



CellSolutions™ Density Reagent

Catalog Number: DR-101L (1 L)
DR-101G (4 x 1 L)

INTENDED USE

CellSolutions™ Density Reagent (CS-DR) is used as part of a differential centrifugation procedure designed to rid cytology samples of interfering excess debris, inflammation and mucus. 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-DR was developed and specially formulated for use with:
CellSolutions™ General Cytology Preservative (C-101)
CellSolutions™ Blue Preservative (CB-102)
CellSolutions™ Red Lytic General Cytology Preservative (CR-102)
CellSolutions™ GluCyte™ Cell Adherent (GC 100)
CellSolutions™ Glass Slides (GCK D4)
CellSolutions™ 12 mL Polypropylene Centrifuge Tubes (GCK D1)

Qualified medical personnel are responsible for processing specimens with CS-DR, as well as any preceding steps in specimen preparation including collection and preservation of samples. CS-DR 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

CS-DR is a dilute solution of macromolecular polysaccharide. Cell suspensions are layered on top of the CS-DR and centrifuged to remove interfering excess debris, inflammation and mucus from the resulting cell pellet. Refer to the recommended specimen preparation guidelines for the sample type to be processed.

COMPOSITION / ACTIVE INGREDIENTS

<u>Substance</u>	<u>% WT</u>	<u>CAS No.</u>	<u>EC No.</u>
Sodium Azide	0.1%	26628-22-8	247-852-1

HAZARDS AND PRECAUTIONS

Hazard statement(s)



H302 Harmful if swallowed

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 Sodium Azide).

STORAGE REQUIREMENTS AND SHELF LIFE

Store CS-DR 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 up 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 one of the CellSolutions™ Preservatives for 30 minutes or longer.
2. Specimens processed with CS-DR should be re-suspended with CellSolutions™ General Cytology Preservative, CellSolutions™ Red Lytic General Cytology Preservative, or CellSolutions™ Blue Preservative.

LIMITATIONS OF THE PROCEDURE

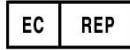
1. CS-DR is not a preservative fluid and should not be used for storage of cytology samples.
2. For single use only. Once a specimen has been processed using CS-DR, the CS-DR cannot be reused for another specimen.



CellSolutions™ Density Reagent Instructions for Use
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BIBLIOGRAPHY

Bigras G, Rieder MA, Lambercy J, Kunz B, Chatelain J-P, Reymond O, Cornaz D:
Keeping collecting device in liquid medium is mandatory to ensure optimized liquid-
based cervical cytology sampling. J Lower Genital Tract Disease 2003;7:168-174