

ThinPrep® Stain Nuclear Stain

Instructions for Use



INTENDED USE

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

SUMMARY AND EXPLANATION

ThinPrep Nuclear Stain is an aqueous solution that serves to stain the nuclei 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 Nuclear Stain will differentially stain the nuclei of cells without interfering with cytoplasmic staining and morphology.

COMPOSITION

An aqueous solution of Acetic acid, Aluminium Sulfate, Ethylene Glycol, Hematoxylin and Sodium Iodate. CAS 107-21-1, CAS 10043-01-3

WARNINGS

Warning. Contains Aluminum Sulfate, Glacial acetic acid, Ethylene glycol.

H302 - Harmful if swallowed.

For In Vitro Diagnostic Use. Not for external or internal use in humans or animals. May be harmful if swallowed. May cause eye irritation on contact.

PRECAUTIONS

P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves and eye/face protection.

Avoid contact with eyes. Keep container closed when not in direct use. Use within 60 days after first opening of container. 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 between 15°C (59°F) and 25°C (77°F). Use within 60 days after first opening of container or by the expiration date marked on the container, whichever comes first.

ThinPrep® Stain Nuclear Stain

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 Nuclear Stain cannot be substituted with any other solution.

PERFORMANCE CHARACTERISTICS

When used as directed, ThinPrep Nuclear Stain will stain the nuclei of cells on cytologic slide preparations.

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.



Manufacturer



Consult instructions for use



In vitro diagnostic medical device



Use by



Batch code



Temperature limitation



Authorised representative in the European Community



Catalogue number



Irritant, Respiratory Tract Irritation, Dermal Sensitizer



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