

# ThinPrep™ Stain Nuclear Stain

# Instructions for Use





### **INTENDED USE**

ThinPrep<sup>TM</sup> 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<sup>TM</sup> 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.hologicsds.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.

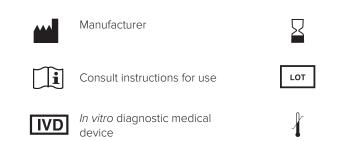




Authorised representative in

the European Community

# ThinPrep™ Stain Nuclear Stain



Batch code

REF

Catalogue number

Irritant, Respiratory Tract
Irritation, Dermal Sensitizer

Made in USA

Open here

EC REP



Quantity

UK Conformity Assessed (Great Britain)

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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Use by

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