

Oncology

B·R·A·H·M·S CgA II KRYPTOR

First and only fully automated chromogranin A assay worldwide

Thermo Scientific™ B·R·A·H·M·S™ CgA II KRYPTOR™ is an automated immunofluorescent assay using Time-Resolved Amplified Cryptate Emission (TRACE™) technology for quantitative determination of Chromogranin A concentration in human serum

- Broad measuring range and automatic dilution up to 1,000,000 ng/mL
- Excellent precision and lot-to-lot stability
- Short incubation time: 29 min

Clinical Interest

B·R·A·H·M·S CgA II KRYPTOR is to be used in conjunction with other clinical methods as an aid in monitoring of disease progression during the course of disease and treatment in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs, grade 1 and grade 2).



Measure CgA
Now FDA cleared

Easy handling, strong performance

Sample volume	14 µL
Sample type	Serum
Incubation time	29 min
Linear direct measuring range	20...3,000 ng/mL
Upper measuring range with automatic dilution	up to 1,000,000 ng/mL
Limit of Quantitation (LoQ)	20 ng/mL
Kit stability on board (in-use stability)	29 days
Calibrator	1 point
Calibration stability	15 days
Metrological traceability	No international CgA reference preparation available, internal preparation of synthetic CgA used as standard
Reference range limit (95th percentile)	187.0 ng/mL
Analyte stability	48h at room temperature 48h at 2-8°C 3 months at -20°C 4 freeze/thaw cycles

Precision		
CgA concentration [ng/mL]	Repeatability % CV	Within-Laboratory % CV
23.0	5.2 %	10.0 %
26.0	5.1 %	9.9 %
34.6	3.7 %	8.8 %
56.3	2.8 %	8.4 %
86.3	1.7 %	8.3 %
132	1.3 %	7.1 %
228	1.7 %	6.9 %
463	1.1 %	4.4 %
744	1.6 %	2.8 %
1,177	1.1 %	4.0 %
1,825	1.3 %	4.7 %
2,687	1.6 %	7.4 %
CgA concentration [ng/mL]	Between-Site % CV	Reproducibility % CV
25.7	5.8%	9.0%
53.6	0.0%	7.1 %
104	2.8%	4.2 %
515	2.5%	3.8 %
1,089	3.6%	5.8%
1,723	0.0%	5.4 %
2,923	6.1%	7.2%
92,561	3.0%	5.6 %

Method comparison

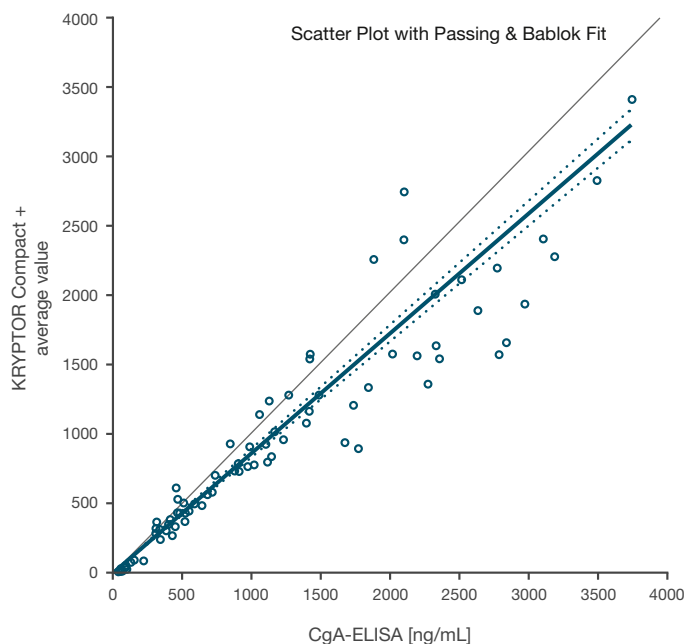


Figure 1: A comparison of the B-R-A-H-M-S CgA II KRYPTOR assay (y) with a commercially available Chromogranin A assay (x) using clinical serum samples gave the following correlation [ng/mL]:

Number of samples measured: 139
 Passing/Bablok: $y = 0.87x - 7.53$
 r (Spearman) = 0.96

The sample concentrations were between 23.4 and 3 728 ng/mL.

Products

B-R-A-H-M-S CgA II KRYPTOR

Kit, reagents for 50 determinations

B-R-A-H-M-S CgA II KRYPTOR CAL

Calibrator kit, 6 vials

B-R-A-H-M-S CgA II KRYPTOR QC

Control kit, 2 levels (3 vials per level)

References:

Comprehensive summary of performance can be found in the Instructions for Use for each assay or in the User Manual of your B-R-A-H-M-S KRYPTOR instrument.

Clinical Diagnostics

Thermo Fisher Scientific
 B-R-A-H-M-S GmbH
 Neuendorfstr. 25
 16761 Hennigsdorf
 Deutschland

+49 (0)3302 883 0
 +49 (0)3302 883 100 Fax
 info.brahms@thermofisher.com
 www.thermoscientific.com/brahms

Learn more at thermofisher.com/chromogranin-a
 or email us at info.brahms@thermofisher.com

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