

# ThinPrep™ Stain Nuclear Stain

## Instructions for Use

UK  
CA CE

### **INTENDED USE**

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

### **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.

## **SAFETY AND PERFORMANCE CHARACTERISTICS**

When used as directed, ThinPrep Nuclear Stain will stain the nuclei 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](http://www.hologicds.com) for the entire Safety Data Sheet.

## **Revision History**

Revision	Date	Description
AW-24892-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.

## ThinPrep™ Stain Nuclear Stain



Manufacturer



Use by



Authorised representative in the European Community



Consult instructions for use



Batch code



Catalogue number



*In vitro* diagnostic medical device



Temperature limitation



Irritant, Respiratory Tract Irritation, Dermal Sensitizer



Quantity



Made in USA



Open here



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.



UK Conformity Assessed (Great Britain)



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