

PRODUCT INFORMATION

# Fujirebio Diagnostics EIA Kit



Only available outside the US



# Future.

The best way to predict the future is to create it.

*Only by truly understanding the needs of patients, and by collaborating closely with clinicians and laboratorians worldwide, we can continue to develop new and innovative IVD testing solutions.*

# Present.

Today, we are a world-leading healthcare company.

*We have more than 1,200 employees worldwide dedicated to providing our customers with excellent products and service at every step.*

# Past.

More than 50 years of pioneering expertise in IVD.

*Founded in 1950 in Japan, Fujirebio launched its first in vitro diagnostic (IVD) test kit in 1966. This was the start of a strong and long-lasting tradition for conceiving, developing, producing and marketing high quality IVD testing solutions worldwide.*





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# Diagnostics for Cancer and Brain Damage

**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.

## Biomarkers

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



*Technician working with the establishment of new hybridomas in our laboratory in Sweden.*

# Fujirebio Diagnostics

## Reagents and Laboratory tests

Fujirebio Diagnostics is a world leader in *in vitro* diagnostics and the gold standard manufacturer of cancer biomarker assays worldwide. The company provides a wide range of high quality antibodies and laboratory tests for the detection of different biomarkers, such as tumor antigens. Fujirebio Diagnostics has extensive expertise in the development, manufacturing, and commercialization of *in vitro* diagnostic products for a variety of conditions and diseases. The wide range of antibodies are the core of Fujirebio Diagnostics' product portfolio and are available in both manual EIA format and supplied as raw material to large diagnostics companies for system adaptation.

## About us

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

CanAg Diagnostics AB, now Fujirebio Diagnostics AB, was founded in 1992 in Sweden. In 2006 they joined Fujirebio Diagnostics, to strengthen the company's product offerings, distribution network, and research and development capabilities.

## CanAg brand

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. CanAg<sup>®</sup> is a registered trademark of Fujirebio Diagnostics AB.



*The name Fujirebio, pronounced  
Fuji-Ray-Bee-Oh,  
symbolizes restoration of health.*





# Fujirebio Diagnostics EIA Kit



## Standard EIA Microplate format

The kits are based on a standard EIA microplate format. The tests use a microplate coated with an anti-ligand (streptavidin), a solid-phase ligand (biotin) conjugated catching monoclonal antibody (MAb), ready-to-use calibrators, enzyme (HRP) conjugated detecting MAb, Controls – high and low and a one-component enzyme substrate (TMB).

## Tumor Marker EIA Kit

Fujirebio Diagnostics' tumor marker kits 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 a test for brain damage after e.g. acute brain trauma, stroke and hypoxia.

The tumor marker kits may be adapted on a wide range of microplate instruments, giving considerable flexibility and cost efficiency for the users. The kits are available through a global Distributor Network.

## FEATURES & BENEFITS

- Simple and robust protocols
- Ready to Use reagents
- Simple one and two-step sandwich assays
- Coated microplates
- Proprietary, characterized, high affinity antibodies
- Low sample volume

CanAg® is a registered trademark of Fujirebio Diagnostics AB

# Gynecological Cancer

## CanAg CA125 EIA

400-10

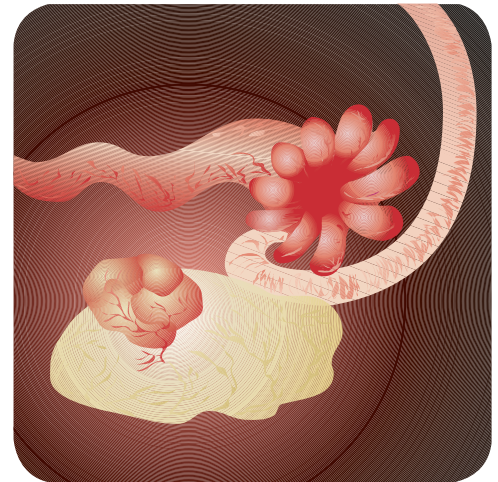
Determination of the CA125 antigen is of clinical utility in ovarian cancer of epithelial origin. It can be used for monitoring disease progression and regression, and for detection of recurrence.

### 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  
**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

404-10

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 EIA, ARCHITECT CA 125 II or Lumipulse G CA125 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.

