

ThinPrep™ Stain Rinse II Solution

Instructions for Use

UK
CA CE



INTENDED USE

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

SUMMARY AND EXPLANATION

ThinPrep Rinse II Solution is an alcohol-based 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 II Solution will remove excess ThinPrep Nuclear Stain from cellular components, enhancing nuclear staining and clarifying cytoplasm.

COMPOSITION

An alcoholic solution of Ethyl alcohol, Ethylene glycol, and Isopropanol. CAS 64-17-5, CAS 107-21-1, CAS 67-63-0

WARNINGS

Danger. Flammable. Contains Ethyl alcohol, Ethylene glycol.
 H302. Harmful if swallowed.
 H319. Causes serious eye irritation.
 H225. Highly flammable liquid and vapor.
 For In Vitro Diagnostic Use. Not for external or internal use in humans or animals.

PRECAUTIONS

P210. Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
 P280. Wear protective gloves/protective clothing/eye protection/face protection.
 P308 + P313. IF exposed or concerned: Get medical advice/attention.
 P301 + P312. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
 P305 + P351 + P338. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P302 + P352. IF ON SKIN: Wash with plenty of soap and water.
 P403 + P233. Store in a well-ventilated place. Keep container tightly closed.
 P370 + P378. In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
 P501. Dispose of contents/container in accordance with local/regional/national/international regulation.

PRETREATMENT

No reconstitution, mixing, or dilution is required.

STORAGE

Store unused ThinPrep Rinse 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, direct sunlight, and incompatible substances. Do not use ThinPrep Rinse II Solution beyond the expiration date marked on the container.

ThinPrep™ Stain Rinse II Solution

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.

LIMITATIONS OF PROCEDURE

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

SAFETY AND PERFORMANCE CHARACTERISTICS

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

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-24900-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.

ThinPrep™ Stain Rinse II Solution



Manufacturer



Catalogue number



Flammable



Consult instructions for use



Use by



Irritant, Respiratory Tract Irritation, Dermal Sensitizer



In vitro diagnostic medical device



Batch code



Open here



Authorised representative in the European Community



Temperature limitation



Quantity



Made in USA



UK Conformity Assessed (Great Britain)



Ethanol



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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