



BestPrep® General Cytology Preservative

Catalog Numbers: C-101 (10 mL vial)
C-101-50 (50 x 10 mL vials)
C-101-200 (8 x 25 x 10 mL vials)
C-101-500 (20 x 25 x 10 mL vials)
C-101L (1 L)
C-101G (4 x 1 L)

INTENDED USE

BestPrep® General Cytology Preservative (CS-GCP) is a preservative fluid formulated for the preservation of HPV and other DNA and intact cells in suspension. Thin-layer cytology slides are processed from the cell suspensions using the CellSolutions™ Automated and GluCyte™ Manual Methods for cytology slide preparation. These slide preparations are evaluated for the presence of cancer or its precursor lesions by cytotechnologists and pathologists trained to evaluate CellSolutions™ prepared slides.

CS-GCP was developed and specially formulated for use with:

CellSolutions™ GluCyte™ Cell Adherent (GC 100)

CellSolutions™ Glass Slides (GCK D4)

CellSolutions™ 12 mL Polypropylene Centrifuge Tubes (GCK D1)

CellSolutions™ Filter Kit (CS-400F)

Cervex-Brush® (380100324) or equivalent device

PapCone Cervical Cell Scraper

CS-GCP was tested for antimicrobial effectiveness against *Escherichia coli*, *Klebsiella Pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans*, *Staphylococcus Epidermidis* and *Proteus Vulgaris* and found to be effective.

Qualified medical personnel are responsible for the collection and preservation of samples using CS-GCP. CS-GCP is recommended for the preservation and preparation of cytology samples collected from: brushings, scrapings and fine needle aspiration biopsies. For in vitro diagnostic use.

SUMMARY AND EXPLANATION

CS-GCP is a cytology preservative specially formulated to lyse red blood cells and keep the resulting hemoglobin along with tissue fluids, red cell membranes and other extraneous macromolecules from precipitating. Such precipitates can compromise slide preparation and microscopic interpretation.



CS-GCP also preserves small tissue fragments (micro-biopsies) found in some cytology collections, making them available for post-fixation in formalin for subsequent histological processing by preparing cell blocks.

Papanicolaou or other staining systems can be used to stain the slides. CS-GCP preserved cells are also compatible with most immunostaining procedures.

COMPOSITION / ACTIVE INGREDIENTS

<u>Substance</u>	<u>% WT</u>	<u>CAS No.</u>	<u>EC No.</u>
Denatured Ethanol	22.5%	64-17-5	200-578-6

HAZARDS AND PRECAUTIONS

Hazard statement(s)

H226 Flammable liquid & vapour

Not considered flammable for transportation purposes.

For precautionary statements refer to SDS.

GENERAL PRECAUTIONS

Wear powder free gloves, a lab coat and eye protection. Universal precautions should be followed when working with clinical samples. Do not allow CellSolutions™ reagents to come in contact with an open wound. DO NOT INGEST (contains denatured alcohol, antimicrobial compounds, solvents and other proprietary preservatives).

STORAGE REQUIREMENTS AND SHELF LIFE

Store CS-GCP at the recommended temperature range of 15°-30°C. Product expiration date that determines shelf life is located on the outside packaging of the product. The product shelf life once opened remains valid until the expiration date, provided the bottle is stored closed and at the recommended temperature range of 15°-30°C .

DISPOSAL CONSIDERATIONS

Treat all used products as hazardous material and dispose of in accordance with all applicable laws for the territory. For additional disposal considerations refer to SDS.

SPECIMEN COLLECTION AND STABILITY

1. CellSolutions recommends using the Cervex brush or equivalent for cervicovaginal collection.
2. Allow cytology samples to fix in CS-GCP for 30 minutes or longer.
3. Hemoglobin from moderately bloody samples has been shown to stay soluble for 7 days at the recommended temperature range of 2°-30°C.
4. Processed cytology specimens are stable in CS-GCP for two weeks at the recommended temperature range of 2°-30°C for both cytology and DNA based testing.

