Introduction

Fujirebio Diagnostics is a world leader in *in vitro* diagnostics and the gold standard manufacturer of cancer biomarker assays worldwide. We have extensive expertise in the development, manufacturing, and commercialization of *in vitro* diagnostic products for a variety of disease states. Fujirebio Diagnostics’ range of antibodies against tumor antigens are the core of our assay kits, available in both manual assay formats (RIA and EIA) and as custom developed products for use through our partners’ systems worldwide.

In 2006, CanAg Diagnostics merged with Fujirebio Diagnostics, Inc. to form the largest manufacturer of oncology biomarkers in the industry. Fujirebio Diagnostics have maintained the CanAg brand name for those EIA kits that CanAg customers around the world have come to associate with superior quality and reliability.

Fujirebio Diagnostics is a fully owned subsidiary of Fujirebio Inc., Tokyo, Japan. Fujirebio Inc. was established in 1950 and its ultimate goal is to contribute to medical treatment and human welfare worldwide as a Global life science company. Fujirebio, Inc. has been a pioneer in the field of clinical diagnostics with a focus on cancer markers, infectious disease, hormone and thyroid testing.

Quality

Fujirebio Diagnostics is committed to providing quality products that meet the requirements of our customers. Our quality management system encompasses every aspect of product realization, from design through manufacturing and product shipment to allow us to achieve the high standards required by regulatory authorities and our customers.

*All in vitro* diagnostic products are CE marked. The CE-mark indicates that the product complies with the requirements of the European In Vitro Diagnostics Directive 98/79/EC. All Fujirebio Diagnostics’ kits are manufactured in one of our ISO13485 certified facilities located in Gothenburg, Sweden or Malvern, PA, USA.
CONTENT

Working for better diagnostics 2

Diagnostics for cancer and brain damage 4

GYNECOLOGICAL CANCER
CanAg CA125 EIA 5
HE4 EIA 5
CanAg SCC EIA 6

LUNG CANCER
CanAg NSE EIA 6
CYFRA 21-1 EIA 7
CanAg ProGRP EIA 7
MESOMARK® EIA 10

Marker Significance 8
Product Specifications 9

GASTROINTESTINAL CANCER
CanAg CA242 EIA 10
CanAg CEA EIA 11
CanAg CA19-9 EIA 11

PROSTATE CANCER
CanAg PSA EIA 12
CanAg Free PSA EIA 12

BREAST CANCER
CanAg CA15-3 EIA 13

OTHER
Liver Cancer – CanAg AFP EIA 13
Malignant Melanoma – CanAg S100 EIA 14

TUMOR MARKER CONTROLS
CanChek 15
Tumor Marker Control 15
Cancer is one of the major causes of death in the western world second only to cardiovascular disease. Every third person will develop cancer and every fourth person will ultimately die from cancer. For improved outcomes and survival rates it is essential to detect cancer early.

Biochemical substances are released from cells and can be used as markers of disease in patient blood samples. These biomarkers may be used in cancer diagnosis/management (tumor markers) or as markers of brain damage (Biochemical Markers of Brain Damage, BMBD).

Serological tumor and brain damage marker determinations represent an important patient management tool in, among others, the following applications:

- Identification of disease at an early stage in combination with other diagnostic tools
- Generation of prognostic information
- Follow up of the effectiveness of treatment
- Monitoring the course of disease
- Early detection of recurrent disease

**Laboratory Tests**

Our tests make it possible to detect and/or monitor all of the most common forms of solid tumors, such as gastrointestinal, squamous cell, liver, pancreatic, prostate, ovarian, breast, skin and lung cancer. The company has also developed markers for brain damage after e.g. acute brain trauma, stroke, and hypoxia.

Our kits can be used on a wide range of microplate instruments giving considerable flexibility and cost efficiency for hospitals and laboratories. The kits are available globally through our Distributor Network.
CanAg CA125 EIA

Determination of the CA125 antigen is of clinical utility in ovarian cancer. It can be used for:
1. Differential diagnosis between ovarian tumors and benign disease.
2. Monitoring disease progression and regression.
3. Prognosis of survival time.
4. Early detection of recurrence.

