




## 1. Intended Use


SureThin® Cytology Preservative is intended to be used for the recovery of cells from a cell collection device; for the dispersion of a cell sample to form a cell suspension; and for the preservation of the morphology of cells during transport and storage. Cells preserved in SureThin® Cytology Preservative can be used for a variety of cytological purposes including morphological and immunocytochemical evaluations, nucleic acid probe-based testing, and flow cytometry studies.


## 2. Product Description

SureThin® Cytology Preservative is a buffered methanolic solution that can disperse and preserve the cells in many types of cytological samples. This formulation can disperse mucus and lyse red blood cells, allowing them to be separated from the cells of clinical interest. It also permeabilizes cells by extracting lipids from the cell membranes, thereby pre-conditioning the cells for staining and other processes; stabilizes the cell morphology by denaturing cellular proteins; and has anti-bacterial and anti-viral properties.

Two versions of SureThin® Cytology Preservative are available. One version (Blue label) is intended for the preservation of most types of cytological samples while the second version (Red label) is intended for use with cervical cytology samples. SureThin® “Lysis” solution is also available and can be used in combination with either version of SureThin® Cytology Preservative in cases where the sample contains excessive blood or mucus.

90-1629-00		<ul style="list-style-type: none"> <li>• SureThin® Cytology Cell Preservative.</li> <li>• Tray box of 25 x 20mL vials 500 per master box. (Cat. No. 90-1629-00)</li> <li>• For use with “Non-Gyn” samples</li> </ul>
90-1429-02		<ul style="list-style-type: none"> <li>• SureThin® Cytology Cell Preservative.</li> <li>• Tray box of 25 x 20mL vials. 500 per master box. (Cat. No. 90-1429-02)</li> <li>• For use with cervical cytology (“Gyn”) samples.</li> </ul>
90-1437-00		<ul style="list-style-type: none"> <li>• SureThin® Cytology Cell Preservative.</li> <li>• 32oz Bottle (Cat. No. 90-1437-00)</li> <li>• For use with cervical cytology (Gyn) and Non-Gyn Cytology</li> </ul>

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90-1631-00		<ul style="list-style-type: none"> <li>• SureThin® Lysis Solution</li> <li>• 32oz Bottle (Cat. No. 90-1631-00) Can be used with both SureThin® Cytology Preservative both vials (Gyn and Non-Gyn). Use Lysis Solution if the sample contains excessive blood or mucus.</li> </ul>
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**WARNING: CONTAINS METHANOL**

NOT FOR EXTERNAL OR INTERNAL USE IN HUMANS OR ANIMALS. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED. VAPOR IS HARMFUL IF INHALED. CAUSES EYE AND SKIN IRRITATION. **FLAMMABLE!** CANNOT BE MADE NON-POISONOUS.

Keep away from heat, sparks and flames. Avoid breathing the vapor. Keep the container closed when not in use. Use with adequate ventilation. Wash thoroughly after handling.




**WARNING: POTENTIAL BIOHAZARD**

Although SureThin® Cytology Preservative has anti-bacterial and anti-viral activity, it may not totally disinfect a sample and it will not neutralize prions (PrPsc) such as may be present in a cerebral spinal fluid (CSF) sample from a person having a TSE such as Creutzfeld-Jakob disease.

Always wear gloves when handling human-sourced materials and follow the relevant laboratory Standard Operating Procedures pertaining to the handling of biohazardous materials.

### 3. Storage and Stability

- a) SureThin® Cytology Preservative not containing cytological material may be stored until its expiration date at a temperature of between 15°C and 30°C. (59-86°F).
- b) SureThin® Cytology Preservative containing cytological material intended for morphological evaluation may be stored for at least three weeks (21 days) at a temperature of between 4°C and 37°C (39-99°F) and for at least 6 weeks at a temperature of 15° - 30°C.

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- c) The storage conditions and stability of cell samples in SureThin® Cytology Preservative that are intended for purposes other than morphological evaluation should be determined and validated by the user.

