



Thermo Scientific B-R-A-H-M-S Biomarkers
Tumor Marker Assays



Excellent precision

Confident cancer monitoring

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Thermo Scientific B·R·A·H·M·S Biomarkers

Tumor Markers

Parameter	Clinical Interest	Product	Technology	Size	Article N°
AFP	- Diagnosis and follow-up of hepatocellular carcinomas and of all teratocarcinomas - Follow-up and monitoring of liver metastases originating from different cancers, especially those of the digestive tract	AFP	KRYPTOR	75	816.075
CA 15-3	Follow-up and monitoring of breast cancer patients	CA 15-3	KRYPTOR	75	808.075
CA 19-9	Diagnosis, follow-up and monitoring in patients with excretory pancreatic cancer, hepatobiliary and gastric cancer	CA 19-9	KRYPTOR	100	807.100
CA 125 II	Differential diagnosis, follow-up and monitoring of ovarian tumor patients	CA 125 II	KRYPTOR	75	805.075
Calcitonin	- Diagnosis, follow-up and monitoring of medullary thyroid carcinoma (MTC) - Screening for MTC in nodular thyroid disease and follow-up of other calcitonin producing malignant tumors	Calcitonin	IRMA	96	529.096
CEA	Follow-up and monitoring of patients with colorectal cancer in remission (CEA can also be found in other types of cancer (digestive tract glandular cancers, breast, lung, ovary, bladder, thyroid).)	CEA	KRYPTOR	100	817.100
Chromogranin A	Follow-up and monitoring of patients with Neuroendocrine Tumors (NET)	CgA II	KRYPTOR	50	839.050
CYFRA 21-1	Follow-up and monitoring in patients suffering from Non Small Cell Lung Cancer (NSCLC) and follow-up in urinary bladder cancer	CYFRA 21-1	KRYPTOR	50	811.050
Ferritin	Follow-up of certain cancers (metastatic breast cancer, lung cancer, neuroblastoma, teratoblastoma) and hemopathy (Acute Lymphoblastic Leukaemia, Acute Myeloblastic Leukaemia, Hodgkin's disease and non Hodgkin's lymphoma)	Ferritin	KRYPTOR	50	814.050
hCG+β	Follow-up and monitoring of germ cell tumors	hCG+β	KRYPTOR	50	841.050
NSE	- Differential diagnosis, follow-up and monitoring of Small Cell Lung Cancer (SCLC), - Follow-up and monitoring of neuroblastoma	NSE	KRYPTOR	50	821.050
PSA (Total)	Follow-up and monitoring of prostate cancer patients and screening of risk groups	Total PSA	KRYPTOR	100	810.100
PSA (Free)	In combination with Total PSA improved discrimination between prostate cancer and benign prostate hypertrophy (BPH)	Free PSA	KRYPTOR	50	867.050
Prolactin	Hyperprolactinemia screening in Diencephalo-pituitary tumor pathology (prolactinoma, craniopharyngioma, chondroma) or isolated hypogonadism	Prolactin	KRYPTOR	50	824.050
Osteocalcin	Reflection of osteoblast activity and specific and sensitive marker of bone formation rate (e.g. Osteoporosis assessment of bone turnover, cancer with bone metastases, bone tumors)	Osteocalcin	KRYPTOR	50	835.050
		Osteocalcin	RIA	100	57.1
SCC	Follow-up and Monitoring of patients with squamous cell carcinomas of the uterine cervix, lung (NSCLC), head and neck and esophagus	SCC	KRYPTOR	50	812.050
Tg	- Postoperative monitoring of patients with differentiated thyroid carcinoma (papillary, follicular, or oncocytic) - Early detection or exclusion of metastases and tumor recurrence - Postoperative monitoring after thyroidectomy - Determining the effectiveness of subsequent radioiodine therapy	Tg-S	IRMA	100	21.1
		Tg-pluS	IRMA	100	110.1
		Tg-pluS	ILMA	100	111.1
		hTg	KRYPTOR	75	833.075
		hTg sensitive	KRYPTOR	75	832.075

