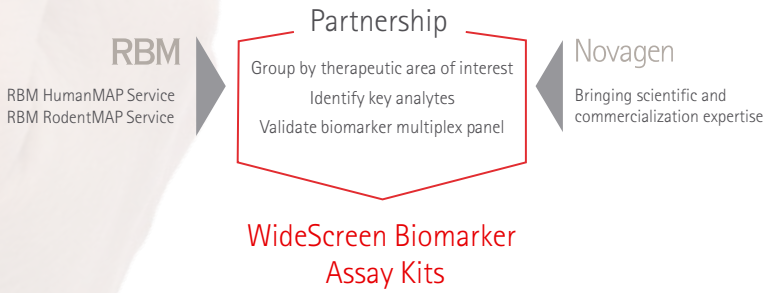
Novagen®

WideScreen™ Biomarker Assay Kits

co-developed with Rules Based Medicine

WideScreen™ Biomarker Assay Kits are the result of an ongoing collaboration between Novagen® and Rules Based Medicine (RBM). A portfolio of products for the Luminex® xMAP® System has been developed containing specific multiplex panel kits that utilize assays validated and used in the HumanMAP® and RodentMAP® service portfolio from RBM. Panels focus on specific therapeutic areas or disease states and allow data generated in discovery and preclinical stages to be correlated to data from later phases of drug development.



WideScreen Biomarker Assay Kits

Key biomarkers for each panel are known to be involved directly or indirectly in a disease process. WideScreen Biomarker Assay Kits are developed for the emerging needs of scientists and address the key biomarker requirements of relevance, validation, and quality.

- Proven **gold standard multiplex assays** used by leading pharma and biotech companies worldwide to provide **valuable insight** into the development of new drugs and proof of concept clinical studies.
- **Extensive validation** in a CLIA-certified laboratory using the CLSI/NCCLS quality standards ensures the ability to generate the **highest quality data** possible to maximize the knowledge gained from precious, often limited, biological samples.

WideScreen Human Cancer Panel 2

A Novagen and RBM partnership

EMD

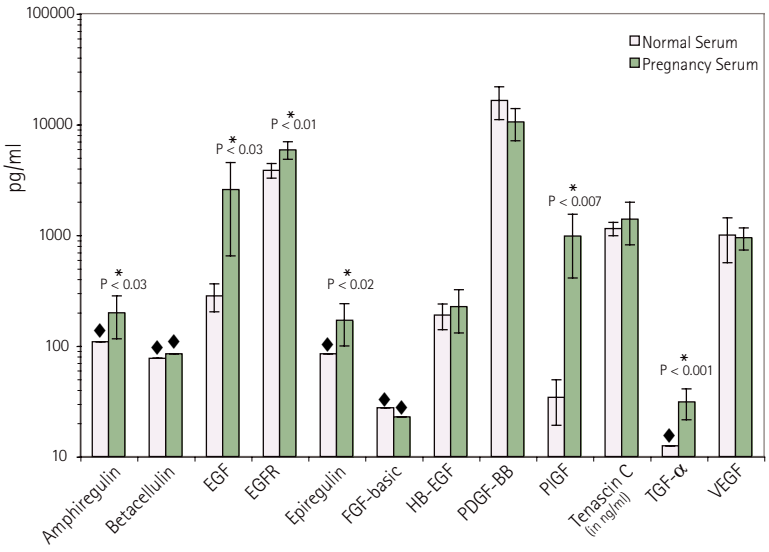
WideScreen™ Human Cancer Panel 2

The WideScreen™ Human Cancer Panel 2 uses the same reagents and technologies developed by Rules Based Medicine (RBM) for use in their industry-leading biomarker testing service along with the expertise of EMD in commercializing and supporting high value products. Accordingly, the kits are supplied with the highest quality and relevant validation data, ensuring that each assay kit meets the stringent quality and performance required in today's demanding research environment.

Growth factors are signaling proteins that promote cell growth, mobility, survival and differentiation. The levels of growth factors in serum or plasma samples can be used as indicators of cellular processes and disease states.

