

First Catalogue of In Vitro Diagnostic Reagent Products Catalogue Exempted from Clinical Trials

No.	Product Category	Product Name	Product Description
1	III-7 Reagents Related to Detection of Tumor Markers	AFP test reagent	It is used to detect alpha-fetoprotein (AFP) in human samples and is mainly used clinically for the diagnosis, efficacy, and prognosis of primary liver cancer.
2	III-7 Reagents Related to Detection of Tumor Markers	Carcinoembryonic antigen (CEA) detection reagent	For the detection of carcinoembryonic antigen (CEA) in human samples, clinically it is mainly used for the observation of curative effect, prognosis and recurrence monitoring of malignant tumors.
3	III-7 Reagents Related to Detection of Tumor Markers	Total prostate specific antigen (tPSA) detection reagent	It is used to detect total prostate specific antigen (tPSA) in human samples. It is mainly used in clinical diagnosis and differential diagnosis of prostate diseases.
4	III-7 Reagents Related to Detection of Tumor Markers	Free prostate specific antigen (fPSA) detection reagent	Used to detect free prostate-specific antigen (fPSA) in human samples. The ratio of fPSA/tPSA can be used in the differential diagnosis of prostate cancer and benign prostatic hyperplasia.
5	III-7 Reagents Related to Detection of Tumor Markers	Free prostate specific antigen (cPSA) detection reagent	It is used to detect prostate-specific antigen (cPSA) binding in human samples and is used clinically for the auxiliary diagnosis and differential diagnosis of prostate cancer.
6	III-7 Reagents Related to Detection of Tumor Markers	Cytokeratin 19 Fragment (CYFRA21-1) Detection Reagent	It is used to detect cytokeratin fragment 19 (CYFRA21-1) in human samples, and it is mainly used clinically for the observation of curative effect of non-small cell lung cancer and recurrence monitoring.
7	III-7 Reagents Related to Detection of Tumor Markers	Squamous cell carcinoma antigen (SCC) detection reagent	For the detection of squamous cell carcinoma antigens in human samples, it is mainly used clinically for the diagnosis of cervical cancer, non-small cell cancer, and the like.
8	III-7 Reagents Related to Detection of Tumor Markers	Neuron Specific Enolase (NSE) Detection Reagents	For the detection of neuron-specific enolase in human samples, it is mainly used for

			the diagnosis of small cell lung cancer (SCLC) and the differential diagnosis of non-small cell lung cancer (NSCLC). It is used to monitor the condition of SCLC and neuroblastoma. Change, treatment response, and monitoring of recurrence.
9	III-7 Reagents Related to Detection of Tumor Markers	Human epididymis protein 4 (HE4) detection reagent	It is used for the detection of epididymal protein 4 (HE4) antigen in human samples. It is mainly used clinically for the diagnosis and therapeutic monitoring of ovarian cancer.
10	III-7 Reagents Related to Detection of Tumor Markers	Cancer Antigen 125 (CA125) Detection Reagent	It is used to detect cancer antigen 125 (CA125) in human samples. It is mainly used clinically for the diagnosis and treatment monitoring of ovarian cancer and other diseases.
11	III-7 Reagents Related to Detection of Tumor Markers	Cancer Antigen 15-3 (CA15-3) Detection Reagent	For the detection of cancer antigen 15-3 (CA15-3) in human samples, clinically used for the treatment of breast cancer efficacy and prognosis observation.
12	III-7 Reagents Related to Detection of Tumor Markers	Carbohydrate Antigen 19-9 (CA19-9) Detection Reagent	It is used to detect carbohydrate antigen 19-9 (CA19-9) in human samples and is used clinically for the auxiliary diagnosis of pancreatic cancer and other gastrointestinal malignancies.
13	III-7 Reagents Related to Detection of Tumor Markers	Carbohydrate Antigen 242 (CA242) Detection Reagent	It is used to detect carbohydrate antigen (CA242) in human samples. It is mainly used clinically in the diagnosis and monitoring of pancreatic cancer, colorectal cancer, and other gastrointestinal cancers.
14	III-7 Reagents Related to Detection of Tumor Markers	Carbohydrate Antigen 50 (CA50) Detection Reagent	It is used to detect carbohydrate antigen 50 (CA50) in human samples and is used clinically to monitor the progress of disease and efficacy of digestive system tumors (such as pancreatic cancer).
15	III-7 Reagents Related to Detection of Tumor Markers	Cancer Antigen 72-4 (CA72-4) Detection Reagent	It is used to detect cancer antigen 724 (CA72-4) in human samples and is mainly used in clinical diagnosis and