ILMA Immunoluminometric Assay, manual
RIA Radio Immunoassay, manual
IRMA Immunoradiometric Assay, manual

KRYPTOR Immunofluorescent Assay, automated
FAS Functional Assay Sensitivity
AAS Analytical Assay Sensitivity

Measuring Range	Reference Range	FAS	AAS	Time to Result	Sample	Sample Volume
0.23 – 700 ng/mL 0.23 – 500000 ng/mL ¹	<13.11 ng/mL	1.2 ng/mL	0.23 ng/mL	9 min	Serum/plasma without citrate	14 µL
0.3 – 500 U/mL 0.3 – 40000 U/mL ¹	<30 U/mL	<1.0 U/mL	0.3 U/mL	14 min	Serum/plasma without citrate	8 µL
1.2 – 700 U/mL 1.2 – 600000 U/mL ¹	<37 U/mL	7.2 U/mL	1.2 U/mL	14 min	Serum	50 µL
1.0 – 600 U/mL 1.0 – 100000 U/mL ¹	<35 U/mL	7.8 U/mL	1.0 U/mL	29 min	Serum/plasma without citrate	50 µL
0.9 pg/mL up to highest Standard concentration (around 674 pg/mL)	<9.5 pg/mL	n.a.	0.9 pg/mL	19 h	Serum	200 µL
0.2 – 160 ng/mL 0.2 – 100000 ng/mL ¹	<3 ng/mL	1.0 ng/mL	<0.2 ng/mL	39 min	Serum/plasma without citrate	70 µL
11.8 – 3000 ng/mL 11.8 – 1000000 ng/mL ¹	Serum: <101.9 ng/mL EDTA plasma: <76.3 ng/mL	13.7 ng/mL	11.8 ng/mL	29 min	Serum/EDTA plasma	14 µL
0.16 – 35 ng/mL 0.16 – 4000 ng/mL ¹	<3.3 ng/mL	0.4 ng/mL	0.16 ng/mL	19 min	Serum/plasma without citrate	70 µL
0.8 – 1200 ng/mL 0.8 – 500000 ng/mL ¹	Women: 121 ng/mL Men: 274 ng/mL	4.4 ng/mL	0.8 ng/mL	19 min	Serum, heparin plasma	26 µL
2 – 2000 IU/L 2 – 1000000 IU/L ¹	<5 IU/L	6 IU/L	2 IU/L	14 min	Serum	26 µL
0.8 – 200 ng/mL 0.8 – 10000 ng/mL ¹	<12.5 ng/mL	4.4 ng/mL	0.8 ng/mL	59 min	Serum	70 µL
0.04 – 70 ng/mL 0.04 – 100000 ng/mL ¹	<4 ng/mL	0.16 ng/mL	0.04 ng/mL	19 min	Serum/plasma without citrate	50 µL
0.02 – 15 ng/mL 0.02 – 20000 ng/mL ¹	Ratio Free PSA/Total PSA: <19% Prostate cancer >19% BHP	0.12 ng/mL	0.02 ng/mL	29 min	Serum/plasma without citrate	70 µL
5 – 4600 µIU/mL 5 – 1000000 µIU/mL ¹	depends on sex and age	n.a.	5 µIU/mL	19 min	Serum/plasma without citrate	26 µL
0.2 – 270 ng/mL 0.2 – 2700 ng/mL ¹	depends on sex and age	1.9 ng/mL	0.4 ng/mL	14 min	Serum/plasma without citrate	8 µL
0.54 ng/mL up to highest Standard concentration (around 78 ng/mL)	depends on sex and age	1.8 ng/mL	0.54 ng/mL	24 h	Serum, plasma	50 µL
0.1 – 100 µg/L 0.1 – 500 µg/L ¹	<1.9 µg/L	<0.34 µg/L	0.1 µg/L	44 min	Serum	50 µL
0.05 ng/mL ² up to highest Standard concentration (around 500 ng/mL ²)	<1 ng/mL ² : metastasis- and recurrence-free patients 2 – 70 ng/mL ² : healthy subjects	0.3 ng/mL ²	0.05 ng/mL ²	20.5 h	Serum	50 µL
0.08 ng/mL ² up to highest Standard concentration (around 250 ng/mL ²)	<1 ng/mL ² : metastasis- and recurrence-free patients	<0.2 ng/mL ²	0.08 ng/mL ²	23 h	Serum	100 µL
0.02 ng/mL ² up to highest Standard concentration (around 250 ng/mL ²)	<1 ng/mL ² : metastasis- and recurrence-free patients	<0.15 ng/mL ²	0.02 ng/mL ²	23 h	Serum	100 µL
0.17 – 250 ng/mL ² 0.17 – 200000 ng/mL ^{1,2}	0.3 – 58 ng/mL ² (median: 5.5 ng/mL ²): healthy subjects	≤0.5 ng/mL ²	0.17 ng/mL ²	59 min	Serum/plasma without citrate	50 µL
0.09 – 200 ng/mL ³ 0.09 – 200000 ng/mL ^{1,3}	1.6 – 61.3 ng/mL ³ (median: 10.8 ng/mL ³): healthy subjects	0.15 ng/mL ³	0.09 ng/mL ³	59 min	Serum	70 µL