SPECIFICATIONS

Results within: 4 hours
Detection limit: < 1.5 U/mL
Measuring range: 1.5-500 U/mL (may be extended by sample dilution)
Sample volume: 25 µL
Hook effect: No hook up to 50 000 U/mL
Stability: 18 months at 2-8° C
Incubation temp: 20-25° C
Detection: 620 nm or 405 nm

ORDERING INFORMATION

Prod. No. 400-10
CanAg CA125 EIA
For 96 determinations

HE4 EIA

The HE4 EIA is an enzyme immunometric assay for the quantitative determination of HE4 in human serum. The HE4 EIA is intended to be used as an aid in monitoring response to therapy for patients with invasive epithelial ovarian cancer. It is further intended to be used with the CanAg CA125 and ARCHITECT CA 125 II assay for in vitro diagnostic use as an aid in estimating the risk of epithelial ovarian cancer in premenopausal and postmenopausal women presenting with pelvic mass.

Numerous published studies show that a woman’s outcome is better when her ovarian cancer surgery is performed by a gynecologic oncologist. An estimation of the risk of ovarian cancer in a patient presenting with a pelvic mass may therefore be a helpful tool in determining who should be referred to a gynecologic oncologist for her surgery.

SPECIFICATIONS

Results within: 3 hours
Detection limit: ≤ 15 pM
Measuring range: 15-900 pM (may be extended by sample dilution)
Sample volume: 25 µL
Hook effect: No hook up to 300 000 pM
Stability: 18 months at 2-8° C
Incubation temp: 20-25° C
Detection: 620 nm or 405 nm

ORDERING INFORMATION

Prod. No. 404-10
HE4 EIA
For 96 determinations
CanAg SCC EIA

Squamous cell carcinoma antigen (SCCA) is a serological marker for squamous cell carcinomas (SCC) of the uterine cervix, lung, head and neck, vulva, and esophagus. Serum concentrations of SCCA in patients with SCC are correlated to the clinical stage, tumor volume and to the degree of histological differentiation of the tumor.

**SPECIFICATIONS**
- Results within: 2 hours, one step procedure
- Detection limit: $< \ 0.3 \ \mu g/L$
- Measuring range: $< 0.3-50 \ \mu g/L$
  (may be extended by sample dilution)
- Sample volume: 25 µL
- Hook effect: No hook up to 50 000 µg/L
- Stability: 18 months at 2-8° C
- Incubation temp: 20-25° C
- Detection: 620 nm or 405 nm

**ORDERING INFORMATION**
- Prod. No. 800-10
- CanAg SCC EIA
  For 96 determinations

CanAg NSE EIA

Determination of NSE antigen is of clinical utility in small cell lung cancer. It can be used for:
1. Differential diagnosis between Non Small Cell Lung Cancer (NSCLC) and Small Cell Lung Cancer (SCLC).
2. Monitoring disease progression and regression in patients with SCLC.
3. Early detection of recurrent disease.
4. Prognosis of survival time.

**SPECIFICATIONS**
- Results within: 2 hours, one step procedure
- Detection limit: $< 1 \ \mu g/L$
- Measuring range: 1-150 µg/L
  (may be extended by sample dilution)
- Sample volume: 25 µL
- Hook effect: No hook up to 200 000 µg/L
- Stability: 18 months at 2-8° C
- Incubation temp: 20-25° C
- Detection: 620 nm or 405 nm

**ORDERING INFORMATION**
- Prod. No. 420-10
- CanAg NSE EIA
  For 96 determinations
Lung Cancer

CYFRA 21-1 EIA

The CYFRA 21-1 EIA is a one-step, solid phase, quantitative assay for the measurement of soluble cytokeratin 19 fragments in serum. The measurement of CYFRA 21-1 levels may be useful in the monitoring and prognosis of non-small cell lung cancer. Elevated levels of cytokeratin 19 fragments are seen in serum from patients also in several other cancers such as esophagus, head-& neck and breast cancer.

