

For Better Life Through Genomics
G E N O M I N E

Kidney Cancer Diagnostic Kit

Multiplex Human Renal Cell carcinoma Biomarker Test Kit

ELISA kit for Human Renal Cell Carcinoma

A simple antibody-based blood test designed to detect kidney cancer

- ✓ Non-invasive, highly Accurate Diagnostics
- ✓ In vitro Kidney Cancer Diagnostics
- ✓ Luminex MAP-based multiplex Assay and ELISA-based single Assay Kit
- ✓ 7 cancer diagnostic kits under development

Multiplex Human Renal Cell Carcinoma Detection Kit

Description

Multiplex Human Renal Cell Carcinoma Biomarker Panel

Trade Name

GenoPlex MAP

Background Information

GENOMINE Inc. offers the GENOPLEX MAP Human Renal Cell Carcinoma detection kit. The Cancer Biomarker Panel includes Four-Plex assay, which simultaneously measures four serum biomarkers, Nicotinamide N-methyltransferase (NNMT), Secretagogen (SCGN), Non-metastatic cells 1 (NM23) and L-plastin (LCP). The combination of the four serum biomarkers that discriminate between disease-free and Renal Cell Carcinoma patients was characterized and validated by GENOMINE Inc. and Yonsei University Medical School. Using a scoring algorithm, the profile of four biomarkers in circulation was used to detect all stages of Renal Cell Carcinoma patients with high sensitivity and accuracy. The assays can be used to quantify these biomarkers in serum, plasma, and cell/tissue culture supernatant samples. The kit is for research use only.



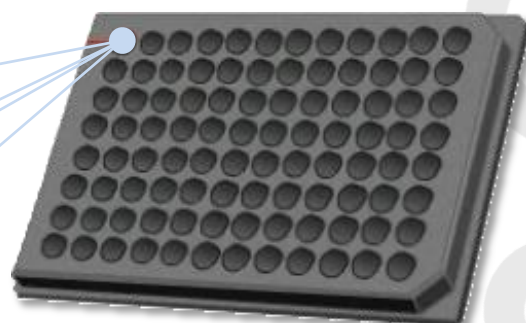
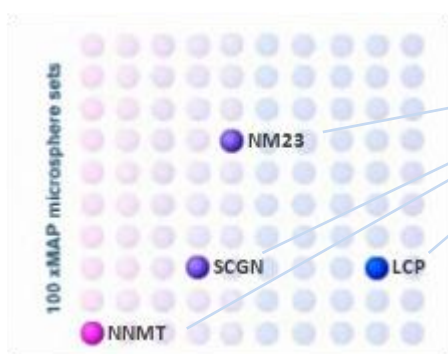
Specification

Species Reactivity	Human	Therapeutic Areas	Oncology
Quality Assurance	Tested against ELISAs	Array Type	Antibody Arrays
Kit or Assay Type	Cancer Kits Multiplex Assays	Cross Reactivity	Non detectable or negligible within the panel
Configuration	Premixed	Detection Methods	Luminex xMAP
Sensitivity	NNMT : 8 pg/mL SCGN : 12 pg/mL NM23 : 21 pg/mL LCP : 21 pg/mL	Accuracy	NNMT : 98.6% SCGN : 97.5% NM23 : 96.8% SCGN : 97.1%
Precision (%)	Intra Assay: <7.4 - 15.3 Inter Assay: <5.1 - 10.4	(pg/ml)	NNMT: 8 - 6,000 SCGN: 12 - 9,000 NM23: 21 - 6,000 LCP: 21 - 15,000

Assay General

Advantages and Benefits

- Detecting of 4 kidney cancer markers in a single well
- Highly sensitive
- Multiplexing reduces costs and time
- Generates more data with less sample



Procedure

Sample and bead incubation buffer

↓ Shaking incubation
Filtering and washing

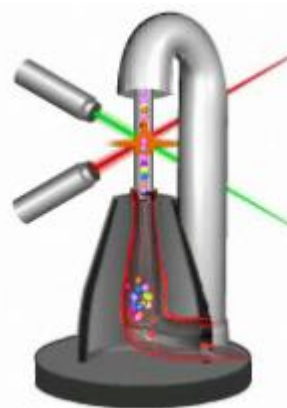
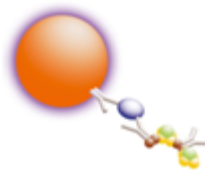
Biotin-labeled detection antibody

↓ Shaking incubation
Filtering and washing

Streptavidin R-PE

↓ Shaking incubation
Filtering and washing

Read in Luminex system



Clinical Test Results

Assay : GenoPlex MAP

(multiplex human renal cell carcinoma(RCC) biomarker test kit)

Multiple marker data analysis : logistic regression & ROC

Healthy : 121 plasma
RCC Patient : 125 plasma

Sensitivity : 94%
Specificity : 92%
AUC : 0.965



Clinical Application & Implication

Application

- Screening test for Non- high risk population
- Screening test for kidney cancer in a high-risk population
- Treatment monitoring for post-surgery patients