¹ Range with automatic dilution

² Calibrated against International Standard CRM 457 with a factor of 2, i.e. 1 ng/mL is equal to 1.92 ng/mL^{CRM457} (95% CI 1.75-2.09).

³ Calibrated 1:1 against International Standard CRM 457.



Tumor markers on KRYPTOR Systems – excellent precision and reproducibility

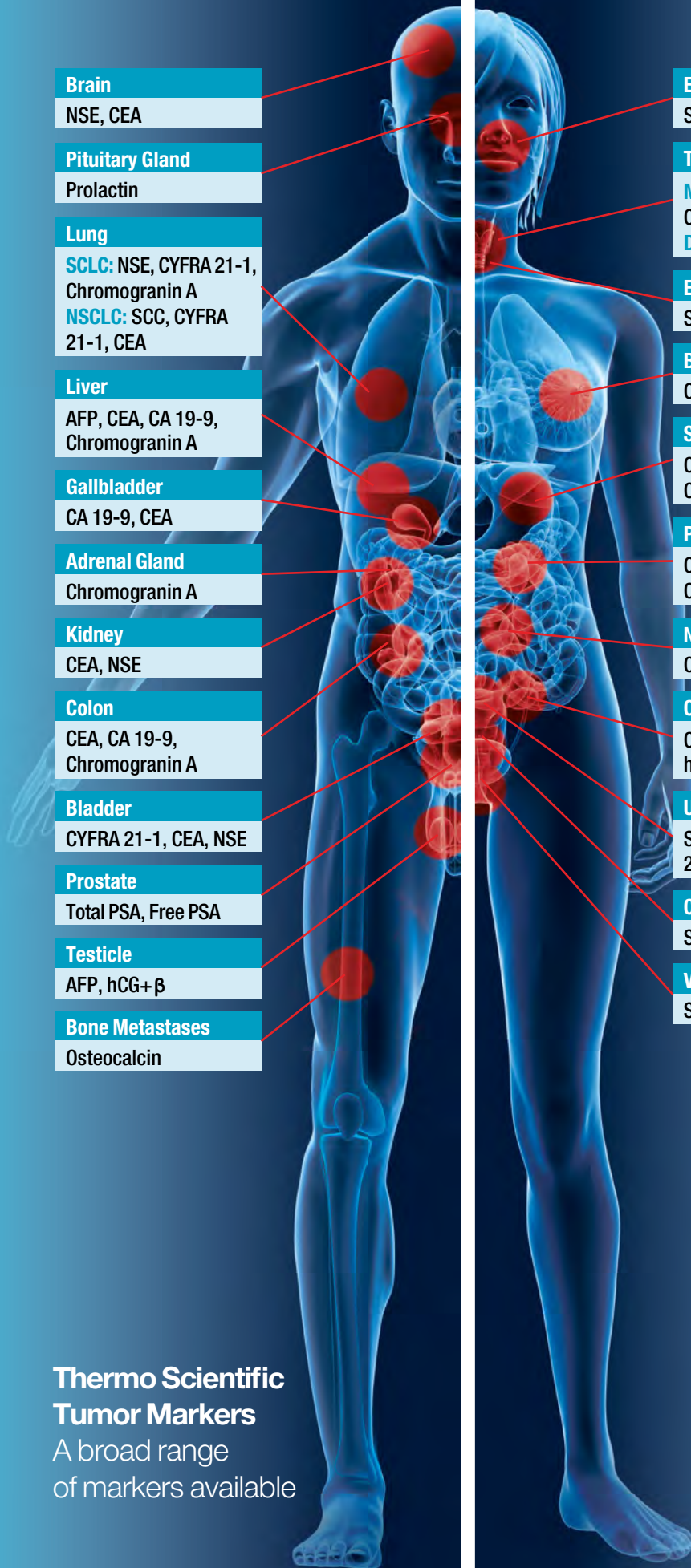
The unique TRACE™ technology utilised by KRYPTOR™ Systems eliminates the need for washing and separation steps, which significantly reduces the imprecision and variability inherent in many other systems.