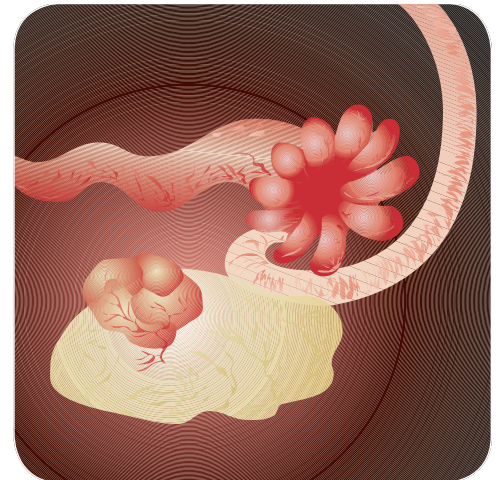
Numerous published studies show that the outcome for the woman is better when her ovarian cancer surgery is performed by a gynecologic oncologist. An estimation of the risk of ovarian cancer in a patient presenting with a pelvic mass may therefore be a helpful tool in determining who should be referred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

### SPECIFICATIONS

**Results within:** 3 hours  
**Detection limit:** LoD ≤ 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  
**Incubation temp:** 20-25 °C  
**Detection:** 620 nm or 405 nm

### ORDERING INFORMATION

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

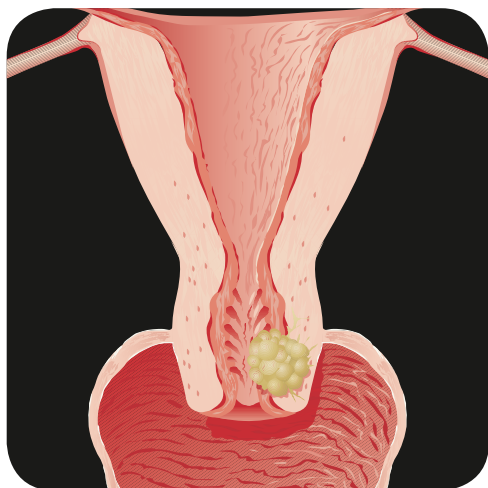




# Gynecological Cancer/Lung Cancer

## CanAg SCC EIA

800-10



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:**  $\leq 0.3 \mu\text{g/L}$   
**Measuring range:**  $0.3\text{-}50 \mu\text{g/L}$   
*(may be extended by sample dilution)*  
**Sample volume:**  $25 \mu\text{L}$   
**Hook effect:** No hook up to  $50\,000 \mu\text{g/L}$   
**Incubation temp:**  $20\text{-}25^\circ\text{C}$   
**Detection:**  $620 \text{ nm}$  or  $405 \text{ nm}$

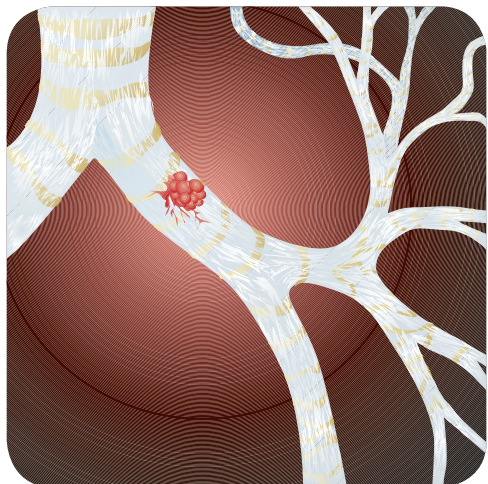
### ORDERING INFORMATION

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



## CanAg NSE EIA

420-10



Determination of Neuron Specific Enolase (NSE) is of clinical utility in small cell lung cancer. It can be used for:

1. As an aid in 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.

### SPECIFICATIONS

**Results within:** 2 hours, one step procedure  
**Detection limit:**  $< 1 \mu\text{g/L}$   
**Measuring range:**  $1\text{-}150 \mu\text{g/L}$   
*(may be extended by sample dilution)*  
**Sample volume:**  $25 \mu\text{L}$   
**Hook effect:** No hook up to  $200\,000 \mu\text{g/L}$   
**Incubation temp:**  $20\text{-}25^\circ\text{C}$   
**Detection:**  $620 \text{ nm}$  or  $405 \text{ nm}$