High risk population

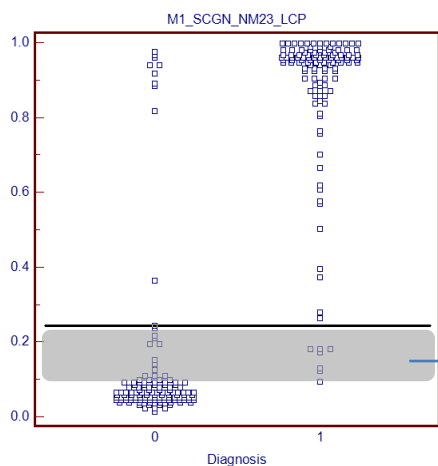
GenoPlex Kidney Cancer Test Kit

If positive (or in Grey Zone)

Ultra sound, CT scan and MRI

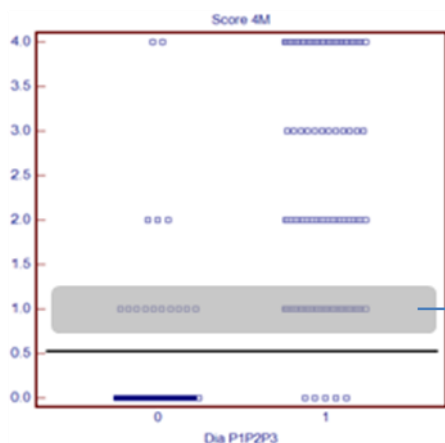
If positive

Invasive Cytopathological Diagnosis



Grey Zone

Test sample application by scoring



score

Healthy : 0 or 1

Kidney cancer patient : 2, 3 or 4

Grey Zone



NNMT Detection kit for human Renal cell carcinoma by ELISA

Description

Test kit for the detection of NNMT

Trade Name

NNMT ELISA kit

Background Information

NNMT (Nicotinamide N-methyltransferase) is a cytoplasmic enzyme which is mainly expressed in the liver where it metabolizes xenobiotics. NNMT has been previously identified as a candidate biomarker for colorectal cancer. Its elevation in tissue and plasma/serum of patient of renal cell carcinoma was also reported. This "NNMT ELISA kit" is an in vitro testing product for quantitative detection of NNMT in human serum/plasma based on the ELISA methods.





Specification

Species Reactivity	Human	Therapeutic Areas	Oncology
Quality Assurance	ELISA	Detection Method	ELISA
Kit or Assay Type	Cancer Kits	Packaging	96 tests
Configuration	Precoated	Detection Methods	ELISA Reader (Visible Light)
Precision (%)	Intra Assay(CV): 4.0% Inter Assay(CV): 7.2%	Key Application	Cancer detection NNMT Assay ELISA

Clinical Test Results

Assay : NNMT ELISA kit (Test kit for the detection of NNMT)

Healthy : 61 plasma
RCC Patient : 62 plasma

Sensitivity : 82.3%
Specificity : 91.8%
AUC : 0.898



Company profile

Business Area:

Cancer diagnostic kits, Biomarkers, Proteome analysis service

GENOMINE is a proteomics company focused on the discovery, development and commercialization of biomarkers and diagnostic kits for early detection of cancers.

GENOMINE is dedicated to the development of in vitro antibody-based assays for a select group of cancers that are difficult to accurately diagnose without resorting to expensive and invasive methods like biopsies, resulting in numerous, unnecessary procedures at a considerable cost to patients and the health care industry.

Through a long term of collaborative research with medical doctors in cancer hospitals, we successfully discovered novel biomarkers for kidney cancer and developed into immunoassay format to meet clinical test standard. It showed a high sensitivity and specificity in a trial of patients with kidney cancer.

GENOMINE currently has 7 cancer diagnostic programs under development designed to assist with the early detection of cancer, thereby reducing suffering, saving lives and cutting healthcare costs.



Company profile

Product pipeline

Product	Discovery	Verification	Assay Development	Clinical Validation	Commercialization
Kidney Cancer					
Ovarian Cancer					
Liver Cancer					
Cervical Cancer					
Lung Cancer					
Breast Cancer					
Pancreatic Cancer					

Patents

- **Diagnostic Composition and Kit For Renal Cell Carcinoma**
KR 10-2008-0076462, PCT/KR2008/004562, UP 12/672.498
- **Method and Kit for Isolating and Fractioning Phosphoproteins**
KR 10-2008-0057308, PCT/KR2008/003515, UP 12/675,758

Publications

- **Panel of Candidate Biomarkers for Renal Cell Carcinoma.**
Journal of proteome research, 2010 May 11;9(7):3710-19
- **Proteomic molecular portrait of interface zone in breast cancer.**
Journal of proteome research, 2010 Sep 21.



Cancer Diagnostic Kit

Potential Collaboration

Genomine intends to seek collaborations with diagnostic companies and clinical research groups.

Clinical research and marketing collaborations in all stages are welcomed. Genomine is also conducting discovery of useful biomarkers of disease, and proteome analysis for customers in exchange for research funding or a future royalty payment.