It is this precise and consistent measurement of analyte concentration which makes tumor markers on KRYPTOR Systems an invaluable tool in the monitoring of cancer disease and in control of therapy.

Brain
NSE, CEA
Pituitary Gland
Prolactin
Lung
SCLC: NSE, CYFRA 21-1, Chromogranin A
NSCLC: SCC, CYFRA 21-1, CEA
Liver
AFP, CEA, CA 19-9, Chromogranin A
Gallbladder
CA 19-9, CEA
Adrenal Gland
Chromogranin A
Kidney
CEA, NSE
Colon
CEA, CA 19-9, Chromogranin A
Bladder
CYFRA 21-1, CEA, NSE
Prostate
Total PSA, Free PSA
Testicle
AFP, hCG+ β
Bone Metastases
Osteocalcin

ENT (Ear, Nose, and Throat)
SCC, CYFRA 21-1, CEA
Thyroid
MTC: Calcitonin, Chromogranin A, CEA
DTC: Thyroglobulin, CEA
Esophagus
SCC, CYFRA 21-1, CEA
Breast
CA 15-3, CEA
Stomach
CEA, CA 19-9, Chromogranin A
Pancreas
CA 19-9, CEA, Chromogranin A
Neuroendocrine Tumors
Chromogranin A, NSE
Ovary
CA 125 II, CEA, AFP, hCG+ β
Uterus
SCC, HCG+ β , CYFRA 21-1
Cervix
SCC, CYFRA 21-1, CEA
Vagina, vulva
SCC

**Thermo Scientific
Tumor Markers**
A broad range
of markers available



Thermo Scientific

B·R·A·H·M·S CgA II KRYPTOR

Article number: 839.050

The first and only fully automated CgA assay worldwide

Chromogranin A is indicated for the follow-up and therapy monitoring of patients with Neuroendocrine Tumors. The immunoassay **Thermo Scientific™ B·R·A·H·M·S™ CgA II KRYPTOR** is the first and only fully automated Chromogranin A assay worldwide. Patients and laboratories benefit from its

- superior assay precision
- shortest time to result: 29 min
- broadest measuring range up to 3000 ng/mL

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Clinical Diagnostics

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