

ThinPrep™ Stain Bluing II Solution

Instructions for Use



INTENDED USE

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

SUMMARY AND EXPLANATION

ThinPrep Bluing II 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 II Solution will darken those cellular components stained by the ThinPrep Nuclear Stain, enhancing nuclear morphology.

COMPOSITION

An aqueous Tris buffer.

WARNINGS

For In Vitro Diagnostic Use.

Not for external or internal use in humans or animals. May cause eye irritation. May cause skin irritation. May cause irritation of the respiratory tract. May be harmful if ingested.

PRECAUTIONS

Keep out of reach of children.

Avoid contact with skin and eyes. Wash hands thoroughly after handling.

Keep container tightly 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 II Solution between 15°C (59°F) to 30°C (86°F) in the container provided, in a cool, dry, well-ventilated area away from sources of heat, combustible materials, and incompatible substances. Do not use ThinPrep Bluing II 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 instruction provided in the ThinPrep Stain User’s Manual. ThinPrep Bluing II Solution cannot be substituted with any other solution.

SAFETY AND PERFORMANCE CHARACTERISTICS

When used as directed on cytologic slide preparations, ThinPrep Bluing II 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

Get medical advice/attention if you feel unwell.
See www.hologicds.com for the entire Safety Data Sheet.

Revision History

Revision	Date	Description
AW-24902-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.



Manufacturer



Catalogue number



Batch code



Consult instructions for use



Use by



Temperature limitation



In vitro diagnostic medical device



Authorised representative in the European Community



Open here



Made in USA



UK Conformity Assessed (Great Britain)



Quantity



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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