RECOMMENDED SPECIMEN PREPARATION

Processing Cervicovaginal Brushings and Scrapings using 10mL vial

- 1) Follow the collection device manufacturer's instructions for use for collecting a specimen.
- 2) Securely close the lid of the 10mL vial.
- 3) Mix and allow the material to fix for 30 minutes or longer.
- 4) Transport to the lab for processing.

**** F50 STOP:** Refer to CellSolutions™ F50 Operator's Manual for next processing steps. Continue to step 5 if using CellSolutions™ CS30 or Manual Method.

- 5) Transfer the required sample volume for HPV testing depending on the HPV manufacturer's protocol.
- 6) Transfer the remaining sample to a CellSolutions™ 12 mL centrifuge tube for cytology preparation.
- 7) Concentrate sample by centrifugation (10 minutes at 800 x g).
- 8) Decant and properly discard supernatant.
- 9) Leave the sample tube inverted and place on a paper towel for 1 minute.
- 10) Blot the sample tube until no more fluid appears on the paper towel.
- 11) Vortex cell pellet for 5 seconds. Large pellets may require 10 seconds.
- 12) Prepare slide(s) using CellSolutions™ automated or manual methods for slide preparation.
- 13) Allow cell suspension to dry on the slide, then stain and coverslip.
- 14) Re-suspend sample in 2 mL of CS-GCP for storage.

Processing Fine Needle Aspirations (FNA)

Air-dried as well as preserved material is often helpful when examining FNA samples. Air-dried slides should be prepared before fixation.

- 1) Rinse needle and syringe with up to 10 mL of CS-GCP.
- 2) Mix and allow the material to fix for 30 minutes or longer.

**** F50 STOP:** Refer to CellSolutions™ F50 Operator's Manual for next processing steps. Continue to step 3 if using CellSolutions™ CS30 or Manual Method.

- 3) Transfer sample into a CellSolutions™ 12 mL centrifuge tube.
- 4) Concentrate sample by centrifugation (10 minutes at 800 x g).
- 5) Decant and properly discard supernatant.
- 6) Leave the sample tube inverted and place on a paper towel for 1 minute.
- 7) Blot the sample tube until no more fluid appears on the paper towel.
- 8) Vortex cell pellet for 5 seconds. Large pellets may require 10 seconds.
- 9) Prepare slide(s) using CellSolutions™ automated or manual methods for slide preparation.
- 10) Allow cell suspension to dry on the slide, then stain and coverslip.
- 11) Re-suspend sample in 2 mL of CS-GCP for storage.

Processing Non-Cervicovaginal Brushings and Scrapings

- 1) Follow the collection device manufacturer's instructions for use for collecting a specimen.
- 2) Securely close the lid of the 10mL vial.
- 3) Mix and allow the material to fix for 30 minutes or longer.
- 4) Transport to the lab for processing.

**** F50 STOP:** Refer to CellSolutions™ F50 Operator's Manual for next processing steps. Continue to step 5 if using CellSolutions™ CS30 or Manual Method.

- 5) Transfer sample into a CellSolutions™ 12 mL centrifuge tube.
- 6) Concentrate sample by centrifugation (10 minutes at 800 x g).
- 7) Decant and properly discard supernatant.
- 8) Leave the sample tube inverted and place on a paper towel for 1 minute.
- 9) Blot the sample tube until no more fluid appears on the paper towel.
- 10) Vortex cell pellet for 5 seconds. Large pellets may require 10 seconds.
- 11) Prepare slide(s) using CellSolutions™ automated or manual methods for slide preparation.
- 12) Allow cell suspension to dry on the slide, then stain and coverslip.
- 13) Re-suspend sample in 2 mL of CS-GCP for storage.

LIMITATIONS OF THE PROCEDURE

1. A cytologic sample should be preserved in CS-GCP as soon as possible after collection. Ideally this should be carried out in the clinic where the sample is collected. Once an unpreserved sample becomes degraded it will be unsatisfactory for further processing and examination.
2. Grossly bloody samples may retain red cell remnants in spite of treatment in CS-GCP.
3. For single use only. Once a container of CS-GCP a specimen transferred into it, it cannot be reused for another specimen.

** *F-50 STOP* refers to operators using the CS-F50 processor to process specimens.



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BIBLIOGRAPHY

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