CellSolutions™ GluCyte™ Cell Adherent

Catalog Number: **GC-100NE (component of GCK-500-M)**
GC-100ANE (component of GCK-500-A)
GC-25NE (component of GCK-100-M)

INTENDED USE

CellSolutions™ GluCyte™ Cell Adherent (GluCyte™) is used in processing slides for microscopic evaluation from liquid-based cytology samples. 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.

GluCyte™ was developed and specially formulated for use with:
BestPrep®General Cytology Preservative (C-101)
CellSolutions™ Blue Preservative (CB-102)
CellSolutions™ Red Lytic General Preservative (CR-102)
CellSolutions™ CellSolutions™ Density Reagent (DR-101)
BestPrep®Glass Slides (GCK D4)
BestPrep®12 mL Polypropylene Centrifuge Tubes (GCK D1)

Qualified medical personnel are responsible for processing specimens with GluCyte™, as well as any preceding steps in specimen preparation including collection and preservation of samples. GluCyte™ is recommended for processing the following preserved specimen types: urine, washings, body fluids, brushings and scrapings, and sputum. For in vitro diagnostic use.

SUMMARY AND EXPLANATION

GluCyte™ allows for transfer and adherence of liquid-based cytology samples to microscope slides. The samples are allowed to dry on the slides and do not require additional fixation. Papanicolaou or other staining systems can be used to stain the slides.

COMPOSITION / ACTIVE INGREDIENTS

Substance	% WT	CAS No.	EC No.
Ethanol	23.5%	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)

STORAGE REQUIREMENTS AND SHELF LIFE

Store GluCyte™ at the recommended temperature range of 2º-30º 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 2º-30º 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

The clinician collects the sample using either a Rovers® Cervex brush or equivalent approved sampling device. The brush head is removed from the handle and dropped into the CellSolutions™ General Cytology Preservative Vial. The vial is then tightly capped, labeled and sent to the laboratory.

LIMITATIONS OF THE PROCEDURE

1. GluCyte™ is not a preservative fluid and should not be used for storage of cytology samples.

2. For single use only. Once a specimen has been processed using GluCyte™, the GluCyte™ cannot be reused for another specimen.

3. Use only CellSolutions™ authorized consumables with the GluCyte™ system. Use of other manufacturer's consumables (e.g. slides, density reagent etc.) has not been validated.

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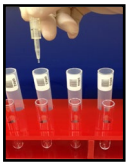
GluCyte™ Manual Method Procedure

1. Vortex the specimen vial for approximately 10 seconds. This will disaggregate many of the cell clusters and ensure specimen homogeniety. Diagnostic cell clusters will usually remain intact. Transfer the entire specimen to a properly labeled 12mL clarified polypropylene centrifuge tube. The collection device(s) will remain in the vial.
**Add 2ml of CellSolutions™ Density Gradient to the 12ml tube before sample transfer if using the cleaning step.*

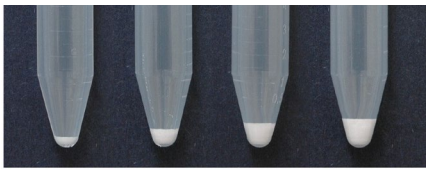
2. Centrifuge tube(s) in a horizontal rotor at 800 x g for 10 minutes. Be sure to balance the centrifuge before starting it.

3. After centrifugation, carefully decant the fluid from the centrifugation tube, leaving behind the cell pellet. The tube(s) should be inverted in one quick smooth motion to an angle of approximately 80º so that the fluid drains down one side of the tube.

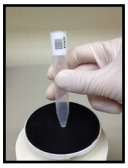
4. Once fluid removal has slowed to a light drip, the inverted tube(s) should be placed on an absorbent towel for one minute. until there is no more fluid residue appearing on the towel. Once the fluid removal is complete, return the tube(s) to the upright position. Place the tube(s) in the processing rack.



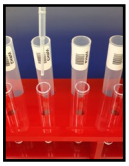
5. Observe the size of the cell pellet and dilute with the corresponding amount of de-ionized water using the Diluent Dispenser. The diagram to the right can be used as a guide for the dilution.



6. Use the GluCyte™ dispenser to add 200ul of GluCyte™ Cell Adherent to the 13x75mm (or 12x75mm) disposable tube.

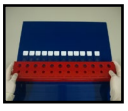


7. Vortex the diluted cell pellet for 5 seconds. Visually check to ensure that the cell pellet is broken up. Vortex longer if necessary.



8. Using a transfer pipette, transfer 2 drops of the cell mixture into the 13x75mm (or 12x75mm) disposable tube containing the GluCyte™ Cell Adherent. Residual material remaining in the pipette should be returned to the centrifuge tube. Samples with a small (non-visible) pellet will require that 100ul of GluCyte™ Cell Adherent is added directly to the centrifuge tube containing the sample. Mix/vortex the sample for 5 seconds.

9. Use the same transfer pipette to transfer 2 drops of the GluCyte™ suspension to a properly labeled specially coated microscope slide resting on a level surface. The drops should spread evenly to a diameter of 12-14um, and dry within 60 minutes into a stable, circular monolayer of cells. The pipette may be placed into the small tube to mark the place of the last specimen processed.



10. When one rack of slides has been prepared, use the tube rack to push the slides to the rear of the plexi-square. You are now ready to process additional slides. The drying of slides requires a minimum of one hour. When the drying process is complete, the slides are ready for manual or automated staining and cover-slipping.