### ORDERING INFORMATION

Prod. No. 420-10  
CanAg NSE EIA  
For 96 determinations





# Lung Cancer

## CYFRA 21-1 EIA

### 211-10

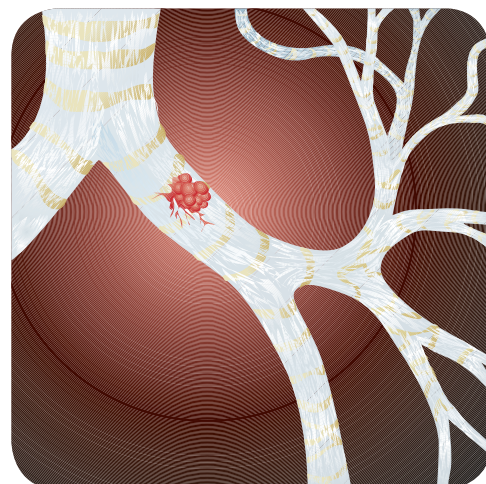
The CYFRA 21-1 EIA is a one-step, solid phase, quantitative assay for the measurement of soluble cytokeratin 19 fragments in serum. The assay is to be used as an aid in monitoring disease progression during the course of disease and treatment in lung cancer patients. Serial testing for patient CYFRA 21-1 assay values should be used in conjunction with other clinical methods used for monitoring 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:** LoD  $\leq$  0.12 ng/mL  
**Measuring range:** 0.5-50 ng/mL  
*(may be extended by sample dilution)*  
**Sample volume:** 50  $\mu$ L  
**Hook effect:** No hook up to 1 100 ng/mL  
**Incubation temp:** 20-25° C  
**Detection:** 620 nm or 405 nm

#### ORDERING INFORMATION

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



## CanAg ProGRP EIA

### 220-10

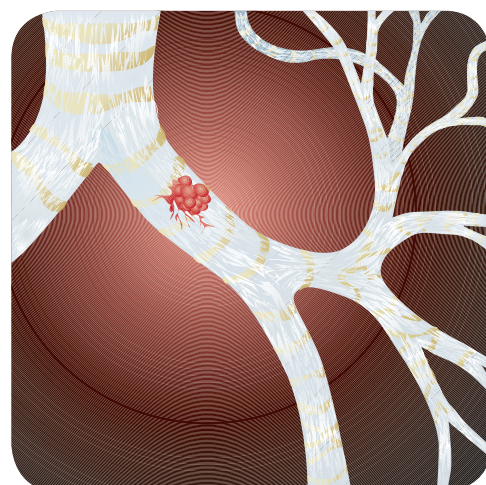
ProGRP is the precursor of the gut hormone GRP (Gastrin Releasing Peptide). Fragments of ProGRP in serum has been shown to be elevated in patients diagnosed with Small Cell Lung Cancer (SCLC). The assay is a one-step immunoassay that utilizes biotinylated Anti-ProGRP polyclonal antibody and horseradish 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:**  $<$  10 ng/L  
**Measuring range:** 10-2 000 ng/L  
*(may be extended by sample dilution)*  
**Sample volume:** 50  $\mu$ L  
**Hook effect:** No hook up to 1 500 000 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)	CA242	CA19-9	SOC	CA125	HE4	CA15-3	NSE	CEA	CYFRA 21-1	ProGRP	MESOMARK	PSA	Free PSA	AFP	S100
<b>GASTROINTESTINAL</b>															
Colorectal	■	■						■							
Pancreatic	■	■													
Esophagus			■					■	■						
<b>GYNECOLOGICAL</b>															
Ovarian				■	■										
Cervical			■	■				■	■						
Endometrial				■	■										
<b>LUNG</b>															
NSCLC			■	■				■	■						
SCLC							■	■	■	■					
Malignant Mesothelioma											■				
Prostate												■	■		
Breast						■		■	■						
Liver														■	
Germ Cell / Testicular														■	
Thyroid								■							
Head & Neck			■					■	■						
Melanoma															■