**SPECIFICATIONS**

| Results within: | 2 hours, one step procedure |
| Detection limit: | ≤ 0.5 ng/mL |
| Measuring range: | 0.5-50 ng/mL |
| Sample volume: | 50 µL |
| Hook effect: | No hook up to 11 000 ng/mL |
| Stability: | 18 months at 2-8° C |
| Incubation temp: | 20-25° C |
| Detection: | 620 nm or 405 nm |

**ORDERING INFORMATION**

Prod. No. 211-10  
CanAg CYFRA 21-1 EIA  
For 96 determinations

CanAg ProGRP EIA

ProGRP is the precursor of the gut hormone GRP (Gastrin Releasing Peptide). ProGRP is stable in serum and has been shown to be elevated in patients diagnosed with Small Cell Lung Cancer (SCLC). The assay is a one-step immunoassay that utilizes biotinylated Anti-ProGRP polyclonal antibody and horseradish peroxidase (HRP) labeled Anti-ProGRP Monoclonal Antibody E146 in Streptavidin coated microtiter strips for the measurement of ProGRP in serum.

**SPECIFICATIONS**

| Results within: | 3 hours, one step procedure |
| Detection limit: | 2 ng/L |
| Measuring range: | 2-1000 ng/L |
| Sample volume: | 50 µL |
| Stability: | 18 months at 2-8° C |
| Calibrator range: | 0-1000 ng/L |
| Incubation temp: | 20-25° C |
| Detection: | 450 nm |

**ORDERING INFORMATION**

Prod. No. 220-10  
CanAg ProGRP EIA  
For 96 determinations
### Marker Significance

#### CANCER (localization)

<table>
<thead>
<tr>
<th>Cancer</th>
<th>CA125</th>
<th>CA19-9</th>
<th>SCC</th>
<th>CA15-3</th>
<th>CA15-3</th>
<th>MCA</th>
<th>CEA</th>
<th>CYFRA 21-1</th>
<th>ProGRP</th>
<th>MESOMARK</th>
<th>PSA</th>
<th>Free PSA</th>
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</table>

#### Marker Significance

- **Gastrointestinal**
  - Colorectal
  - Pancreatic
  - Esophagus

- **Gynecological**
  - Ovarian
  - Cervical
  - Endometrial

- **Lung**
  - NSCLC
  - SCLC
  - Malignant Mesothelioma

- **Prostate**
- **Breast**
- **Liver**
- **Germ Cell / Testicular**
- **Thyroid**
- **Head & Neck**
- **Melanoma**

**MARKER SIGNIFICANCE**

- **less**
- **more**
<table>
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<tr>
<th>Marker</th>
<th>Catalog Number</th>
<th>Sample</th>
<th>Results Within</th>
<th>Detection Limit</th>
<th>Measuring Range</th>
<th>Sample Volume</th>
<th>High Dose Hook</th>
<th>Normal Range</th>
<th>Within-run CV (%)</th>
<th>Between-day CV (%)</th>
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<td>CA242</td>
<td>101-10</td>
<td>Serum</td>
<td>4 hours two-step</td>
<td>&lt; 1 U/mL</td>
<td>1 - 150 U/mL</td>
<td>25 µL</td>
<td>&gt; 150 000 U/mL</td>
<td>&lt; 25 U/mL</td>
<td>3.8 - 4.7</td>
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<td>Serum</td>
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<td>1 - 240 U/mL</td>
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<td>≤ 0.3 µg/L</td>
<td>0.3 - 50 µg/L</td>
<td>25 µL</td>
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<td>1.9 - 2.4</td>
<td>1.1 - 1.9</td>
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<td>Serum</td>
<td>4 hours two-step</td>
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<td>1.5 - 500 U/mL</td>
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<td>&gt; 50 000 U/mL</td>
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<td>2.9 - 4.4</td>
<td>3.1 - 4.0</td>
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<td>HE4</td>
<td>404-10</td>
<td>Serum</td>
<td>3 hours two-step</td>
<td>&lt; 15 pM</td>
<td>15 - 900 pM</td>
<td>25 µL</td>
<td>&gt; 300 000 pM</td>
<td>&lt; 150 pM</td>
<td>1.4 - 3.7</td>
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<td>CA15-3</td>
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<td>1 - 250 U/mL</td>
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<td>1 - 150 µg/L</td>
<td>25 µL</td>
<td>&gt; 200 000 µg/L</td>
<td>&lt; 13 µg/L</td>
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<td>25 µL</td>
<td>&gt; 250 000 ng/mL</td>
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<td>CYFRA 21-1</td>
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<td>Serum</td>
<td>2 hours one-step</td>
<td>≤ 0.5 ng/mL</td>
<td>0.5 - 50 ng/mL</td>
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<td>&gt; 1 100 ng/mL</td>
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<td>ProGRP</td>
<td>220-85</td>
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<td>4 - 2 000 ng/mL</td>
<td>50 µL</td>
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<td>1.3 - 6.9</td>
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<td>MESOMARK</td>
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<td>Serum</td>
<td>3 hours</td>
<td>&lt; 0.3 nM</td>
<td>0.3 - 320 nM</td>
<td>10 µL</td>
<td>&gt; 10 291 nM</td>
<td>&lt; 1.5 nM</td>
<td>1.1 - 5.3</td>
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<td>50 µL</td>
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<td>n/a</td>
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<td>≤ 0.5 µg/L</td>
<td>0.5 - 500 µg/L</td>
<td>25 µL</td>
<td>&gt; 40 000 µg/L</td>
<td>&lt; 10 µg/L</td>
<td>1.6 - 2.0</td>
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<td>Serum</td>
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<td>&gt; 150 µg/L</td>
<td>&lt; 0.1 µg/L</td>
<td>1.3 - 2.5</td>
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MESOMARK® EIA