The WideScreen™ Human Cancer Panel 2 (Growth Factors) is a pre-mixed multiplex bead kit of quantitative antibody-based assays for simultaneous detection of twelve human growth factors found in biological fluids: amphiregulin, betacellulin, EGF, EGFR, epiregulin, FGF-basic, HB-EGF, PDGF-BB, PlGF, tenascin C, TGF-α, and VEGF. The kit includes all the reagents, controls, and buffers needed to analyze the above proteins in serum samples, plasma, and tissue culture supernatants using the Luminex® xMAP® System.

Growth Factor Levels in Human Sera



WideScreen Human Cancer Panel 2 was used to measure growth factor levels in randomly selected serum samples from normal (n=5) and pregnant patients (n=4). Values that fall at or below the corrected least detectable dose (LDD) are marked ♦. Significantly elevated levels of several growth factors and shed receptor were observed in the serum samples from pregnant patients.

Growth Factor Secretion by Human Cell Lines and PBMC

Cells were grown to confluence and stimulated as indicated. Supernatants were clarified and diluted prior to testing. Targets that were below the assay level of detection are denoted by (•). Results showing high level biomarker expression are consistent with reports from the literature.

		A-549		MDA-MB-468		HT-1080		PBMC		MCF-7		HUVEC	
Assay		–	+ PMA	–	+ PMA	–	+ PMA	–	+ ConA	–	+ PMA	–	+ PMA
Amphiregulin	(pg/ml)	381	3,100	145	172	•	435	•	583	15,600	169,000	•	•
Betacellulin	(pg/ml)	•	•	•	•	•	•	•	•	•	•	•	•
EGF	(pg/ml)	•	•	9	6	•	•	53	64	•	•	•	•
EGFR	(pg/ml)	22	16	18,500	39,000	•	36	22	31	•	19	•	•
Epiregulin	(pg/ml)	•	54	68	52	•	•	•	22	•	•	•	•
FGF-basic	(pg/ml)	•	•	13	20	•	•	•	•	•	•	•	•
HB-EGF	(pg/ml)	•	•	55	69	150	331	26	104	19	379	42	599
PDGF-BB	(pg/ml)	•	•	195	180	•	•	260	329	2,000	3,030	428	2,170
PlGF	(pg/ml)	11	8	9	11	690	483	•	•	17	44	281	1,190
Tenascin C	(ng/ml)	•	•	214,000	543,000	360,000	752,000	•	•	•	•	•	•
TGF-α	(pg/ml)	•	4	5	5	4	17	•	•	53	236	•	•
VEGF	(pg/ml)	1,810	3,530	35,700	36,800	29,700	33,400	15	41	10,900	41,600	•	26

• = Low

WideScreen™ Human Cancer Panel 2

Performance Characteristics

Species	Human, other species not tested	
Sample Size	6 µl	
Sample Types	Serum, plasma, tissue culture supernatant	
Linearity	Dilution	Range
% recovery across dilutions	1:10	79%-127%
	1:20	69%-122%
	1:40	77%-140%
Intra-assay CV	3%-12%	
Inter-assay CV	4%-21%	
Cross-reactivity	Negligible	
Matrix Interference	Hemoglobin (5 mg/ml)	98% to 195%
Analyte recovery in the presence of:	Bilirubin (0.2 mg/ml)	90% to 143%
	Triglycerides (5 mg/ml)	114% to 229%

Analyte	Standard Range	Assay LDD*	Average Recovery from Serum	Average Recovery from EDTA Plasma
Amphiregulin	2.0-4480 pg/ml	25 pg/ml	76%	90%
Betacellulin	2.4-5270 pg/ml	17 pg/ml	70%	100%
EGF	1.1-2416 pg/ml	5.7 pg/ml	60%	86%
EGFR	1.8-3835 pg/ml	23 pg/ml	52%	78%
Epiregulin	4.1-9017 pg/ml	17 pg/ml	50%	69%
FGF-basic	1.1-2346 pg/ml	5.5 pg/ml	109%	119%
HB-EGF	2.1-4568 pg/ml	3.0 pg/ml	93%	59%
PDGF-BB	6.9-15,000 pg/ml	31 pg/ml	80%	111%
PlGF	0.91-2000 pg/ml	5.1 pg/ml	97%	108%
Tenascin C	3.5-7752 ng/ml	12 ng/ml	99%	70%
TGF-α	0.56-1227 pg/ml	2.5 pg/ml	59%	80%
VEGF	2.2-4760 pg/ml	16 pg/ml	97%	128%