# Product Specifications

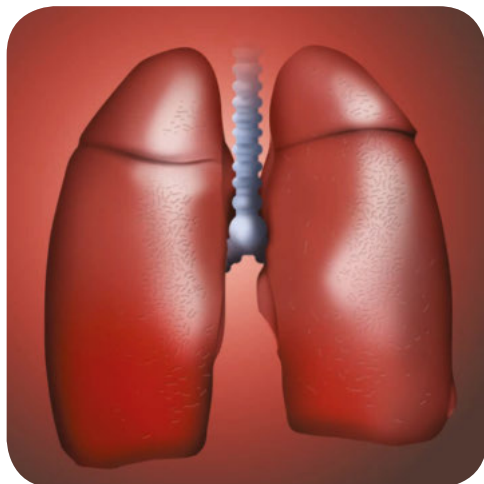
MARKER	Catalogue Number	Sample	Results Within	Detection Limit	Measuring Range	Sample Volume	High Dose Hook	Normal Range	Within-Run CV (%)	Between-Day CV (%)
CA242	101-10	Serum	4 hours two-step	< 1 U/mL	1 - 150 U/mL	25 µL	> 150 000 U/mL	< 25 U/mL	3.8 - 4.7	2.2 - 3.8
CA19-9	120-10	Serum	4 hours two-step	< 1 U/mL	1 - 240 U/mL	25 µL	> 50 000 U/mL	< 37 U/mL	3.3 - 4.5	6.2 - 7.0
SCC	800-10	Serum	2 hours one-step	≤ 0.3 µg/L	0.3 - 50 µg/L	25 µL	> 50 000 µg/L	< 1.2 µg/L	1.9 - 2.4	1.1 - 1.9
CA125	400-10	Serum	4 hours two-step	< 1.5 U/mL	1.5 - 500 U/mL	25 µL	> 50 000 U/mL	< 35 U/mL	2.9 - 4.4	3.1 - 4.0
HE4	404-10	Serum	3 hours two-step	≤ 15 pM	15 - 900 pM	25 µL	> 300 000 pM	< 150 pM	1.4 - 2.4	0.0 - 5.1
CA15-3	200-10	Serum	3 hours one-step	< 1 U/mL	1 - 250 U/mL	25 µL	> 7 500 U/mL	< 30 U/mL	3.0 - 3.7	5.6 - 11
NSE	420-10	Serum	2 hours one-step	< 1 µg/L	1 - 150 µg/L	25 µL	200 000 µg/L	< 10.5 µg/L	1.7 - 3.5	3.7 - 5.5
CEA	401-10	Serum	2 hours one-step	≤ 0.25 µg/L	0.25 - 75 µg/L	25 µL	> 250 000 µg/L	< 5 µg/L	2.1 - 2.7	1.5 - 2.7
CYFRA 21-1	211-10	Serum	2 hours one-step	< 0.12 ng/mL	0.5-50 ng/mL	50 µL	> 1 100 ng/mL	< 1.8 ng/mL	2.4 - 5.1	1.4 - 5.1
ProGRP	220-10	Serum	3 hours one-step	< 10 ng/L	10 - 2 000 ng/L	50 µL	> 1 500 000 ng/L	< 60 ng/L	1.3 - 6.9	0.8 - 4.4
MESOMARK	801-900	Serum	3 hours two-step	< 0.3 nM	0.3 - 320 nM	10 µL	> 10 291 nM	< 1.5 nM	1.1 - 5.3	-
PSA Total	340-10	Serum	2 hours one-step	< 0.1 µg/L	0.1 - 60 µg/L	25 µL	> 23 000 µg/L	< 4 µg/L	1.5 - 2.7	0.8 - 2.2
Free PSA	350-10	Serum	2 hours one-step	≤ 0.03 µg/L	0.03 - 10 µg/L	50 µL	> 5 000 µg/L	n/a	1.3 - 1.9	1.8 - 3.0
AFP	600-10	Serum	2 hours one-step	≤ 0.5 µg/L	0.5 - 500 µg/L	25 µL	> 40 000 µg/L	< 10 µg/L	1.6 - 2.0	1.4 - 2.0
S100	708-10	Serum	4 hours two-step	≤ 10 ng/L	10 - 3 500 ng/L	50 µL	> 150 000 ng/L	< 90 ng/L	1.3 - 2.5	1.5 - 2.5



# Lung Cancer/Gastrointestinal Cancer

## MESOMARK®

801-900



MESOMARK® is an assay for the quantitative measurement of Soluble Mesothelin Related Peptide (SMRP) in human serum. 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

**Results within:** 3 hours  
**Detection limit:** < 0.3 nM  
**Measuring range:** 0.3-320 nM  
*(may be extended by sample dilution)*  
**Sample volume:** 10 µL  
**Hook effect:** No hook up to 10 291 nM  
**Calibrator range:** 0-32 nM  
**Incubation temp:** 20-25° C  
**Detection:** 450 nm

