

# Critical Raw Materials

Cell Culture Derived Antigens and Antibodies



# Critical Raw Materials

## Antigens and antibodies for tumor markers, pituitary hormones, cardiac markers and fertility diagnostics from recombinant and human cell culture sources

Bio-Rad's Critical Raw Materials are cell culture derived antigens and antibodies from human and recombinant cell lines for use in diagnostic controls and calibrators. These products are developed and manufactured using state of the art technologies, are non-infectious and eliminate the unpredictability associated with native and animal sourced materials. They are in use by many leading diagnostic companies, including Bio-Rad's own industry-leading quality controls. Have confidence with Bio-Rad's Critical Raw Materials as part of your secure supply chain.

## Applications and Grade Definitions

### To assist in matching descriptive grades with common uses

#### Highly Purified Grade

Contains minor contaminants by PAGE analysis. Tumor marker antigens CA 15-3, CA 19-9 and CA 125 are assayed and confirmed to contain  $\leq 15\%$  on a U/U basis of cross contaminating tumor markers as specified on product information sheets. This product is recommended for use as an immunogen to make antibodies or for labeling (i.e., enzyme or radio). It is also suitable for the manufacture of multiple analyte controls.

#### Partially Purified Grade

Contains serum protein contaminants, and additional glycoproteins of other tumor markers in varying levels. Contaminants are not assayed in this grade of product. These partially pure products are often used to manufacture single analyte calibrators and controls.

#### Low Cross Reactivity, Partially Purified Grade

Contains serum protein contaminants, but is assayed for other tumor marker glycoprotein contaminants. As an example, Ovarian Tumor Antigen, LCR, PP Grade, is assayed for CA 15-3 and CA 19-9 and contains  $< 25\%$  on a U/U basis. This product is best suited for the manufacture of multiple analyte tumor marker controls.

#### Concentrate Grade

Available as a low cost alternative to low cross reactivity, partially pure grades for some cell culture products. This grade contains fetal bovine serum and/or human serum protein and is not assayed for other glycoprotein contaminants. As an example, GI Tumor Antigen, cell culture concentrate, (#42502300), is not assayed for CA 15-3 and CA 125. This product is best suited for the manufacture of multiple analyte tumor marker controls when the client is willing to determine acceptable cross reactivity levels.

#### Customized Grades

Many of our low cross reactivity or highly purified tumor marker antigen products are customized to meet customer specifications. Additional cross reactants may be added or the percentages of cross reactants may be altered. Quantitation methods, tumor marker analyte concentrations or buffers are typical customized items. Highly pure grades of tumor marker antigens can be altered to remove azide or applied to non-immunoassay uses such as ELISpot assays. An example of a customized grade is our 22502313, Breast Tumor Ag., CC, PP, LCR, Plus with testing and specifications similar to the 22502310.



## Cancer Marker Antigens

### Alpha-Fetoprotein Antigen (AFP)

AFP is a 70 kD major fetal serum glycoprotein with an unknown function that is synthesized in the liver, yolk sac and fetal gastrointestinal tract. Serum elevations are seen in either pregnant women or patients with cirrhosis and hepatitis. Increases in serum levels aid in diagnosis, classification and monitoring of non-seminomatous testicular cancer as well as primary hepatocellular carcinoma.

#### Ordering Information

Cat #	Source	Grade
<b>AFP Ag., CC, HP</b>		
13752600	Human Cell Culture . . . . .	Highly Purified

### Beta 2-Microglobulin (B2M/ $\beta$ 2M)

Beta 2-Microglobulin ( $\beta$ 2 microglobulin, B2M, beta-2-m, Beta2 Microglobulin,  $\beta$ 2-M) is an 11 kD prognostic tumor marker and light chain of the class I major histocompatibility complex (MHC-I) on the surface of many cells. It is also found in the serum in a free form. Levels of Beta 2-Microglobulin elevated in the blood is correlated with a larger amount of tumor (tumor mass) and reduced kidney function in multiple myeloma patients. Decreasing levels of Beta 2-Microglobulin in a multiple myeloma patient can indicate that the treatment is working, while static or increasing levels can show the patient is not responding to treatment.

