

# CellSolutions<sup>TM</sup> Small Filter Kit

Catalog Number: CS-400FS (400 Tests)

#### **INTENDED USE**

CellSolutions<sup>TM</sup> Filter Kit (CS-400FS) consists of a single use disposable dual filter and a glass microscope slide that is designed for processing liquid based cytology specimens on the CS-F50 instrument. The filter separates excess mucus, blood, and inflammatory cells from the targeted cellular components of the sample. The system will then apply the cells onto a glass slide. The filter is designed specifically for the CS-F50 to accommodate the moving parts of the instrument and allow for proper functioning and sample preparation. The filters are packaged in units of 400.

CS-400FS was developed for use with: CellSolutions<sup>TM</sup> F50 Processor (CS-F50)

Qualified medical personnel are responsible for processing specimens with CS-F50, as well as any preceding steps in specimen preparation including collection and preservation of samples. The CS-F50 is recommended for processing the following preserved specimen types: urine, washings, body fluids, brushings and scrapings, sputum, and other non-gynecological specimens. 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**

A single filter consists of a single use dipsosable filter composed of a filter cap and thin membrane filter.

NOTE: The filter is optimized for specimens lacking a visible cell pellet after specimen concentration via centrifugation. Only these hypocellular specimens should be processed using the CS-1FS.

Once the filter and microscope slide are loaded onto the CS-F50, the preserved sample is added to the filter cap and the CS-F50 is started. A cytology slide free from obscuring mucus, blood, and inflammatory cells is produced. Refer to the the recommended specimen preparation guidelines and CS-F50 Operator's Manual for further instructions.

#### 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<sup>TM</sup> reagents to come in contact with an open wound.

# STORAGE REQUIREMENTS AND SHELF LIFE

Store CS-400FS 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.

# DISPOSAL CONSIDERATIONS

Treat all used products as hazardous material and dispose of in accordance with federal, state and local requirements.

### SPECIMEN COLLECTION AND STABILITY

- 1. Allow cytology samples to fix in CellSolutions<sup>TM</sup> F50 General Cytology Preservative for 30 minutes or longer.
- 2. Refer to the CS-F50 Operator's Manual for Processing Instructions and use of the CS-400FS Filter Kit.

# LIMITATIONS OF THE PROCEDURE

- 1. For single use only. Once a specimen has been processed using a filter and glass slide, the filter unit and slide cannot be reused for another specimen.
- 2. The CS-1FS-01 is designed to process specimens with no visible pellet after specimen concentration via centrifugation. In this case, the entire specimen should be transferred to a CellSoutions vial and processed according to the CS-F50 Operator's Manual. Using the CS-1FS-01 filter for processing cellular specimens (i.e. visible pellet post centrifugation) can result in unsatisfactory thick preparations.



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EC REP

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