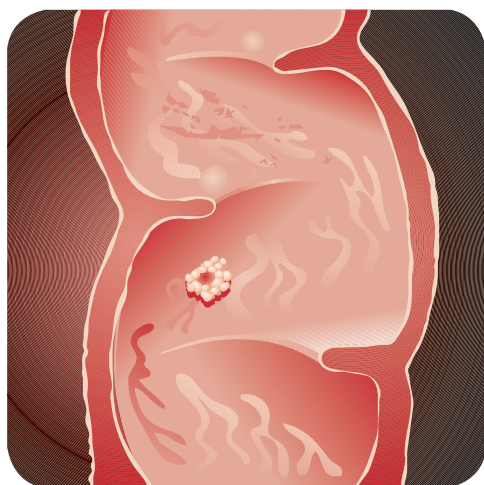
### ORDERING INFORMATION

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



## CanAg CA242™ EIA

101-10



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

**Results within:** 4 hours  
**Detection limit:** < 1 U/mL  
**Measuring range:** 1-150 U/mL  
*(may be extended by sample dilution)*  
**Sample volume:** 25 µL  
**Hook effect:** No hook up to 150 000 U/mL  
**Incubation temp:** 20-25° C  
**Detection:** 620 nm or 405 nm

### ORDERING INFORMATION

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



# Gastrointestinal Cancer

## CanAg CEA EIA

401-10

Carcinoembryonic Antigen (CEA) is secreted from tumor cells and is a widely used serological marker of gastrointestinal carcinomas, lung cancer, and breast cancer. In colorectal cancer, the clinical use of CEA testing for monitoring response to therapy and for documenting progressive disease is well established. CEA may also be present in benign gastrointestinal inflammatory diseases or in hepatobiliary diseases. These observations make it necessary to emphasize that the CEA assay should not be used as a cancer-screening test.

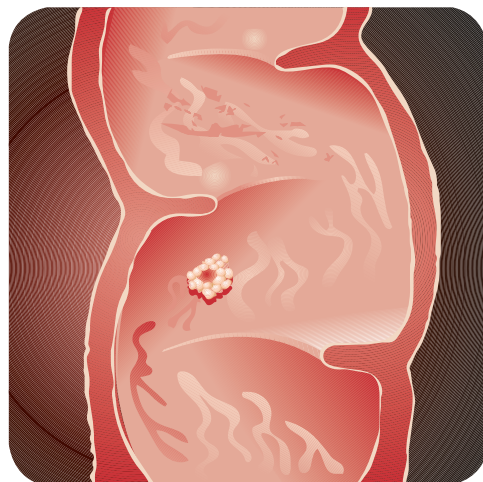
The antibodies in the CanAg CEA EIA target the gold epitope IV and V for optimal clinical sensitivity and specificity.

### SPECIFICATIONS

<b>Results within:</b>	2 hours, one step procedure
<b>Detection limit:</b>	$\leq 0.25 \mu\text{g/L}$
<b>Measuring range:</b>	0.25-75 $\mu\text{g/L}$ <i>(may be extended by sample dilution)</i>
<b>Sample volume:</b>	25 $\mu\text{L}$
<b>Hook effect:</b>	No hook up to 250 000 $\mu\text{g/L}$ at 405 nm
<b>Incubation temp:</b>	20-25° C
<b>Detection:</b>	620 nm or 405 nm

### ORDERING INFORMATION

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



## CanAg CA19-9 EIA

120-10

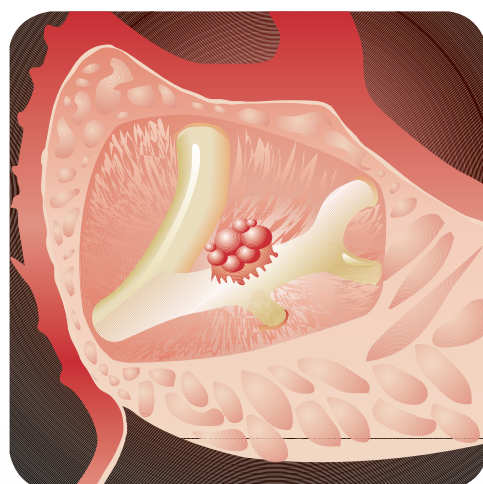
CA19-9 is a well established marker for differentiation between malignant and benign pancreas disease, to follow up patients undergoing treatment and to detect recurrence. The incidence of pancreatic cancer continues to increase in the industrialized world. One way to improve the poor prognosis of pancreatic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

