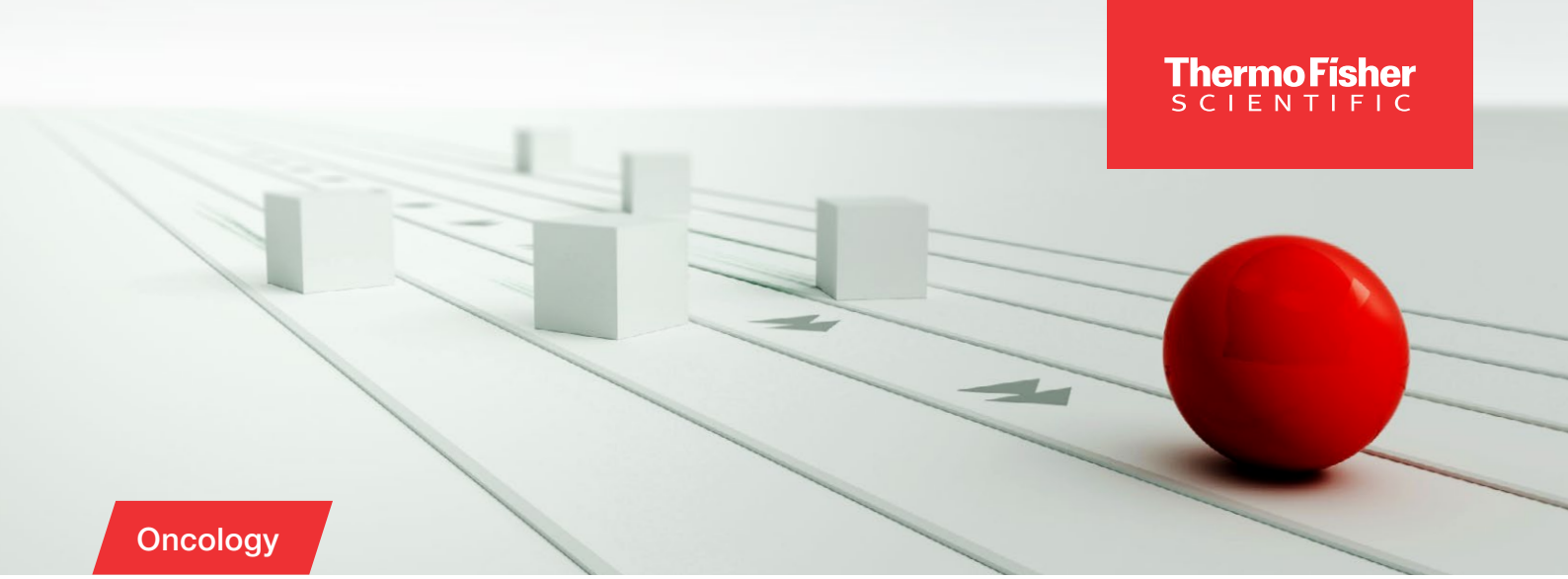

Oncology

B·R·A·H·M·S CgA II KRYPTOR Assay

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 for the determination of the concentration of Chromogranin A (CgA) in human serum or plasma (EDTA)

- 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

- Follow-up and monitoring of patients with neuroendocrine tumors (NETs)
- Identification of progression of NETs
- Together with metanephrines in the diagnosis of pheochromocytomas
- Therapy monitoring of patients with prostate cancer for identification of neuroendocrine differentiation of the tumor

Unique clinical cut-off available

Easy handling, strong performance	
Sample volume	14 µL
Sample type	Serum/EDTA plasma
Incubation time	29 min
Linear direct measuring range	16.6…3,000 ng/mL
Upper measuring range with automatic dilution	up to 1,000,000 ng/mL
Limit of Quantitation (LoQ)	16.6 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)	101.9 ng/mL
Analyte stability	48h at room temperature 48h at 2-8°C 3 months at -20°C* 4 freeze/thaw cycles

