



## TUMOR MARKER ASSAY FOR BREAST CANCER

### Early Detection of Cancer Recurrence

For enhanced detection of breast cancer recurrence, Fujirebio Diagnostics, Inc. (FDI) is the exclusive source for the CA 15-3 radioimmunoassay. CA 15-3 is an *in vitro* diagnostic device for the quantitative determination of DF3 antibody-defined antigen, encoded by the MUC 1 gene, in serum and plasma of patients previously treated for stage II or stage III breast cancer.

#### ■ Improved Patient Management

CA 15-3's proven accuracy provides physicians with reliable diagnostics, facilitating more effective monitoring of breast cancer patients who are clinically free of the disease.

#### ■ Reproducible Results, Minimal Assay Interference

The CA 15-3 assay utilizes two monoclonal antibodies in a forward sandwich format, providing reproducible results with little assay interference. CA 15-3's strong assay reproducibility offers the ability to more accurately observe patients' response to therapy, leading to earlier detection of cancer recurrence.

#### ■ Most Sensitive Breast Cancer Marker, Supports Early Detection of Metastasis

CA 15-3 has been characterized in clinical studies as the most sensitive test in detecting metastatic breast disease.<sup>1</sup> Additionally, CA 15-3 provides good specificity of detection. Rising assay values provide a lead-time to detection of recurrences as compared to routine methods of clinical detection.

#### ■ Trusted and Accepted by Physicians Worldwide

Supported by over 2000 peer-reviewed publications, CA 15-3 is the most widely published tumor marker specific to breast cancer. CA 15-3 is manufactured in a proven high-quality process, resulting in a consistent and dependable tumor marker assay.

1. Dnistrian, AM., et al: "Evaluation of CA M26, CA M29, CA 15-3 and CEA as circulating tumor markers in breast cancer patients," *Breast Cancer Research and Treatment*, (1990).



## FDI: THE TRUSTED NAME IN ONCOLOGY DIAGNOSTICS

In the field of oncology diagnostics, Fujirebio Diagnostics, Inc. (FDI) is the name people trust. Formerly Centocor Diagnostics, we pioneered the development of monoclonal antibody technology. Today, FDI is still the unparalleled leader in tumor marker assays worldwide, with innovative products that are unmatched in quality and dependability. FDI's extensive menu of diagnostic products sets the standard for excellence:

- Supported by thousands of peer-reviewed articles
- Endorsed by prestigious academic institutions and medical centers worldwide
- Proven manufacturing process and ISO 9001 certified quality system
- Distributed worldwide by leading healthcare organizations

### FDI's Tumor Marker Assays include:

**CA 125II™\* (Ovarian Cancer)** – Used for the quantitative determination of OC 125-defined antigen in serum of women with primary epithelial invasive ovarian cancer, excluding those with cancer of low malignant potential.

**CA 19-9™\* (Pancreatic Cancer)** – Used for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas.

**CA 15-3®\* (Breast Cancer)** – Used for the quantitative determination of DF3-defined antigen in serum or plasma of patients previously treated for stage II or stage III breast cancer.

**CYFRA 21-1™\***

**CA 72-4®\***

### Other Diagnostic Products:

**FITC Anti-Rabies Monoclonal Globulin** – Used in the direct fluorescent antibody procedure for the *in vitro* detection of rabies in brains and submaxillary glands.

**For more information, call +1.610.240.3800 or visit [www.fdi.com](http://www.fdi.com)**

\* These products are registered in compliance with the European **CE** mark.

+ Not for distribution in the United States.

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