MESOMARK EIA is an enzyme linked immunosorbent assay for the quantitative measurement of soluble mesothelin related peptide (SMRP). The assay is a standard sandwich assay that utilizes two monoclonal antibodies, 4H3 and OV569, in the capture and detection of SMRP. SMRP has been shown to be elevated in patients diagnosed with malignant mesothelioma, an asbestos related cancer of the pleural lining of the lungs, heart, and abdomen.

**SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Specification</th>
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<td>Results within</td>
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**ORDERING INFORMATION**

Prod. No. 801-900
MESOMARK EIA
For 96 determinations

CanAg CA242™ EIA

CA242 is the latest generation marker of colorectal and pancreatic cancer. The high specificity of CA242 is useful for differentiating between pancreatic cancer and benign hepatobiliary disease. CA242 also gives prognostic information in pancreatic as well as in colorectal cancer. The combined use of CA242 with CEA (Carcino Embryonic Antigen) shows improved sensitivity both pre- and post-operatively.

**SPECIFICATIONS**

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<td>1-150 U/mL</td>
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<tr>
<td>Sample volume</td>
<td>25 µL</td>
</tr>
<tr>
<td>Hook effect</td>
<td>No hook up to 150 000 U/mL</td>
</tr>
<tr>
<td>Stability</td>
<td>18 months at 2-8° C</td>
</tr>
<tr>
<td>Incubation temp</td>
<td>20-25° C</td>
</tr>
<tr>
<td>Detection</td>
<td>620 nm or 405 nm</td>
</tr>
</tbody>
</table>

**ORDERING INFORMATION**

Prod. No. 101-10
CanAg CA242 EIA
For 96 determinations
CanAg CEA EIA

Carcinoembryonic antigen (CEA) is a general tumor marker, which shows clinical utility in gastrointestinal cancer as well as breast and lung cancer. The CanAg CEA EIA is a solid-phase non-competitive assay based on the direct sandwich technique. The antibodies used target the Gold epitope 4 and 5 for optimal clinical sensitivity and specificity and non-specific interference.

**SPECIFICATIONS**

- Results within: 2 hours, one step procedure
- Detection limit: < 0.25 µg/L
- Measuring range: 0.25-75 µg/L (may be extended by sample dilution)
- Sample volume: 25 µL
- Hook effect: No hook up to 250 000 µg/L
- Stability: 18 months at 2-8° C
- Incubation temp: 20-25° C
- Detection: 620 nm or 405 nm

**ORDERING INFORMATION**

Prod. No. 401-10
CanAg CEA EIA
For 96 determinations

CanAg CA19-9 EIA

CA19-9 is a well established marker for differentiation between malignant and benign pancreas disease, to follow up patients undergoing treatment and to detect recurrence. The incidence of pancreatic cancer continues to increase in the industrialized world. One way to improve the poor prognosis of pancreatic cancer is early detection of the tumor combined with a possibly curative resection.

