HOLOGIC®

ThinPrep® Stain Nuclear Stain

Instructions for Use

℞ only

INTENDED USE

ThinPrep® Nuclear Stain is intended to be used in a Papanicoulaou staining procedure in conjunction with any ThinPrep Rinse Solution, ThinPrep Bluing Solution, ThinPrep Orange G Solution, and ThinPrep EA Solution.

SUMMARY AND EXPLANATION

ThinPrep Nuclear Stain is an aqueous solution that serves to stain the nuclei of cells on slide preparations for cytologic evaluation.

PRINCIPLES OF PROCEDURE

When used in conjunction with the ThinPrep staining solutions and cytologic slide preparations, ThinPrep Nuclear Stain will differentially stain the nuclei of cells without interfering with cytoplasmic staining and morphology.

COMPOSITION

An aqueous solution of Acetic acid, Aluminium Sulfate, Ethylene Glycol, Hematoxylin and Sodium Iodate. CAS 107-21-1, CAS 10043-01-3

WARNINGS

Warning. Contains Aluminum Sulfate, Glacial acetic acid, Ethylene glycol.

H302—Harmful if swallowed.

For *In Vitro* Diagnostic Use. Not for external or internal use in humans or animals. May be harmful if swallowed. May cause eye irritation on contact.

PRECAUTIONS

P264—Wash hands thoroughly after handling.

P280—Wear protective gloves and eye/face protection.

Avoid contact with eyes. Keep container closed when not in direct use. Use within 60 days after first opening of container. Results with non-ThinPrep cytology samples have not been evaluated. Do not use if primary packaging is damaged.

PRETREATMENT

No reconstitution, mixing or dilution is required.

STORAGE

Store between 15°C (59°F) and 25°C (77°F). Use within 60 days after first opening of container or by the expiration date marked on the container, whichever comes first.

ThinPrep® STAIN

ThinPrep® Stain Nuclear Stain

APPEARANCE AND INTEGRITY

Opaque, non-sterile solution.

SPECIMEN COLLECTION AND PREPARATION

For use with gynecologic cytology samples that have been processed on any ThinPrep Processor.

PROCEDURE

See the ThinPrep Stain User's Manual for specific staining protocols.

LIMITATIONS OF PROCEDURE

Must be used according to the instructions provided in the ThinPrep Stain User's Manual. ThinPrep Nuclear Stain cannot be substituted with any other solution.

PERFORMANCE CHARACTERISTICS

When used as directed, ThinPrep Nuclear Stain will stain the nuclei of cells on cytologic slide preparations.

DISPOSAL

Dispose in accordance with all applicable regulations.

FIRST AID MEASURES

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. See www.hologicsds.com for the entire Safety Data Sheet.

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Following is an explanation of the symbols that may appear on your product.

Symbol	Title	Description	Standard information
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Consult instructions for use	Indicates the need for the user to consult the instructions for use. When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or an appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5
	Temperature limit	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Do not re-use	Indicates a medical device that is intented for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.2

And this product is marked with the following pictogram:

Symbol	Title
	Irritant, Respiratory Tract Irritation, Dermal Sensitizer

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US English AW-19607-003 Rev. 001 8-2020