

ThinPrep™ Stain Rinse Solution

Instructions for Use



INTENDED USE

ThinPrep™ Stain Rinse Solution is intended to be used in a Papanicolaou staining procedure in conjunction with ThinPrep Stain Nuclear Stain, ThinPrep Stain Bluing Solution, ThinPrep Stain Orange G Solution, and ThinPrep Stain EA Solution. For professional use.

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.

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.



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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.

SAFETY AND PERFORMANCE CHARACTERISTICS

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

If any serious incident occurs related to this device or any components used with this device, report it to Hologic Technical Support and the competent authority local to the patient and/or user.

Refer to the ThinPrep Imaging System operator's manual.

DISPOSAL

Dispose in accordance with all applicable regulations.

FIRST AID MEASURES

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

Revision History

Revision	Date	Description
AW-24890-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.



Manufacturer



Authorised representative in the European Community



Batch code



Consult instructions for use



Catalogue number



Temperature limitation



In vitro diagnostic medical device



Use by



Open here



Quantity



Made in USA



UK Conformity Assessed (Great Britain)



Product meets the requirements for CE marking in accordance with EU-IVD Regulation 2017/746



Caution: Federal (USA) law restricts this device sale by or on the order of a physician, or any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device and are trained and experienced in the use of the product.



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