

CellSolutions™ Filter Kit

Catalog Number: CS-400F (400 Tests)

INTENDED USE

CellSolutions™ Filter Kit (CS-400F) consists of a single use disposable dual filter (CS-1F-01) and a glass microscope slide (MS-432) 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-400F was developed for use with:
CellSolutions™ 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 CS-1F-01 filter consists of a single use disposable filter composed of a filter cap and thin membrane filter. Once the filter and microscope slide (MS-432) 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™ reagents to come in contact with an open wound.

STORAGE REQUIREMENTS AND SHELF LIFE

Store CS-400F 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.

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™ 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-400F Filter Kit.

LIMITATIONS OF THE PROCEDURE

1. For single use only. Once a specimen has been processed using a filter (CS-1F-01) and glass slide (MS-432), the filter unit and slide cannot be reused for another specimen.



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