HOLOGIC®

ThinPrep® Stain EA Solution

Instructions for Use

℞ only

INTENDED USE

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

SUMMARY AND EXPLANATION

ThinPrep EA Solution is an alcoholic solution that serves to stain the cytoplasm 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 EA Solution will stain the cytoplasm of cells without interfering with nuclear staining and morphology.

COMPOSITION

An alcoholic solution of Ethanol, Isopropyl Alcohol, Methanol, and proprietary biological dyes. CAS-64-17-5, CAS 67-56-1, CAS 67-63-0

WARNINGS

Danger. Flammable. Contains Ethanol, Isopropyl Alcohol, Methanol.

H302—Harmful if swallowed.

H312—Harmful in contact with skin.

H319—Causes serious eye irritation.

H371—May cause damage to organs.

H225—Highly flammable liquid and vapor.

For *In Vitro* Diagnostic Use. Not for external or internal use in humans or animals. Cannot be made non-poisonous.

PRECAUTIONS

P260—Do not breathe vapors.

P210—Keep away from heat/sparks/open flames/hot surfaces.

P280—Wear protective gloves/protective clothing/eye protection/face protection.

Wash hands thoroughly after handling. Keep container tightly closed when not in direct use. Use with adequate ventilation. 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.

ThinPrep® Stain EA Solution

STORAGE

Store ThinPrep EA Solution at 15°C (59°F) to 30°C (86°F) in the container provided. Do not use ThinPrep EA Solution beyond the expiration date marked on the container.

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 EA Solution cannot be substituted with any other solution.

PERFORMANCE CHARACTERISTICS

When used as directed, ThinPrep EA Solution will stain the cytoplasm 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 pictograms:

Symbol	Title
	Flammable

Symbol	Title
	Irritant, Respiratory Tract Irritation, Dermal Sensitizer

Symbol	Title
	Respiratory Sensitizer, Target Organ Toxicity

Hologic, Inc. • 250 Campus Drive • Marlborough, MA 01752 USA
Tel: +1 508 263-2900 • www.hologic.com

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