

CellSolutions™ F50 General Cytology Preservative

Catalog Numbers: CF-101 (10 mL vial)
CF-101-25 (25 x 10 mL vials)
CF-101-200 (8 x 25 x 10 mL vials)
CF-101-400 (16 x 25 x 10 mL vials)
CF-101L (1 L)
CF-101G (4 x 1 L)
CF-101-100 (100 x 30mL)

INTENDED USE

CellSolutions™ F50 General Cytology Preservative (CS-FGCP) is a preservative fluid formulated for the preservation of cells in suspension. Thin-layer cytology slides are processed from the cell suspensions using the CellSolutions™ F50 processor. 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-FGCP was developed and specially formulated for use with:
CellSolutions™ F50 Processor
CellSolutions™ Filter Kit (CS-400F) components
CellSolutions™ Red Lytic Preservative (CR-101)

CS-FGCP was tested for antimicrobial effectiveness against *Escherichia coli*, *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans*, and *Aspergillus niger* and found to be effective.

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

WARNING: Intended for preparation of non-gynecological cytology specimens only. This product is not cleared by the Food and Drug Administration (FDA) for the preparation and diagnosis of gynecological (cervicovaginal cytology) specimens

SUMMARY AND EXPLANATION

CS-FGCP 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-FGCP 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.

Centrifugation is used to separate the cellular specimen from the solubilized proteins.

Papanicolaou or other staining systems can be used to stain the slides. CS-FGCP 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

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).

STORAGE REQUIREMENTS AND SHELF LIFE

Store CS-FGCP at the recommended temperature range of 2°-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 2°-30° C .

DISPOSAL CONSIDERATIONS

Treat all used products as hazardous material and dispose of in accordance with federal, state and local requirements. For additional disposal considerations refer to SDS.

RECOMMENDED PREPARATION UPON RECEIPT OF SPECIMEN

1. Allow cytology samples to fix in CS-FGCP for 30 minutes or longer.
2. Hemoglobin from moderately bloody samples has been shown to stay soluble for a minimum of 7 days at the recommended temperature range of 2°-30° C.
3. Cytology specimens are stable in CS-FGCP for six months at the recommended temperature range of 2°-30° C.

Processing Brushings and Scrapings

- 1) Once the sample has been collected, the collection device is rinsed vigorously in CS-FGCP in an appropriately sized container (10 mL vial). Ideally the head of the collection device is removed and submersed in the CS-FGCP. Once a collection device has been rinsed in CS-FGCP it cannot re-enter the patient.
- 2) Prepare slide(s) using CellSolutions™ F50 processor for slide preparation. See F50 Operators Manual for instructions.
- 3) Stain and coverslip.

Processing Fine Needle Aspirations (FNA)

Air-dried conventional smears 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-FGCP.
- 2) Mix and allow the material to fix for 30 minutes or longer.
- 3) Prepare slide(s) using CellSolutions™ F50 processor for slide preparation. See F50 Operators Manual for instructions.

Processing Fluids

- 1) Transfer 50mL of well mixed specimen to a properly labeled conical 50mL centrifuge tube.
- 2) Centrifuge the specimen for 10 minutes at 800g.
- 3) Decant the supernatant being sure not to disturb the cell pellet.
- 4) Observe the specimen. If the specimen is bloody (red or brown) in appearance, add 30mL of CellSolutions Red Lytic Preservative to the specimen tube. Vortex and invert the tube to mix the sample. Allow the sample to sit for 15-30 minutes.
- 5) Centrifuge the specimen for 10 minutes at 800g.
- 6) Decant the supernatant being sure not to disturb the cell pellet.
- 7) Observe the specimen. If the specimen is still bloody in appearance, steps 4-7 can be repeated 2 additional times.
- 8) Observe the pellet volume. If a pellet is not visible, transfer a vial of CS-FGCP (CF-101) to the 50mL tube. Vortex the specimen and transfer the contents back to the properly labeled 10mL vial. If the pellet is visible and < 1mL, transfer 2-3 drops of the

sample into a properly labeled 10mL CS-FGCP vial (CF-101). If a pellet is visible and >1 mL, transfer 1-2 drops of the sample into a properly labeled 10mL CS-FGCP (C-101) vial. The specimen should be vortexed prior to any transfers to break up the cell pellet and allow for the transfer to the properly labeled CS-FGCP vial.

9) Allow the specimen to fix for a minimum of 30 minutes for optimal fixation.

10) Prepare slide(s) using CellSolutions™ F50 processor for slide preparation. See F50 Operators Manual for instructions.

LIMITATIONS OF THE PROCEDURE

1. A cytologic sample should be preserved in CS-FGCP 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-FGCP.
3. For single use only. Once a container of CS-FGCP a specimen transferred into it, it cannot be reused for another specimen.

BIBLIOGRAPHY

Keebler CM: Cytopreparatory Techniques. In Bibbo M (ed) Comprehensive Cytopathology. 1st ed. Philadelphia, PA WB Saunders, 1991, pp. 881-906.



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