#### Ordering Information

Cat #	Source	Grade
<b>r-Beta 2-Microglobulin Ag., PP</b>		
12003871	E. coli . . . . .	Partially Purified

### Breast Tumor Antigen (CA 15-3)

A high molecular weight mucin-like glycoprotein (identified as MUC-1) of 300-450 kD is localized in the alveoli and ducts of mammary glands. Distinct epitopes have been identified by monoclonal antibodies DF3 and 115D8. Alternative MUC-1 cancer assays, such as CA 27.29, have identified slightly different epitopes, which are all variably expressed on the same set of tumor related mucins. Clinically, CA 15-3 is used primarily as a marker for both early detection and relapse of breast cancer. Increased CA 15-3 levels are also associated with colon, lung, and hepatic tumors.

#### Ordering Information

Cat #	Source	Grade
<b>Breast Tumor Ag., CC, HP</b>		
22502000	Human Cell Culture. . . . .	Highly Purified
<b>Breast Tumor Ag., CC, PP, LCR</b>		
22502310	Human Cell Culture. . . . .	Low Cross Reactivity, Partially Pure
<b>Breast Tumor Ag., CC, PP, LCR Plus</b>		
22502313	Human Cell Culture. . . . .	Low Cross Reactivity, Partially Pure
<b>Breast Tumor Ag., CC, PP</b>		
22502300	Human Cell Culture. . . . .	Partially Purified

## Carcinoembryonic Antigen (CEA)

CEA is a large glycoprotein (~200 kD) consisting of a single polypeptide chain with varying carbohydrate components. Elevated CEA levels can be detected in smokers, patients with colorectal polyps, pancreatitis, liver disease, pulmonary infections, inflammatory bowel disease and renal failure. Clinically, CEA is used to determine tumor recurrence post-operatively following resection due to colon carcinoma.

### Ordering Information

Cat #	Source	Grade
<b>CEA Ag., CC, HP</b>		
30002100	Human Cell Culture	Highly Purified
<b>CEA Ag., CC, PP</b>		
30002300	Human Cell Culture	Partially Purified
<b>CEA Ag., PP</b>		
30001300	Human Fluids	Partially Purified

## Cancer Antigen Tag-72 (CA 72-4)

TAG-72 is a large mucin-like glycoprotein that was originally defined by the monoclonal antibody B72.3. TAG-72 is widely distributed in different types of carcinomas. When used for immunohistochemistry, TAG-72 can be used to classify epithelial-derived cancers and in differentiating an adenocarcinoma from a mesothelioma. TAG-72 is used in monitoring gastric cancer patients either undergoing treatment or in remission.

### Ordering Information

Cat #	Source	Grade
<b>Cancer Ag., TAG-72 Ag., CC, HP</b>		
12006548	Human Cell Culture	Highly Purified

## Cytokeratin-19 Antigen (Cyfra 21-1)

A soluble 40 kD cytokeratin fragment found in the cytoplasm of epithelial cells that is released into the serum following apoptosis. Clinical studies in lung and bronchial cancer patients demonstrate that Cyfra 21-1 levels aid in the diagnosis and follow-up of non-small cell and squamous cell carcinoma of the lung.

### Ordering Information

Cat #	Source	Grade
<b>Cytokeratin 19 Ag., PP, CC, LCR</b>		
34002301	Human Cell Culture	Partially Purified, LCR (No Azide)

## Ferritin

Ferritins (MW: ~ 450 kD) are polymeric proteins composed of 2 subunits: a heavy chain, and a light chain polypeptide, that reversibly bind and store iron in the liver, spleen and bone marrow. Ferritin light chain is the main intracellular iron storage protein. Recombinant Human Ferritin Light Chain is produced in *E.coli* as a single non-glycosylated polypeptide having a molecular weight of 19 kD. Clinically, the monitoring of serum ferritin levels aids in the diagnosis and management of iron metabolic disorders. Serum levels increase in hepatic diseases, various malignancies, inflammation and late stage hemochromatosis. Ferritin levels are also indicative of the erosion of iron stores during pregnancy. Genetic defects in the light chain ferritin gene are linked with several neurodegenerative disorders.

### Ordering Information

Cat #	Source	Grade
<b>r-Ferritin Ag., Lt Chain, HP</b>		
12000196	<i>E. coli</i>	Highly Purified

## Gastrointestinal Tumor Antigen (CA 19-9)

A large glycoprotein of molecular weight ~210 kD, CA 19-9 is a cell surface antigen located on MUC-1 whose carbohydrate determinant is defined as a sialylated lewis A blood group antigen. Elevated in patients with pancreatic cancer, CA 19-9 is also variably (20-50%) elevated in patients with colorectal, gastric and hepatocellular cancer.