### SPECIFICATIONS

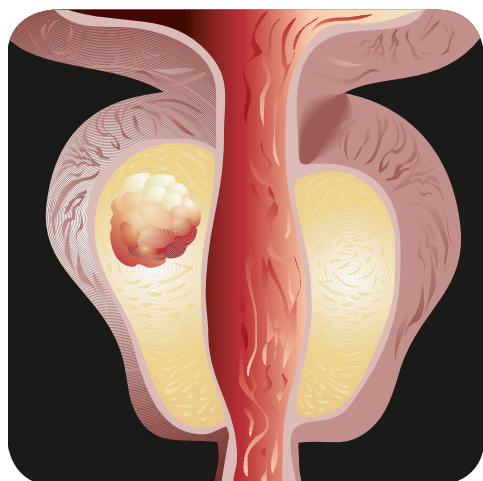
<b>Results within:</b>	4 hours
<b>Detection limit:</b>	$< 1 \text{ U/mL}$
<b>Measuring range:</b>	1-240 $\text{U/mL}$ <i>(may be extended by sample dilution)</i>
<b>Sample volume:</b>	25 $\mu\text{L}$
<b>Hook effect:</b>	No hook up to 50 000 $\text{U/mL}$
<b>Incubation temp:</b>	20-25° C
<b>Detection:</b>	620 nm or 405 nm

### ORDERING INFORMATION

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



# Prostate Cancer



## CanAg PSA EIA

340-10

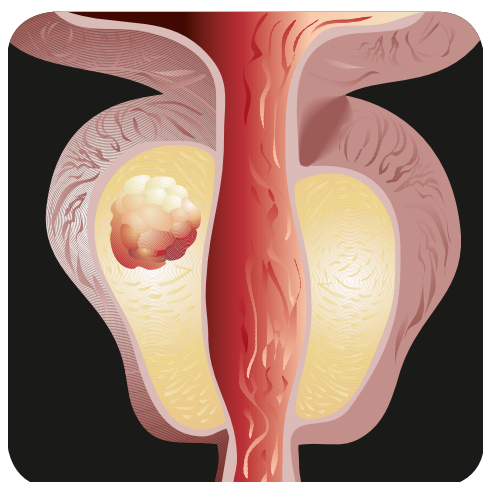
Increasing serum concentrations of PSA (Prostate Specific Antigen) may indicate cancer of the prostate. In patient serum PSA exists in its free form (Free PSA) and in stable complexes with different protease inhibitors. The most important complex is formed with  $\alpha$ 1-antichymo-trypsin (PSA-ACT). 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:**  $< 0.1 \mu\text{g/L}$   
**Measuring range:**  $0.1\text{-}60 \mu\text{g/L}$   
*(may be extended by sample dilution)*  
**Sample volume:**  $25 \mu\text{L}$   
**Hook effect:** No hook up to  $23\ 000 \mu\text{g/L}$   
**Incubation temp:**  $20\text{-}25^\circ \text{C}$   
**Detection:**  $620 \text{ nm}$  or  $405 \text{ nm}$

### ORDERING INFORMATION

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



## CanAg Free PSA EIA

350-10

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:**  $< 0.03 \mu\text{g/L}$   
**Measuring range:**  $0.03\text{-}10 \mu\text{g/L}$   
*(may be extended by sample dilution)*  
**Sample volume:**  $50 \mu\text{L}$   
**Hook effect:** No hook up to  $5\ 000 \mu\text{g/L}$   
**Incubation temp:**  $20\text{-}25^\circ \text{C}$   
**Detection:**  $450 \text{ nm}$