**SPECIFICATIONS**

- Results within: 4 hours
- Detection limit: < 1 U/mL
- Measuring range: 1-240 U/mL (may be extended by sample dilution)
- Sample volume: 25 µL
- Hook effect: No hook up to 50 000 U/mL
- Stability: 18 months at 2-8° C
- Incubation temp: 20-25° C
- Detection: 620 nm or 405 nm

**ORDERING INFORMATION**

Prod. No. 120-10
CanAg CA19-9 EIA
For 96 determinations
CanAg PSA EIA

Increasing serum concentrations of PSA (Prostate Specific Antigen) may indicate cancer of the prostate. In patient serum PSA exists in its free form (Free PSA) and in stable complexes with different protease inhibitors. The most important complex is formed with α1-antichymotrypsin (PSA-ACT). The CanAg PSA EIA determines the total amount of PSA, with the same molar response for free and complexed PSA.

**SPECIFICATIONS**

- **Results within:** 2 hours, one step procedure
- **Detection limit:** < 0.1 µg/L
- **Measuring range:** 0.1-60 µg/L
  
  (may be extended by sample dilution)
- **Sample volume:** 25 µL
- **Hook effect:** No hook up to 23 000 µg/L
- **Stability:** 18 months at 2-8° C
- **Incubation temp:** 20-25° C
- **Detection:** 620 nm or 405 nm

**ORDERING INFORMATION**

- Prod. No. 340-10
- CanAg PSA EIA
- For 96 determinations

CanAg Free PSA EIA

It has been shown that the proportion of free PSA to total PSA in serum is often lower in men with prostate cancer than in men with benign prostatic hyperplasia. Determination of free PSA may therefore be used in conjunction with total PSA as an aid in the differentiation between benign prostatic hyperplasia and prostate cancer.

**SPECIFICATIONS**

- **Results within:** 2 hours, one step procedure
- **Detection limit:** < 0.03 µg/L
- **Measuring range:** 0.03-10 µg/L
  
  (may be extended by sample dilution)
- **Sample volume:** 50 µL
- **Hook effect:** No hook up to 5 000 µg/L
- **Stability:** 18 months at 2-8° C
- **Incubation temp:** 20-25° C
- **Detection:** 450 nm

**ORDERING INFORMATION**

- Prod. No. 350-10
- CanAg Free PSA EIA
- For 96 determinations
Breast Cancer / Liver Cancer

**CanAg CA15-3 EIA**

Breast cancer is the third most frequent form of cancer with a mortality rate of approximately 20 per 100,000 women. CA15-3 is primarily used in the management of breast cancer patients, for monitoring the disease, to follow up the effect of treatment as well as for early detection of recurrence. There is also a positive correlation between low preoperative serum levels of CA15-3 and good prognosis.

**SPECIFICATIONS**

| Results within: | 3 hours, one step procedure |
| Detection limit: | < 1 U/mL |
| Measuring range: | 1-250 U/mL (may be extended by sample dilution) |
| Sample volume: | 25 µL (diluted samples 1:41) |
| Hook effect: | No hook up to 7 500 U/mL |
| Stability: | 12 months at 2-8° C |
| Incubation temp: | 20-25° C |
| Detection: | 620 nm or 405 nm |

**ORDERING INFORMATION**

Prod. No. 200-10
CanAg CA15-3 EIA
For 96 determinations

**CanAg AFP EIA**

AFP is present in low concentrations in serum, but may be markedly increased in patients with cancer of the liver, testis or ovary. The CanAg AFP EIA is a solid-phase non-competitive assay based on the direct sandwich technique using the AFPK51 MAb and AFPK57 MAb for optimal clinical sensitivity, specificity and non-specific interference. The antigenic determinants of AFP have been characterised in an International Workshop under the auspices of ISOBM (ISOBM TD-2 Workshop).

**SPECIFICATIONS**

| Results within: | 2 hours, one step procedure |
| Detection limit: | < 0.5 µg/L |
| Measuring range: | 0.5-500 µg/L (may be extended by sample dilution) |
| Sample volume: | 25 µL |
| Hook effect: | No hook up to 40 000 µg/L |
| Stability: | 18 months at 2-8° C |
| Incubation temp: | 20-25° C |
| Detection: | 620 nm or 405 nm |

**ORDERING INFORMATION**

Prod. No. 600-10
CanAg AFP EIA
For 96 determinations
S100B is a 20 kDa protein belonging to the S100/calmodulin/troponin C super family of EF-hand calcium binding proteins. S100 was originally isolated in 1965 from human brain and was considered as a brain specific protein. Today more than 20 members of the S100 family have been characterised based on structural and functional similarities.