### Ordering Information

Cat #	Source	Grade
<b>GI Ag., CC, HP</b>		
42502000	Human Cell Culture	Highly Purified
<b>GI Ag., CC Conc.</b>		
42502300	Human Cell Culture	Concentrate
<b>GI Ag., L3, CC Conc.</b>		
12000094	Human Cell Culture	Concentrate

## Gastrointestinal Tumor Antigen (CA 50)

A glycoprotein of 210 kD, CA 50 is a carcinoma cell surface epitope whose carbohydrate determinant is similar to the epitope defined by CA 19-9, which is sialylated lewis A. Elevated in most patients with pancreatic cancer, CA 50 is also elevated in patients with colorectal, gastric and hepatocellular cancer.

### Ordering Information

Cat #	Source	Grade
<b>CA-50 Ag., CC Conc.</b>		
27502300	Human Cell Culture	Concentrate

## Gastrointestinal Tumor Antigen (CA 242)

A glycoprotein of 210 kD, CA 242 is a carcinoma cell surface epitope whose carbohydrate determinant is similar to the epitope defined by CA 19-9, which is sialylated lewis A. Elevated in most patients with pancreatic cancer, CA 242 is also elevated in patients with colorectal, gastric and hepatocellular cancer.

### Ordering Information

Cat #	Source	Grade
<b>CA 242 Ag., CC Conc.</b>		
42602300	Human Cell Culture	Concentrate

## Human Epididymis Protein 4 Antigen (HE4)

HE4 (first associated with the human epididymis) belongs to the family of whey acidic four-disulfide core (WFDC) proteins. EU and FDA approved assays can be used as an aid in monitoring recurrence or progressive disease in patients with epithelial and endometrial ovarian cancer. HE4 is being used together with CA 125 to increase positive predictive value for women with possible ovarian cancer recurrence.

### Ordering Information

Cat #	Source	Grade
<b>HE4 Ag., CC, PP, LCR</b>		
83502310	Human Cell Culture	Low Cross Reactivity, Partially Pure

## Immunoglobulin E (IgE) Human Myeloma

Immunoglobulin E (MW: 150kD-900kD) is a gamma-globulin that functions as part of the immune system in protecting the body against infections. Gamma-globulins occur in humans as five different classes, IgG, IgM, IgA, IgE, and IgD, and are synthesized by the B lymphocytes. Diseases resulting from deficiencies of the immunoglobulins typically result in recurrent infections.

### Ordering Information

Cat #	Source	Grade
<b>IGE Ag., CC PP.</b>		
55252300	Human Cell Culture	Partially Purified

## Ovarian Tumor Antigen (CA 125)

A large glycoprotein of molecular weight ~200 kD, CA 125 is a cell surface glycoprotein located on MUC-16 originally identified in human ovarian tumors of serous, endometrial, and clear cell types. Currently, CA 125 is used in the detection of patients with ovarian cancer. CA 125 is also elevated in patients with lung, cervical, fallopian tube, and uterine cancer and in endometriosis.

### Ordering Information

Cat #	Source	Grade
<b>Ov. Cancer Ag., CC, HP</b>		
83752000	Human Cell Culture . . . . .	Highly Purified
<b>Ov. Cancer Ag., CC, PP, LCR</b>		
83752310	Human Cell Culture . . . . .	Low Cross Reactivity, Partially Pure

## Squamous Cell Carcinoma Antigen 1 (SCCA-1)

SCCA-1 is coded by the SERPINB3 gene (serpin peptidase inhibitor, clade B (ovalbumin), member 3), has a molecular weight of ~44.5 kD, and is a subfraction of the tumor associated antigen TA-4. SCCA-1 is a useful tumor marker for detecting, staging, and for monitoring response to therapy in patients with squamous cell carcinoma of the lung. It may also act as a papain-like cysteine protease inhibitor to modulate the host immune response against tumor cells and may also function as an inhibitor of UV-induced apoptosis via suppression of the JNK1 activity (c-JUN [NH (2)-terminal Kinase]).

### Ordering Information

Cat #	Source	Grade
<b>r-SCCA-1 Ag.</b>		
12000860	CHO cell line . . . . .	Partially Purified

# Cardiac Marker Antigens

## Creatine Kinase (CK) MB (CK-MB)

Creatine Kinase MB Isoenzyme (CK-MB) consists of two subunits with a MW of 82 kD. It is one of three isoforms containing either two M subunits (CK-MM), two B subunits (CK-BB) or one of each M and B subunit (CK-MB). This enzyme is used as a follow up test for the biochemical diagnosis of myocardial infarction (MI). CK-MB serum levels increase at 3-8 hours post cardiac infarction and stay elevated for 24-48 hours. Although CK-MB elevated serum levels are highly specific for detecting heart damage, it has largely been replaced by Troponin assays. However, it may be useful if the Troponin determination is abnormal or if a hospitalized patient has a suspected re-infarction.