## 4. Generic Sample Preparation Methods

### A. Samples collected using a brush, scraper or similar sample collection device:

- Sample collection devices made of plastic or other non-porous material are preferred in order to maximize cell recovery from the device. Cells may become trapped in the pores of wooden collection devices such as wooden cervical spatulas which may render them unrecoverable.
- Method 1: The head (sample-containing) end of the collection device can be removed from or cut off of the device handle and placed in a vial of SureThin® Cytology Preservative. The agitation occurring as the vial of SureThin® Cytology Preservative is being transported to the laboratory is generally sufficient to ensure that the collected cells are adequately recovered from the collection device.
- Method 2: Vigorously stirring or agitating the collection device 10-15 times in the SureThin® Cytology Preservative is generally sufficient to recover the cells from the device. The collection device can then be discarded, or the head of the device can be placed in the same vial of SureThin® Cytology Preservative as described under Method 1.
- Cells recovered from a collection device by either of the above methods should be allowed to stand in SureThin® Cytology Preservative for at least 30 minutes before the sample is used in specimen preparation or otherwise additionally processed.
  - The cell suspension in SureThin® Cytology Preservative should be stable for at least 3 weeks at a temperature of between 4°C and 37°C. (39-99°F) and for at least 6 weeks at a temperature of 15° - 30°C when used for morphological evaluation.

### B. Body Fluids (Urine, Bladder Washes, Cerebrospinal Fluid, Serous Effusions):

- Concentrate the sample by centrifugation (600-800xG for 10 minutes).
- Decant and discard the supernate.
- Resuspend the pellet in SureThin® Lysis Solution.
- Concentrate the sample by centrifugation (600-800xG for 10 minutes).
- Decant and discard the supernate.
- Repeat the previous three (3) steps if blood and/or mucus is still evident in the pellet.
- Resuspend the pellet by shaking or vortexing. A small volume of SureThin® Cytology Preservative or SureThin® Lysis Fluid may be added to facilitate this resuspension. The cell-crit of the resulting homogeneous slurry is preferably about 50%.
- Add this cell slurry to a vial of SureThin® Cytology Preservative and shake or vortex to prepare a homogeneous cell suspension.
- Allow the resulting cell suspension to stand in the SureThin® Cytology Preservative for at least 15 minutes before preparing a specimen for evaluation.
  - The cell suspension in SureThin® Cytology Preservative should be stable for at least 3 weeks at a temperature of between 4°C and 37°C. (39-99°F) and for at least 6 weeks at a temperature of 15° - 30°C.

- Select the "Non-Gyn" mode if specimens are to be prepared using the SureThin<sup>®</sup> Processor.

C. Materials Containing Mucus (Sputum, Saliva, Respiratory and Gastrointestinal Samples):

- Samples of these types are typically directly collected into or transferred into SureThin<sup>®</sup> Lysis Solution or equivalent at the point of collection. SureThin<sup>®</sup> Lysis Solution should be added to samples that are received "neat" or in another non-lytic medium before performing the following steps.
- Vortex the sample for ten (10) minutes.
  - Concentrate the sample by centrifugation (600-800xG for 10 minutes).
  - Decant and discard the supernate.
  - Resuspend the pellet in SureThin<sup>®</sup> Lysis Solution.
  - Repeat the previous three steps until the sample is no longer viscous.
  - Concentrate the sample by centrifugation (600-800xG for 10 minutes).
  - Decant and discard the supernate.
- Resuspend the pellet by shaking or vortexing. A small volume of SureThin<sup>®</sup> Cytology Preservative or SureThin<sup>®</sup> Lysis Fluid may be added to facilitate this resuspension. The cell-crit of the resulting homogeneous slurry is preferably about 50%.
- Add this cell slurry to a vial of SureThin<sup>®</sup> Cytology Preservative and shake or vortex to prepare a homogeneous cell suspension.
- Allow the resulting cell suspension to stand in the SureThin<sup>®</sup> Cytology Preservative for at least 15 minutes before preparing a specimen for evaluation.
  - The cell suspension in SureThin<sup>®</sup> Cytology Preservative should be stable for at least 3 weeks at a temperature of between 4°C and 37°C. (39-99°F) and for at least 6 weeks at a temperature of 15° - 30°C when used for morphological evaluation.
  - Select the "Non-Gyn" mode if specimens are to be prepared using the SureThin<sup>®</sup> Processor.

D. Fine Needle Aspirates:

- Fine needle aspirates for cytological evaluation are collected into a syringe that has been prefilled with approximately 2mL of balanced electrolyte solution and immediately transferred into a vial of SureThin<sup>®</sup> Cytology Preservative. Visible cloudiness and/or fragments generally indicates that an adequate sample has been obtained. Samples for immunocytological evaluation should not be transferred into a formalin-containing fixative.
- Concentrate the sample by centrifugation (600-800xG for 10 minutes).
- Decant and discard the supernate.
- Resuspend the pellet in SureThin<sup>®</sup> Lysis Solution.
- Concentrate the sample by centrifugation (600-800xG for 10 minutes).
- Decant and discard the supernate.
- Repeat the previous three (3) steps if blood and/or mucus is still evident in the pellet.
- Resuspend the pellet by shaking or vortexing. A small volume of SureThin<sup>®</sup> Cytology Preservative or SureThin<sup>®</sup> Lysis Fluid may be added to facilitate this resuspension. The cell-crit of the resulting homogeneous slurry is preferably about 50%.
- Add this cell slurry to a vial of SureThin<sup>®</sup> Cytology Preservative and shake or vortex to prepare a homogeneous cell suspension. Residual tissue fragments, if any, may be removed by filtration through tulle.

