



CellSolutions™ Red Lytic General Cytology Preservative

Catalog Number: CR-102 (40mL vial)
CR-102L (1 L)
CR-102G (4 x 1 L)
CR-102-25 (25 cups x 40mL)

INTENDED USE

CellSolutions™ Red Lytic General Cytology Preservative (CS-Lytic) is a preservative fluid formulated for the preservation of non-cervicovaginal (non-gyn) cells in suspension. Thin-layer cytology slides are processed from these 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-Lytic was developed and specially formulated for use with:

CellSolutions™ GluCyte™ Cell Adherent (GC 100)

CellSolutions™ Glass Slides (GCK D4)

CellSolutions™ Density Reagent (DR-101)

CS-Lytic lyses red blood cells very effectively and will handle small amounts of blood solubilizing hemoglobin. There is usually no hemoglobin precipitate or artifact created that can interfere with slide clarity. Qualified medical personnel are responsible for the collection and preservation of samples using CS-Lytic. CS-Lytic is recommended for the preservation and preparation of cytology samples collected from: brushings, scrapings, fine needle aspiration biopsies, sputum and fluids with excessive blood present. For in vitro diagnostic use.

SUMMARY AND EXPLANATION

CS-Lytic 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.

In addition to solubilizing protein and macromolecules, CS-Lytic partially dissolves and softens mucus. This allows the extraction of diagnostic cells, including those from mucoid samples.

CS-Lytic also preserves small tissue fragments (micro-biopsies) found in some cytology collections and makes 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-Lytic preserved cells are also compatible with most immunostaining procedures. Each laboratory should verify immunostaining performance.

COMPOSITION / ACTIVE INGREDIENTS

<u>Substance</u>	<u>% WT</u>	<u>CAS No.</u>	<u>EC No.</u>
Methanol	7-10%	67-56-1	200-659-6
Isopropyl Alcohol	20-30%	67-63-0	200-661-7
Ethylene Glycol	5-7.5%	107-21-1	203-473-3
Formaldehyde	5-7.5%	50-00-0	200-001-8

HAZARDS AND PRECAUTIONS

Hazard statement(s)

H226	Flammable liquid & vapour
H302+H312+H332	Harmful if swallowed, in contact with skin or inhaled
H319	Causes Serious Eye Irritation
H336	May cause drowsiness and dizziness
H371	May cause damage to organs

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 and formaldehyde).

STORAGE REQUIREMENTS AND SHELF LIFE

Store CS-Lytic 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.

SPECIMEN COLLECTION AND STABILITY

1. Allow cytology samples to fix in CS-Lytic 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. Processed cytology specimens are stable in CS-Lytic for six months stored at the recommended temperature range of 2°-30° C.

RECOMMENDED NON-GYN SPECIMEN PREPARATION

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 into a container containing CS-Lytic.
- 2) Mix and allow the material to fix for 30 minutes or longer.
- 3) Transfer contents into an appropriate sized centrifuge tube.
- 4) Concentrate sample by centrifugation (10 minutes at 600 x g).
- 5) Decant and properly discard supernatant.
- 6) Visualize cell pellet. If pellet appears to be absent of blood, proceed to step 7. If the cell pellet is grossly bloody, add 30mL of CS-Lytic, allow the specimen to sit for 15 minutes and repeat steps 4-6.
- 7) Prepare slide(s) using CellSolutions™ automated or manual methods for slide preparation.

Processing Sputum or Muroid Samples

- 1) A 1% Dithiothreitol (DTT)/CS-Lytic solution may be added to the sample before agitation to break up mucus. A stock solution is good for one week when stored at room temperature (15° to 30°C).
- 2) Agitate the DTT/CS-Lytic preserved sample for 30 minutes using a magnetic stirrer or shaker to break up mucus and allow the material to fix. For heavier samples a blender may be used.
- 3) The sample may need to be filtered through a nylon mesh (tulle or bridal veil) when transferring to a conical centrifuge tube. This should be performed under a fume

hood. This will allow removal of small tissue fragments and excess mucus for fixation in formalin and cell block preparation.

- 4) Concentrate the remaining liquid sample by centrifugation (10 minutes at 600 x g).
- 5) Decant and properly discard supernatant.
- 6) Add 30 mL CS-Lytic to the cell pellet.
- 7) Vortex the preserved sample for 5 seconds.
- 8) Concentrate sample by centrifugation (10 minutes at 600 x g).
- 9) Decant and properly discard supernatant.
- 10) Prepare slide(s) using CellSolutions™ automated or manual methods for slide preparation.
- 11) If the sample contains small tissue fragments and/or hardened mucus, these can be removed and post-fixed in formalin for histological processing by preparing a cell block.

Processing Brushings and Scrapings

- 1) Once the sample has been collected, the collection device is rinsed vigorously in CS-Lytic in an appropriately sized container. Ideally the head of the collection device is removed and submersed in the CS-Lytic. Once a collection device has been rinsed in CS-Lytic it cannot re-enter the patient.
- 2) Mix and allow the material to fix for 30 minutes or longer.
- 3) Concentrate sample by centrifugation (10 minutes at 600 x g).
- 4) Decant and properly discard supernatant.
- 5) Visualize cell pellet. If pellet appears to be absent of blood, proceed to step 6. If the cell pellet is grossly bloody, add 30mL of CS-Lytic, allow the specimen to sit for 15 minutes and repeat steps 3-5.
- 6) Prepare slide(s) using CellSolutions™ automated or manual methods for slide preparation.

Processing Fluids (Urine, Washings, Body Fluids)

- 1) Add an equal volume of CS-Lytic to the fresh specimen, when possible.
- 2) Mix and allow the material to fix for 30 minutes or longer.
- 3) Mix the sample and transfer to a 50 mL conical tube. (*Note: For optimum cell recovery, consider processing a minimum of 50 mL of specimen.)
- 4) Concentrate sample by centrifugation (10 minutes at 600 x g).
- 5) Decant and properly discard supernatant.
- 6) Visualize cell pellet. If pellet appears to be absent of blood, proceed to step 7. If the cell pellet is grossly bloody, add 30mL of CS-Lytic, allow the specimen to sit for 15 minutes and repeat steps 4-6.
- 7) Prepare slide(s) using CellSolutions™ automated or manual methods for slide preparation.



LIMITATIONS OF THE PROCEDURE

1. A cytologic sample should be preserved in CS-Lytic 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-Lytic.
3. Do not use CS-Lytic to preserve tissue fragments larger than 5 millimeters in average diameter.
4. For single use only. Once a container of CS-Lytic has a specimen transferred into it, it cannot be reused for another specimen.



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BIBLIOGRAPHY

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