**Least detectable dose.*

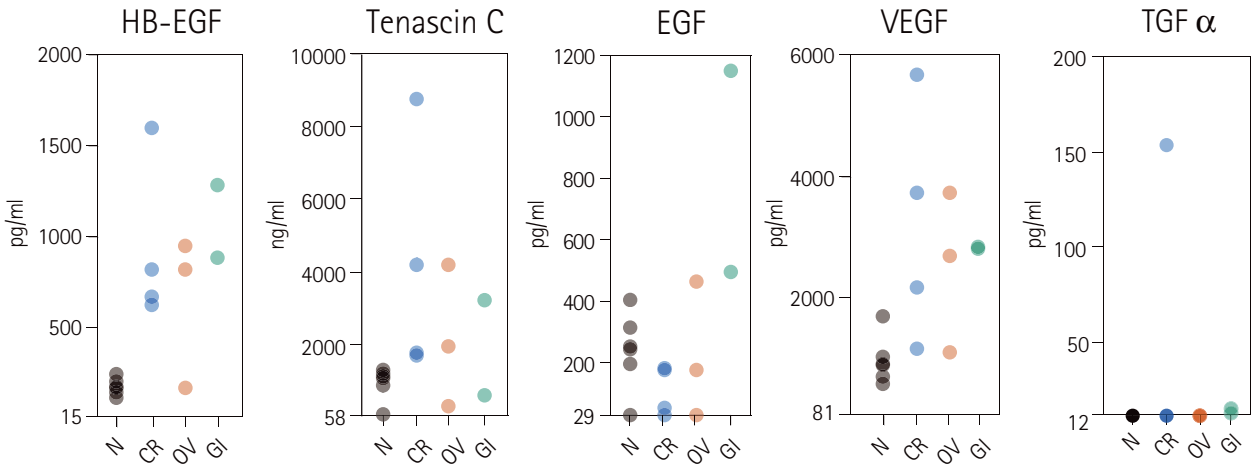
WideScreen™ Human Cancer Panel 2 — 96 tests — Cat. No. 71995-3

Components

- Human Cancer Panel 2:
  - Capture Beads
  - Detection Antibodies
  - Standards Mix
  - Control 1
  - Control 2
- 1X Assay Buffer Type 3
- 1X Sample Dilution Buffer Type 2
- 5X Streptavidin-Phycoerythrin
- Blocking Buffer Type 2
- Standard Curve Diluent Type 2
- 96-well Filter Plate and Sealer

Growth factor levels in normal and disease state serum samples

Select analyte measurements in normal and disease state serum samples: Normal (N, ●, n = 6), Colorectal cancer (CR, ●, n = 4), Ovarian cancer (OV, ●, n = 3), Gastrointestinal cancer (GI, ●, n = 2). Data from two experiments are represented. Data points at or below the corrected least detectable dose (LLD) are plotted on the x-axis. Serum samples from normal individuals had clustered growth factor concentrations, whereas elevated concentrations were found in some disease state patients.



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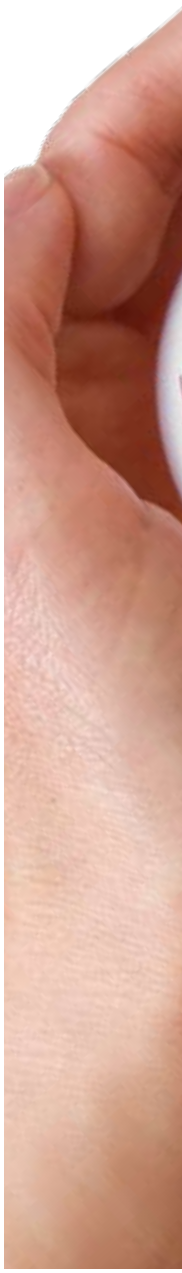
RBM RULES • BASED MEDICINE



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Human Cancer Panel 2

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