dyes and excess of blood.

ADDITIONAL INFORMATION

This product does not contain substances of nature and quantities such as to be classified as being hazardous to human health or the environment pursuant to the provisions of EC Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

NOTICE

Report any serious incident related to the Histolog[®] Dip to SamanTree Medical SA and to your national competent authority.

DESCRIPTION OF SYMBOLS

	Batch Code
	Catalog Number
	In Vitro Diagnostic Medical Device
	Use-by (expiry) Date
	Non-Sterile
	Manufacturer
	Consult Instructions for Use
	Temperature Limit (Storage)
	CE marking of conformity with Directive 98/79/EC and Regulation (EU) 2017/746
	This Way Up
	Keep Dry
	Do not reuse
	Authorized EC Representative
	UKCA marking of conformity with the Medical Devices Regulations 2002 (UK)
	Importer

REVISION TABLE

Ver.	Change description
1.0	Initial version.
1.1	Increase shelf-life after opening.
1.2	Increase shelf-life after opening. Add new warnings.
1.3	Minor wording changes.
1.4	Add translations and change format.
1.5	Add extra reference and version numbers.
1.6	Change manufacturer address.
1.7	Add "Notice", "Composition", "Revision table", EU authorized representative and UK responsible person.
1.8	Update "Storage" and "Procedure" sections Add customer service information



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