

ThinPrep™ Stain Bluing Solution

Instructions for Use



INTENDED USE

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

SUMMARY AND EXPLANATION

ThinPrep Bluing Solution is an aqueous, alkaline solution that darkens the cellular components stained with ThinPrep Nuclear Stain to blue/violet on slide preparations for cytologic evaluation.

PRINCIPLES OF PROCEDURE

When used in conjunction with the ThinPrep staining solutions and cytologic slide preparations, ThinPrep Bluing Solution will darken those cellular components stained by the ThinPrep Nuclear Stain, enhancing nuclear morphology.

COMPOSITION

An aqueous solution of Lithium Carbonate.

WARNINGS

For In Vitro Diagnostic Use.

Not for external or internal use in humans or animals.

May cause eye 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 Bluing Solution at 15°C (59°F) to 30°C (86°F) in the container provided. Do not use ThinPrep Bluing 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.

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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 Bluing Solution cannot be substituted with any other solution.

SAFETY AND PERFORMANCE CHARACTERISTICS

When used as directed on cytologic slide preparations, ThinPrep Bluing Solution will darken the cellular components stained with the ThinPrep Nuclear Stain.

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-24898-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.



Manufacturer



Consult instructions for use



In vitro diagnostic medical device



Quantity



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



Authorised representative in the European Community



Catalogue number



Use by



Made in USA



Batch code



Temperature limitation



Open here



UK Conformity Assessed (Great Britain)




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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