### Ordering Information

Cat #	Source	Grade
<b>r-CK-MB, 10 mg</b>		
12000888	E. coli . . . . .	Highly Purified
<b>r-CK-MB, 5 mg</b>		
12000889	E. coli . . . . .	Highly Purified
<b>r-CK-MB, 1 mg</b>		
12000890	E. coli . . . . .	Highly Purified

## C-Reactive Protein (CRP) Antigen

CRP is a prototypic short pentraxin known to interact with the complement pathway in humans. An increased level of CRP in serum is characteristic of acute inflammation, infection, and certain malignancies. Elevated CRP levels are also known to be closely correlated with the risk of cardiovascular disease.

### Ordering Information

Cat #	Source	Grade
<b>CRP Ag., HP</b>		
33751000	Human Fluids . . . . .	Highly Purified (> 98%)
<b>CRP Ag., PP</b>		
33751300	Human Fluids . . . . .	Partially Purified (> 70%)





## Hormone Marker Antigens and Fertility Marker Antigens

### Follicle-stimulating hormone (FSH)

FSH is a 35 kD glycoprotein containing an alpha and beta subunit hormone which is synthesized and secreted in the anterior pituitary. It regulates the development growth, pubertal maturation and reproductive processes of the body. Disregulation of FSH levels is a result of several disease states including Turner, Swyer, Klinefelter and Kallmann syndromes and hypopituitarism. Most of these secretory abnormalities are associated with infertility.

#### Ordering Information

Cat #	Source	Grade
<b>r-FSH Ag.</b>		
12000214	CHO cell line . . . . .	Concentrate

### Inhibin A

Inhibin A is a dimeric protein consisting of an Inhibin  $\alpha$  and  $\beta_A$  subunits with molecular weight of about 35 kD. It is secreted in females in the ovaries, pituitary gland, placenta and corpus luteum primarily and in males it is secreted from Sertoli cells in the testes. Inhibin A in both males and females inhibits FSH production. It is part of a prenatal screen performed during pregnancy as a marker for Down's syndrome, but also has relevancy in ovarian cancer and male infertility.

#### Ordering Information

Cat #	Source	Grade
<b>r-Inhibin A Ag.</b>		
12000780	CHO Cell Line . . . . .	Concentrate

### Luteinizing Hormone (LH)

Luteinizing Hormone (LH), also known as lutropin and lutrophin, is a ~33 kD tropic hormone which modulates the secretory activity of other endocrine glands and is associated with reproduction by stimulating the ovulation in women and testosterone production in men. It is produced by gonadotropic cells in the anterior hypophysis of the pituitary gland and is required to stimulate follicular development and estradiol synthesis. The heterodimeric glycoprotein hormone, LH, like follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH), is composed of a common (alpha) subunit and specific (beta) subunit, which characterizes each of these hormones. LH is mainly used for infertility treatment, but also to aid in the diagnosis of pituitary disorders as well as dysfunctions with the ovaries or testicles.

#### Ordering Information

Cat #	Source	Grade
<b>r-LH Ag.</b>		
12001007	Mammalian Cell Line . . . . .	Partially Purified

# Diagnostic Antibodies

## Anti-Breast Tumor Antigen (CA 27.29) (MUC-1)

### Monoclonal

#### Ordering Information

Cat #	Product Name	Host	Clone ID	Pairing	Form
22508250	MUC-1 Ag., MoAb, CC, HP (6A4)	Cell Culture	6A4	TBD	Protein A Purified

## Anti-Gastrointestinal Tumor Antigen (CA 19-9)

### Monoclonal

#### Ordering Information

Cat #	Product Name	Host	Clone ID	Pairing	Form
42508250	GI Tumor Ag., MoAb, CC, HP 4C11	Cell Culture	4C11	Self Pairing	Protein A Purified

## Anti-Carcinoembryonic Antigen (CEA)

### Polyclonal

#### Ordering Information

Cat #	Product Name	Host	Clone ID	Form
30005012	CEA Antisera GAH # 2272	Goat	Poly-1	Serum
30005013	CEA Antisera GAH # 2273	Goat	Poly-2	Serum

ISO 13485:2016 Certification



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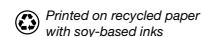
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