HOLOGIC

ThinPrep[™] Stain Bluing II Solution

Instructions for Use



INTENDED USE

ThinPrepTM 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 ThinPrepTM 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

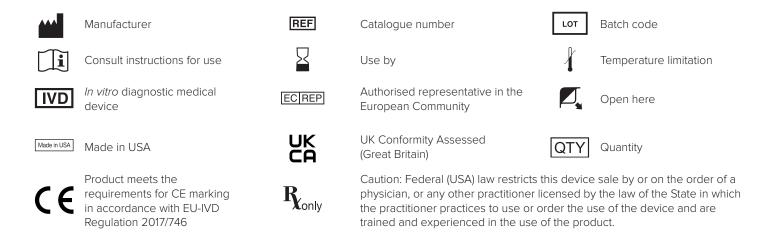
Dispose in accordance with all applicable regulations.

FIRST AID MEASURES

Get medical advice/attention if you feel unwell. See www.hologicsds.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.



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

ECIREP Hologic BV • Da Vinciaan 5 • 1930 Zaventem • Belgium • Tel: +32 2 711 46 80

Australian Sponsor: Hologic (Australia and New Zealand) Pty Ltd • Suite 302, Level 3 • 2 Lyon Park Road Macquarie Park NSW 2113 • Australia • Tel: 02 9888 8000

UK Responsible Person: Hologic, Ltd. • Oaks Business Park • Crewe Road • Wythenshawe Manchester M23 9HZ • United Kingdom