* data on file

thermo scientific

Diagnostic Sensitivity and Specificity

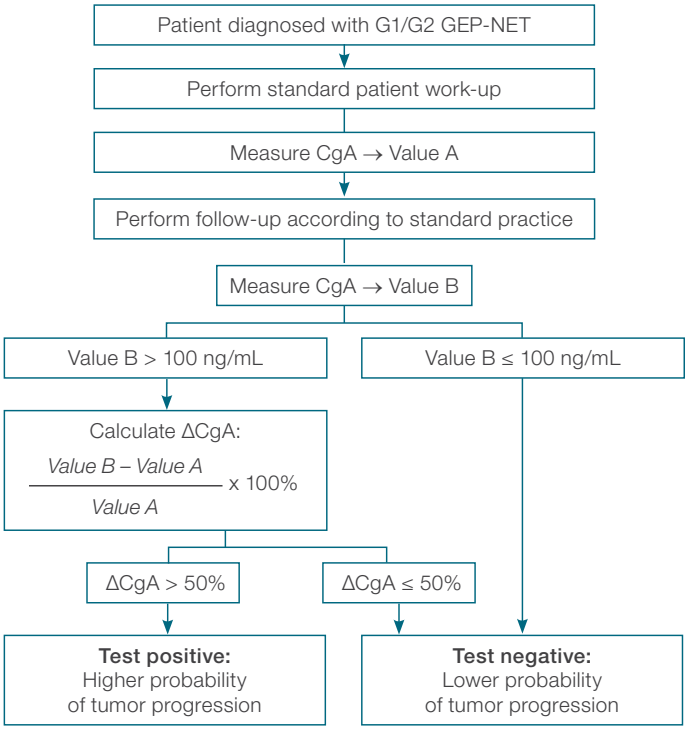

Figure 1: A prospective, multi-center, observational study with 153 evaluable neuroendocrine tumor patients was performed to validate the performance of B·R·A·H·M·S CgA II KRYPTOR assay in monitoring grade 1 and grade 2 GEP-NET progressive or non-progressive disease within 32 months. Course of disease was assessed by standard imaging (CT/MRI scans) and tumors were classified by RECIST 1.1 criteria for progression (progressive disease) vs. no progression (complete response, partial response or stable disease).

Change of CgA was calculated from measurements at consecutive routine monitoring visits within a typical interval of 3-6 months and was considered test-positive if serum CgA concentration increased by more than 50% to an absolute value greater than 100 ng/mL. A positive CgA-change test was shown to be significantly associated with tumor progression ($p < 0.001$) and the following diagnostic performance measures for tumor progression were obtained:

Clinical specificity: = 93.4%; **clinical sensitivity** = 34.4%;
PPV = 57.9%; NPV = 84.3%

Method comparison

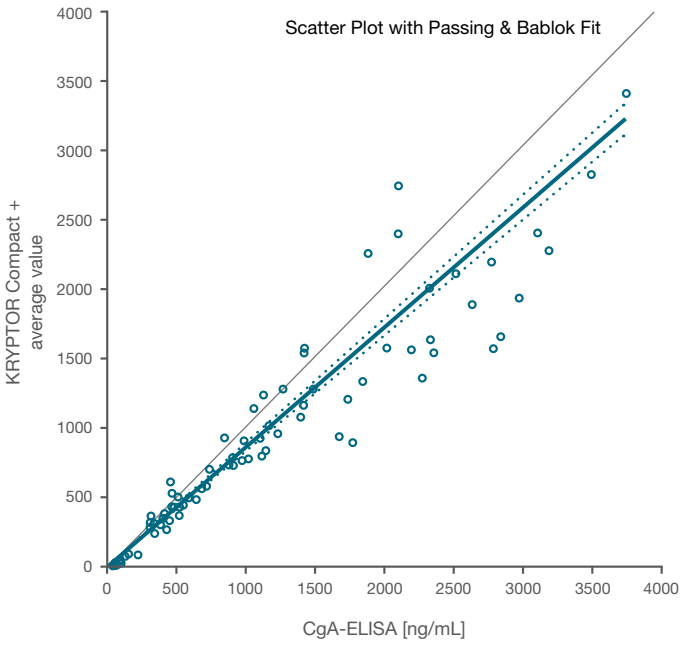

Figure 2: A comparison of the B·R·A·H·M·S CgA II KRYPTOR assay (y) with a commercially available Chromogranin A assay (x) using clinical serum samples gave the following correlation [ng/mL]:

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.

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.

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)

Clinical Diagnostics

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Availability of products in each country depends on local regulatory marketing authorization status.

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