ThinPrep® Stain Rinse Solution

Instructions for Use

℞ only

INTENDED USE

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

SUMMARY AND EXPLANATION

ThinPrep Rinse Solution is an aqueous, detergent solution that removes excess ThinPrep Nuclear Stain from cellular components on slide preparations for cytologic evaluation.

PRINCIPLES OF PROCEDURE

When used in conjunction with the ThinPrep staining solutions and cytologic slide preparations, ThinPrep Rinse Solution will remove excess ThinPrep Nuclear Stain from cellular components, enhancing nuclear staining and clarifying cytoplasm.

COMPOSITION

An aqueous solution of propriety surfactant.

WARNINGS

For *In Vitro* Diagnostic Use.

Not for external or internal use in humans or animals. May cause irritation on contact.

PRECAUTIONS

Avoid contact with eyes.

Wear gloves and eye protection when handling solution.

Keep container closed when not in direct use.

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

APPEARANCE AND INTEGRITY

Clear, non-sterile solution.

ThinPrep® Stain Rinse 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 Rinse Solution cannot be substituted with any other solution.

PERFORMANCE CHARACTERISTICS

When used as directed on cytologic slide preparations, ThinPrep Rinse Solution removes excess ThinPrep Nuclear Stain from cellular components.

DISPOSAL

Dispose in accordance with all applicable regulations.

FIRST AID MEASURES

No ill effects are anticipated. See www.hologicsds.com for the entire Safety Data Sheet.

ThinPrep® Stain Rinse Solution

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

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