

ThinPrep™ Stain EA Solution

Instructions for Use

**INTENDED USE**

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

SUMMARY AND EXPLANATION

ThinPrep EA Solution is an alcoholic solution that serves to stain the cytoplasm of cells on slide preparations for cytologic evaluation.

PRINCIPLES OF PROCEDURE

When used in conjunction with the ThinPrep staining solutions and cytologic slide preparations, ThinPrep EA Solution will stain the cytoplasm of cells without interfering with nuclear staining and morphology.

COMPOSITION

An alcoholic solution of Ethanol, Isopropyl Alcohol, Methanol, and proprietary biological dyes. CAS-64-17-5, CAS 67-56-1, CAS 67-63-0

WARNINGS

Danger. Flammable. Contains Ethanol, Isopropyl Alcohol, Methanol.

H302. Harmful if swallowed.

H312. Harmful in contact with skin.

H319. Causes serious eye irritation.

H371. May cause damage to organs.

H225. Highly flammable liquid and vapor.

For In Vitro Diagnostic Use. Not for external or internal use in humans or animals. Cannot be made non-poisonous.

PRECAUTIONS

P210. Keep away from heat/sparks/open flames/hot surfaces.— No smoking.

P280. Wear protective gloves and eye/face protection.

P260. Do not breathe dust/fume/gas/mist/vapours/spray.

P301 + P310. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P303 + P361 + P353. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305 + P351 + P338. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P304 + P340. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P309 + P311. IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

P370 + P378. In case of fire: Use dry sodium carbonate to extinguish.

P403 + P233. Store in a well-ventilated place. Keep container tightly closed.

P501. Dispose of contents/container in accordance with local/regional/national/international regulation.

ThinPrep™ Stain EA Solution

Wash hands thoroughly after handling. Keep container tightly closed when not in direct use. Use with adequate ventilation. 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 ThinPrep EA Solution at 15°C (59°F) to 30°C (86°F) in the container provided. Do not use ThinPrep EA Solution beyond the expiration date marked on the container.

APPEARANCE AND INTEGRITY

Opaque, 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.

LIMITATIONS OF PROCEDURE

Must be used according to the instructions provided in the ThinPrep Stain User's Manual. ThinPrep EA Solution cannot be substituted with any other solution.

SAFETY AND PERFORMANCE CHARACTERISTICS

When used as directed, ThinPrep EA Solution will stain the cytoplasm of cells on cytologic slide preparations.

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

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. See www.hologicds.com for the entire Safety Data Sheet


Revision History

Revision	Date	Description
AW-24896-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.

ThinPrep™ Stain EA Solution

 Manufacturer	 Catalogue number	 Flammable
 Consult instructions for use	 Use by	 Irritant, Respiratory Tract Irritation, Dermal Sensitizer
 <i>In vitro</i> diagnostic medical device	 Batch code	 Respiratory Sensitizer, Target Organ Toxicity
 Authorised representative in the European Community	 Temperature limitation	 Open here
 Quantity	 Made in USA	 UK Conformity Assessed (Great Britain)
EtOH Ethanol	 Product meets the requirements for CE marking in accordance with EU-IVD Regulation 2017/746	

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

 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