- Allow the resulting cell suspension to stand in the SureThin® Cytology Preservative for at least 15 minutes before preparing a specimen for evaluation.
  - The cell suspension in SureThin® Cytology Preservative should be stable for at least 3 weeks at a temperature of between 4°C and 37°C. (39-99°F) and for at least 6 weeks at a temperature of 15° - 30°C when used for morphological evaluation.
  - Select the “Non-Gyn” mode if specimens are to be prepared using the SureThin® Processor.

E. Core-Needle and other Biopsy Samples:


- Core-needle and other “macro” biopsy samples that are intended for cytological evaluation should be deposited into SureThin® Cytology Preservative or SureThin® Lysis Solution immediately after collection. In consideration of the relatively low rate at which alcohol-based preservatives penetrate thick intact tissues, these samples should be processed as soon as possible after collection in order to ensure adequate cell preservation.

Method 1: Dispersed Cells:

- Homogenize or vigorously vortex the sample in order to disperse the cells.
- Concentrate the sample by centrifugation (600-800xG for 10 minutes).
- Decant and discard the supernate.
- Resuspend the pellet in SureThin® Lysis Solution.
- Concentrate the sample by centrifugation (600-800xG for 10 minutes).
- Decant and discard the supernate.
- Repeat the previous three (3) steps if blood and/or mucus is still evident in the pellet.
- Resuspend the pellet by shaking or vortexing. A small volume of SureThin® Cytology Preservative or SureThin® Lysis Fluid may be added to facilitate this resuspension. The cell-crit of the resulting homogeneous slurry is preferably about 50%.
- Add this cell slurry to a vial of SureThin® Cytology Preservative and shake or vortex to prepare a homogeneous cell suspension.
- Residual tissue fragments should be removed by filtration through tulle.
- If the resulting cell suspension appears to have an excessively high cellularity, it can be diluted with SureThin® Cytology Preservative. Conversely, if the cellularity appears to be too low, it can be increased by pelleting the suspension and resuspending the pellet in a suitable amount of SureThin® Cytology Preservative,
- Allow the resulting cell suspension to stand in the SureThin® Cytology Preservative for at least 15 minutes before preparing a specimen for evaluation.
  - The cell suspension in SureThin® Cytology Preservative should be stable for at least 3 weeks at a temperature of between 4°C and 37°C. (39-99°F) and for at least 6 weeks at a temperature of 15° - 30°C when used for morphological evaluation.
  - Select the “Non-Gyn” mode if specimens are to be prepared using the SureThin® Processor.

Method 2: Touch Preps from Biopsy Samples

- Touch Preps are preferably prepared immediately after the tissue sample has been obtained from the patient, but samples that have been immersed in SureThin® Cytology Preservative may also be used.
- Cut the tissue as appropriate to expose the structure(s) of interest.

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- Immediately press the freshly cut tissue surface against the surface of a microscope slide that has been pre-treated with a cell adhesion promoter. Suitable slides are available commercially or may be prepared as needed.
- Hold the tissue against the slide for several seconds before gently removing it.
- Immediately immerse the slide in SureThin® Cytology Preservative for at least 15 minutes before staining or other processing is performed.
- The resulting preserved specimen may be used as prepared, or it may be fixed by treatment with 95% ethanol or a formalin-based fixative in accordance with laboratory SOP.
- The tissue remaining after the Touch Prep is prepared can be fixed and processed for histological evaluation in accordance with laboratory SOP.

## 5. Limitations

- For in-vitro diagnostic use only.
- The adequacy and utility of the results obtained from samples prepared by the above methods will depend upon the quality of the initial sample. Always use good sample collection technique.
- The elapsed time between the initial collection of the sample and contacting the sample with SureThin® Cytology Preservative should be minimized in order to prevent artifacts and sample degradation.

## 6. Technical Support

Please contact your local Medite representative for additional information and assistance or:

	<b>Medite US Technical Support</b> Medite, Inc. 4203 SW 34th Street, Orlando, FL 32811 Tel. 888-225-2950 or 407-996-9630 Fax 407-996-4931 info@Medite-Group.com.      www.Medite-Group.com
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