### ORDERING INFORMATION

Prod. No. 350-10  
CanAg Free PSA EIA  
*For 96 determinations*





# Breast Cancer/Liver Cancer

## CanAg CA15-3 EIA

200-10

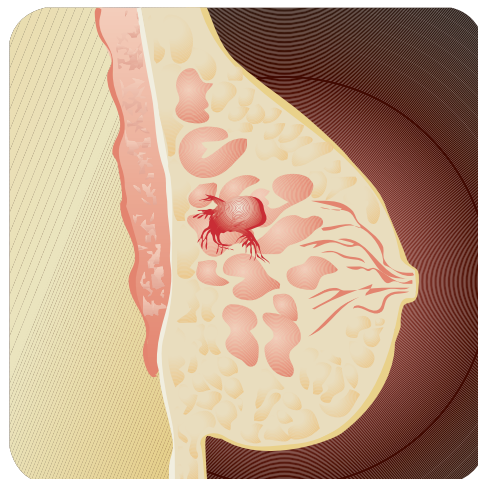
Breast cancer is the third most frequent form of cancer with a mortality rate of approximately 20 per 100,000 women. CA15-3 is primarily used in the management of breast cancer patients, for monitoring the disease, to follow up the effect of treatment as well as for early detection of recurrence. There 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  
**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

600-10

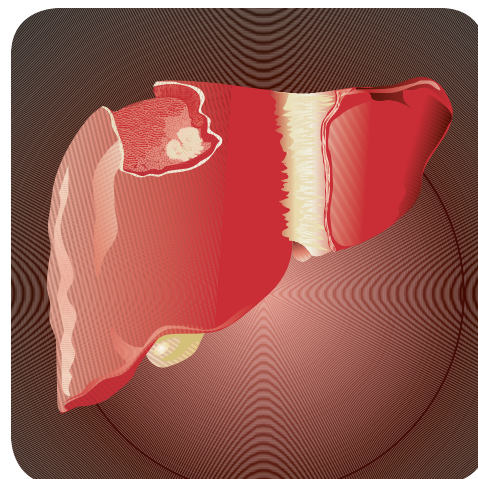
AFP is present in low concentrations in serum, but may be markedly increased in patients with cancer of the liver, testis or ovary. The CanAg AFP EIA is a solid-phase non-competitive assay based on the direct sandwich technique using the AFPK51 MAb and AFPK57 MAb for optimal clinical sensitivity, specificity 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  
**Incubation temp:** 20-25° C  
**Detection:** 620 nm or 405 nm

### ORDERING INFORMATION

Prod. No. 600-10  
CanAg AFP EIA  
For 96 determinations



# Manufacturing, Quality, Research & Development



The hallmark of Fujirebio Diagnostics is the ability to produce monoclonal antibodies and diagnostic kits of a very high quality. The entire manufacturing process is located at Fujirebio Diagnostics in Gothenburg, Sweden. Research & development, laboratories, production and corporate management are housed in a total area of more than 2400 m<sup>2</sup>.

## Quality

All processes involved in the life of our products, from concept through design, production, distribution and use, are in compliance with Current Good Manufacturing Practice (CGMP) as well as the device-specific quality system ISO 13485. The Quality system is also compliant with 21 CFR 820.

## Research & Development

Fujirebio Diagnostics has more than 30 years experience in the development and characterisation of monoclonal antibodies and antigens. The company has in-house core competence within hybridoma and gene technologies for the establishment of new immunoreagents. The broad range of clinically evaluated monoclonal antibodies, some of them under worldwide patents, has proven to be consistently reliable and of the highest quality for development of immunoassays for In Vitro Diagnostic use on different platforms, both manual EIAs and automated analyzers. The large and continuously increasing number of licensing and royalty agreements with major diagnostic companies gives credit to Fujirebio Diagnostics as a reliable business partner.



*To achieve our high goals, maintain the high quality and in efficiently meeting the expectations of our customers, we have a comprehensive quality system.*



# Malignant Melanoma and Brain Damage

## CanAg S100 EIA

708-10

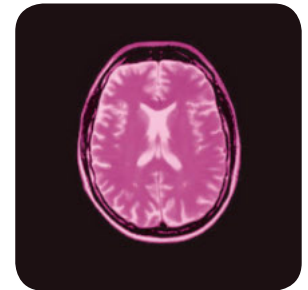
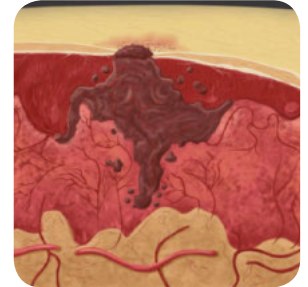
Serum S100B is a sensitive biomarker for Malignant Melanoma. It is also clinically proven to be useful for management of patients with brain damage. With CanAg S100 EIA you can detect both these areas. The CanAg S100 EIA is based on two monoclonal antibodies, targeting two different regions of S100B 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:**  $\leq 10$  ng/L  
**Measuring range:** 10-3 500  $\mu$ g/L  
*(may be extended by sample dilution)*  
**Sample volume:** 50  $\mu$ L  
**Hook effect:** No hook up to 150 000 ng/L  
**Incubation temp:** 20-25° C  
**Detection:** 620 nm or 405 nm