- In brain tissue, S100B is found as hetero- and homodimers of A1 (α)- and B (β)-subunits. The A1- and B-subunits show a high degree of sequence and species homology.
- In the nervous system S100A1B and S100BB dimers exist in high concentration in astrocytes, oligodendrocytes and Schwann cells.
- S100A1B and S100BB are also expressed in a limited proportion of cells outside the nervous system eg. melanocytes, adipocytes and chondrocytes as well as in certain malignant cells, most notably in melanoma.

Serum S100B is a sensitive biomarker for Malignant Melanoma. It is also clinically proven to be useful for management of patients with brain damage.

**CanAg S100 EIA**

The CanAg S100 EIA is a solid-phase, non-competitive direct sandwich assay. The assay is based on two monoclonal antibodies, S23 MAb and S53 MAb, targeting two regions of S100B exposed in both the S100A1B- and S100BB dimer. This antibody combination provides an assay with similar sensitivity for these two forms of S100B.

**SPECIFICATIONS**

- **Results within:** 4 hours
- **Detection limit:** < 0.01 µg/L
- **Measuring range:** 0.01-3.5 µg/L
- **Sample volume:** 50 µL
- **Hook effect:** No hook up to 150 µg/L
- **Stability:** 18 months at 4° C
- **Incubation temp:** 20-25° C
- **Detection:** 620 nm or 405 nm

**ORDERING INFORMATION**

Prod. No. 708-10
CanAg S100 EIA
For 96 determinations
CanChek™

The CanChek tumor marker control is for use as a quality control serum to monitor laboratory testing of Neuron Specific Enolase (NSE), S100B protein and Squamous Cell Carcinoma antigen (SCC). Two levels of the control are provided to enable performance monitoring over the clinical range.

**SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Control</th>
<th>3 vials of level 1</th>
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<tbody>
<tr>
<td></td>
<td>3 vials of level 2</td>
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<tr>
<td>Volume</td>
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<tr>
<td>Stability</td>
<td>24 months</td>
</tr>
</tbody>
</table>

**ORDERING INFORMATION**

Prod. No. 107-20
CanChek Control
For 96 determinations

Tumor Marker Control

Fujirebio Diagnostics Tumor Marker Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, HE4, PSA and Free PSA. Two levels of the control are provided to enable performance monitoring over the clinical range.

**SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Control</th>
<th>3 vials of level 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 vials of level 2</td>
</tr>
<tr>
<td>Volume</td>
<td>6 x 3 mL</td>
</tr>
<tr>
<td>Stability</td>
<td>24 months</td>
</tr>
</tbody>
</table>

**ORDERING INFORMATION**

Prod. No. 108-20
Tumor Marker Control
Oncology

101-10 CanAg CA242™ EIA
Pancreatic & Gastrointestinal Cancer

120-10 CanAg CA19-9 EIA
Pancreatic Cancer

200-10 CanAg CA15-3 EIA
Breast Cancer

211-10 CYFRA 21-1 EIA
Lung Cancer

220-10 CanAg ProGRP EIA
Lung Cancer

340-10 CanAg PSA EIA
Prostate Cancer

350-10 CanAg Free PSA EIA
Prostate Cancer

400-10 CanAg CA125 EIA
Ovarian Cancer

401-10 CanAg CEA EIA
Gastrointestinal, Breast & Lung Cancer

404-10 HE4 EIA
Ovarian Cancer

420-10 CanAg NSE EIA
Lung Cancer

600-10 CanAg AFP EIA
Liver Cancer

708-10 CanAg S100 EIA
Malignant Melanoma

800-10 CanAg SCC EIA
Squamous Cell Carcinoma

801-900 MESOMARK® EIA
Malignant Mesothelioma

Brain Damage

107-20 CanChek
Control for SCC, NSE, S100

108-20 Tumor Marker Control
Control for HE4, CA 15-3, CA 19-9, CA 125, AFP, CEA, TOTAL PSA, FREE PSA, FERRITIN, CA 27.29, CA 242

708-10 CanAg S100 EIA

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