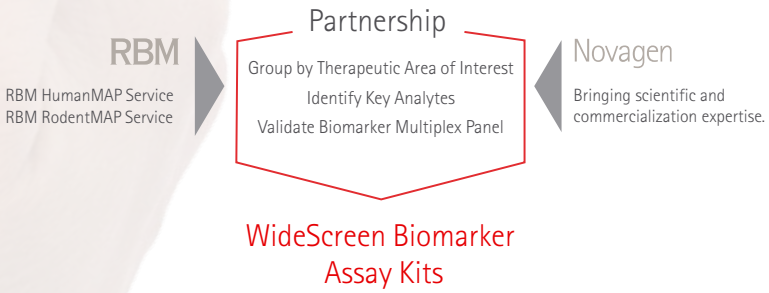
Novagen®

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 laboratory using the 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 1

A Novagen and RBM partnership

EMD

WideScreen™ Human Cancer Panel 1

The WideScreen™ Human Cancer Panel 1 uses the same reagents and technologies developed by Rules Based Medicine (RBM) for the 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.

The WideScreen Human Cancer Panel 1 is a pre-mixed multiplex bead kit of quantitative antibody-based assays for simultaneous detection of six tumor-associated human proteins found in biological fluids: AFP (α-fetoprotein), CA 125, CA 15-3, CA 19-9, CEA (carcinoembryonic antigen), and prolactin. The kit includes all the reagents, controls, and buffers needed to analyze the above proteins in serum, plasma, and tissue culture supernatants using the Luminex® xMAP® System.

WideScreen™ Human Cancer Panel 1

96 tests Cat. No. 71984-3

Components

- Human Cancer Panel 1:
  - Capture Beads
  - Detection Antibodies
  - Standards Mix
  - Control 1
  - Control 2
- 1X Assay Buffer Type 2
- 1X Sample Dilution Buffer Type 1
- 15X Streptavidin-Phycoerythrin
- Blocking Buffer Type 1
- Standard Curve Diluent Type 1
- 96-well Filter Plate and Sealer

Performance Characteristics

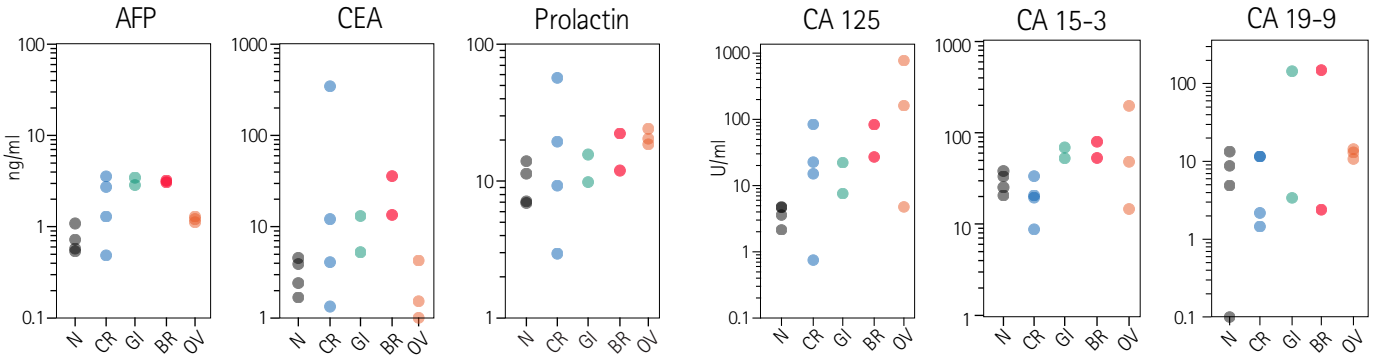
Species	Human, other species not tested.	
Sample Size	6 µl	
Sample Types	Serum, plasma, tissue culture supernatants	
Linearity	Dilution	Range
% recovery across dilutions	1:10	91%-111%
	1:20	92%-103%
	1:40	93%-111%
Intra-assay CV	3%-15%	
Inter-assay CV	7%-24%	
Cross-reactivity	Negligible	
Matrix Interference	Hemoglobin (5 mg/ml)	72% to 100%
Analyte recovery in the presence of:	Bilirubin (0.2 mg/ml)	81% to 92%
	Triglycerides (5 mg/ml)	101% to 126%

Association of Marker with Cancer Type

Marker	Breast	Colorectal	Liver	Lung	Ovarian	Pancreatic
AFP	•		•		•	
CA 125					•	
CA 15-3	•					
CA 19-9		•				•
CEA	•	•		•		
Prolactin	•	•			•	

Analyte	Standard Range	Assay LDD	Average Recovery from Serum	Average Recovery from EDTA Plasma	Normal Range*
AFP	0.15-333 ng/ml	0.15 ng/ml	92%	101%	<20 ng/ml
CA 125	0.55-1200 U/ml	0.30 U/ml	144%	131%	<35 U/ml
CA 15-3	0.18-392 U/ml	0.18 U/ml	96%	108%	<25 U/ml
CA 19-9	0.15-320 U/ml	0.15 U/ml	87%	98%	<37 U/ml
CEA	0.017-37 ng/ml	0.017 ng/ml	76%	84%	<5 ng/ml
Prolactin	0.017-38 ng/ml	0.017 ng/ml	72%	74%	<29 ng/ml**

* Normal range data from American Cancer Society website, www.cancer.org and other sources.
**Pregnant women: 10-209 ng/ml



Tumor marker levels in human sera

The WideScreen Human Cancer Panel 1 multiplex was used to quantify biomarker levels in randomly selected serum samples from normal and disease state patients: Normal (N, ●, n=4); Breast cancer (BR, ●, n=2); Ovarian cancer (OV, ●, n=3); Colorectal cancer (CR, ●, n=4); Gastrointestinal cancer (GI, ●, n=2).

Sera from normal individuals have tumor marker concentrations within the normal range, whereas high concentrations of tumor-associated antigens are found in some disease state patients.

THE POWER INSIDE Luminex® xMAP® TECHNOLOGY Because you want to know more

Visit www.novagen.com/widescreen for the latest information:

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