			1monitoring of malignancy such as gastrointestinal system.
16	III-7 Reagents Related to Detection of Tumor Markers	Tissue Polypeptide Specific Antigen (TPS) Detection Reagent	It is used for the detection of tissue polypeptide specific antigen (TPS) in human samples. It is mainly used clinically for the diagnosis of breast, ovarian, digestive system and other tumors as well as monitoring of therapeutic effects.
17	III-7 Reagents Related to Detection of Tumor Markers	B2 Microglobulin (β 2 MG) Detection Reagent	It is used to detect β 2 microglobulin in human samples and is mainly associated with tumors and multiple myeloma.
18	III-7 Reagents Related to Detection of Tumor Markers	Ferritin detection reagent	For the detection of ferritin in human samples, clinically used mainly for the detection of recurrence and metastasis of malignant tumors.
19	III-7 Reagents Related to Detection of Tumor Markers	S100 Protein Detection Reagent	For the detection of S100 protein in human samples, it is mainly used clinically for the treatment monitoring of central nervous system tumors.
20	III-7 Reagents Related to Detection of Tumor Markers	Human Chorionic Gonadotropin (HCG) Detection Reagent	For the detection of human chorionic gonadotropin (HCG) in human samples, it is clinically used for the auxiliary diagnosis of choriocarcinoma.
21	III-7 Reagents Related to Detection of Tumor Markers	B-human chorionic gonadotropin (β -HCG) detection reagent	For the detection of β -human chorionic gonadotropin (β -HCG) in human samples, it is mainly used clinically for auxiliary diagnosis of choriocarcinoma.
22	III-7 Reagents Related to Detection of Tumor Markers	Prostate alkaline phosphatase (PAP) detection reagent	For the detection of prostate alkaline phosphatase (PAP) in human samples, it is mainly used in the clinical diagnosis of prostate cancer, treatment efficacy and prognosis assessment, and differential diagnosis of metastatic bone tumors.
23	III-7 Reagents Related to Detection of Tumor Markers	Prostate Acid Phosphatase (PACP) Assay Reagent	For the detection of prostate acid phosphatase (PACP) in human samples, it is mainly used clinically to monitor the occurrence of bone metastases in prostate cancer.

24	III-7 Reagents Related to Detection of Tumor Markers	Gastrin-releasing peptide precursor (proGRP) detection reagent	It is used to detect gastrin-releasing peptide precursor (proGRP) in human samples, and is mainly used for the auxiliary diagnosis of small cell lung cancer (SCLC) in clinic. .
25	III-7 Reagents Related to Detection of Tumor Markers	Pepsinogen (PG) I Detection Reagent	For the detection of pepsinogen (PG) I in human samples. The concentration of PGI and the ratio of PGI/II can be used for the diagnosis of gastric cancer.
26	III-7 Reagents Related to Detection of Tumor Markers	Pepsinogen (PG) II Assay Reagents	For the detection of pepsinogen (PG) II in human samples. The concentration of PGII and the ratio of PGI/II can be used for the diagnosis of gastric cancer.
27	III-7 Reagents Related to Detection of Tumor Markers	κ light chain detection reagent	For the detection of κ light chain in human samples (such as serum and urine), it is clinically used for the auxiliary diagnosis of multiple myeloma.
28	III-7 Reagents Related to Detection of Tumor Markers	λ light chain detection reagent	It is used to detect the λ light chain in human samples (such as serum and urine). It is mainly used in the clinical diagnosis of multiple myeloma.
29	III-7 Reagents Related to Detection of Tumor Markers	α -L-Fucosidase Assay Reagents	For the detection of α -L-fucosidase in human samples, it is mainly used for the auxiliary diagnosis of liver cancer.
30	III-7 Reagents Related to Detection of Tumor Markers	Prolactin detection reagent	For the detection of prolactin in human samples, it is mainly used in the clinical diagnosis of prolactinoma.
31	III-7 Reagents Related to Detection of Tumor Markers	Calcitonin detection reagent	It is used to detect calcitonin (CT) in human samples and is mainly used clinically for the auxiliary diagnosis of medullary thyroid carcinoma and small cell lung cancer.

Note:

1. Products listed in the above list are for product self-test or neonate testing purposes and are not part of the product that is exempt from clinical trials.
2. Flow cytometric analysis uses general-purpose counting reagents (counting tubes, counting microspheres), test condition setting reagents (fluorescent compensating microspheres), and other class II products, free from clinical trials.