### ORDERING INFORMATION

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



## Malignant Melanoma

Malignant Melanoma is a skin cancer tumor originating from the melanocytes or pigment producing cells. It accounts for only about 4% of all skin cancers; however it is the most common cause of death in patients with skin cancer. S100B has been shown to be an independent prognostic indicator of survival and disease free survival in more advanced stages of malignant melanoma. S100B is also useful for monitoring the treatment of malignant melanoma patients – decreased marker concentrations reflect therapy response and increased marker concentrations indicate tumor progression. (*Oncology 1999; 56:338-344, British Journal of Dermatology 199;140, 1065-1071*)

## Brain Damage

S100B is used in the management of traumatic brain injury (TBI) patients and has been found to have several clinical applications. Importantly it has emerged as a useful tool to screen patients with mild TBI to assess the need of a CT scan and it has proven to reduce the number of CT scans with 30% and thereby preventing unnecessary patient exposure to radiation. S100B is also useful to predict outcome in moderate to severe TBI patients, to detect secondary injury in TBI patients and to evaluate treatment efficacy (*Acta Neurochir (2017) 159:209-225*).



# Tumor Marker Controls

## CanChek™

### 107-20

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 (SCCA). Two levels of the control are provided to enable performance monitoring over the clinical range.

#### SPECIFICATIONS

**Control:** 3 vials of level 1  
3 vials of level 2  
**Volume:** 6 x 0.75 mL

#### ORDERING INFORMATION

Prod. No. 107-20  
CanChek™



## Tumor Marker Control

### 108-20W

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, CA242, Ferritin, HE4, PSA and Free PSA. Two levels of the control are provided to enable performance monitoring over the clinical range.

#### SPECIFICATIONS

**Control:** 3 vials of level 1  
3 vials of level 2  
**Volume:** 6 x 3 mL

#### ORDERING INFORMATION

Prod. No. 108-20W  
Tumor Marker Control



# Tumor Marker Controls

## Lung Marker Control

### 240-20

This Lung Marker Control is an assayed, two-level control containing Cyfra and ProGRP antigens. The Fujirebio Diagnostics Lung Marker Control can be utilized as an independent, internal quality control to monitor the precision of the laboratory's Lumipulse G Cyfra and ProGRP assays. Laboratories can feel confident releasing their patient results when using a control to assess the long-term accuracy and precision of their Cyfra and ProGRP assays.

#### SPECIFICATIONS

**Control:** 2 vials of level 1  
2 vials of level 2

**Volume:** 4 x 3 mL

#### ORDERING INFORMATION

Prod. No. 240-20  
Lung Marker Control



## Mesothelin Control

### 360-20

Fujirebio Diagnostics Mesothelin Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analysis of the soluble mesothelin related peptides (SMRP) with the LUMIPULSE G system.

#### SPECIFICATIONS

**Control:** 1 vials of level 1  
1 vials of level 2

**Volume:** 2 x 1 mL

#### ORDERING INFORMATION

Prod. No. 360-20  
Mesothelin Control





**Fujirebio Diagnostics, Inc.**  
Malvern, Pennsylvania, USA

**Fujirebio Europe N.V.**  
Ghent, Belgium

**Fujirebio Diagnostics AB**  
Gothenburg, Sweden

**CanAg Diagnostics (Beijing) Co., Ltd.**  
Beijing, China

**Fujirebio Inc.**  
Tokyo, Japan

To find a distributor in your area,  
please visit our website [www.fdab.com](http://www.fdab.com)

**Fujirebio Diagnostics AB**

Elof Lindälvsgata 13  
SE-414 58 Göteborg  
Sweden

+46 31 85 70 30

+46 31 85 70 40

[info@fdab.com](mailto:info@fdab.com)

[www.fdab.com](http://www.fdab.com)

phone

fax

e-mail

website

