

ThinPrep® Stain Orange G Solution

Instructions for Use

CE

Rx only



INTENDED USE

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

SUMMARY AND EXPLANATION

ThinPrep Orange G 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 Orange G Solution will stain the cytoplasm of cells without interfering with nuclear staining and morphology.

COMPOSITION

An alcoholic solution of Ethanol, Methanol, Isopropanol, and Orange G dye. CAS 64-17-5, CAS 67-56-1, CAS 67-63-0

WARNINGS

Danger. Contains Ethanol, Methanol, Isopropanol.

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.

P280 - Wear protective gloves/protective clothing/ eye protection/face protection.

P260 - Do not breathe vapors.

Wash thoroughly after handling. Keep container 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.

ThinPrep® Stain Orange G Solution

STORAGE

Store ThinPrep Orange G Solution at 15°C (59°F) to 30°C (86°F) in the container provided. Do not use ThinPrep Orange G 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.

LIMITATIONS OF PROCEDURE

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

PERFORMANCE CHARACTERISTICS

When used as directed, ThinPrep Orange G Solution will stain the cytoplasm of cells in 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



Authorised representative in the European Community



Catalogue number



Use by



Batch code



Temperature limitation



Flammable



Irritant, Respiratory Tract Irritation, Dermal Sensitizer



Respiratory Sensitizer, Target Organ Toxicity



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