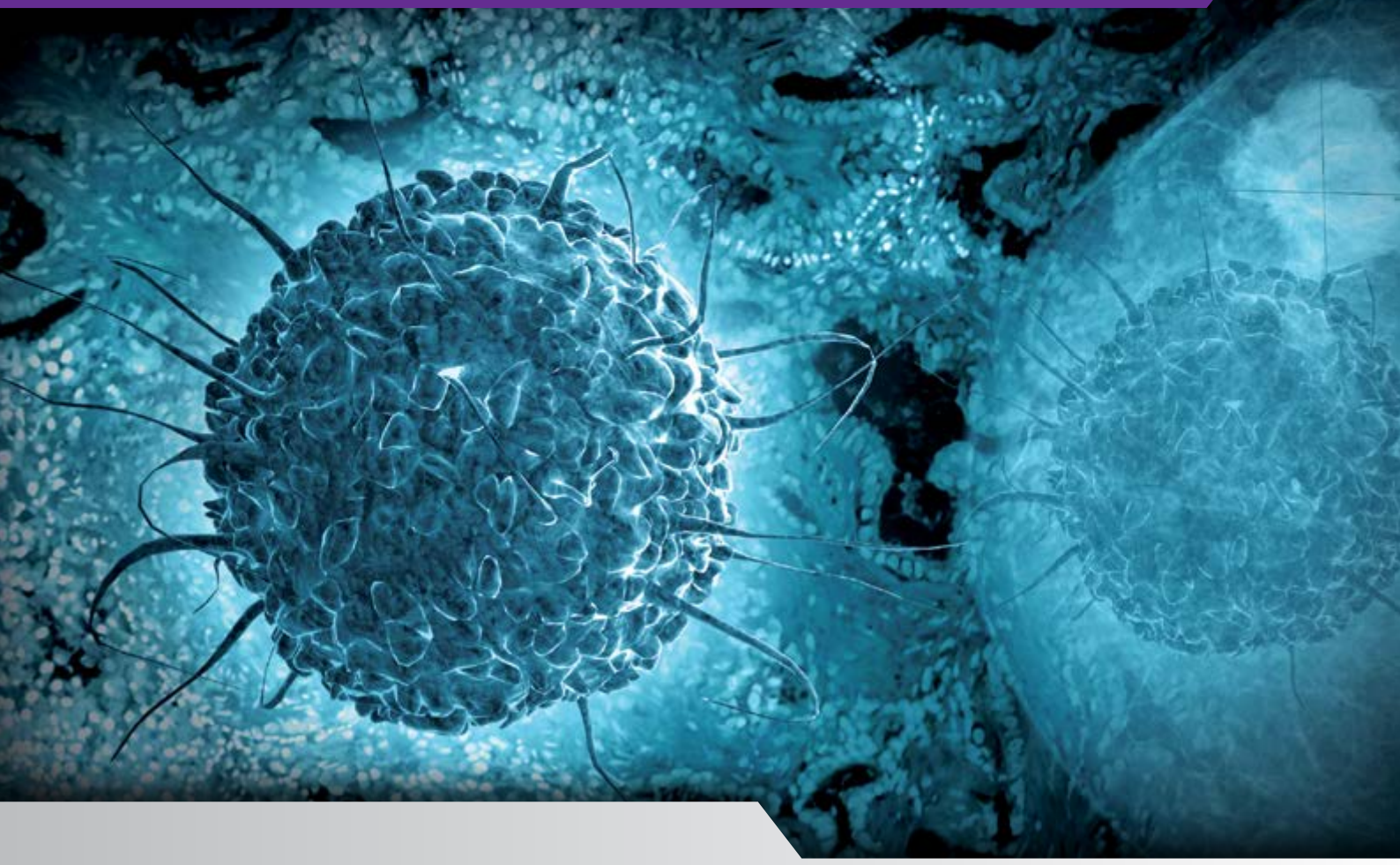
# QUANTITATIVE DETERMINATION OF HUMAN SYNUCLEIN GAMMA

NEW PRODUCT

## *Human Synuclein Gamma ELISA*

- High sensitivity (20 pg/ml)
- Very good analytical characteristics
- Validated for human serum, plasma (EDTA, citrate, heparin) and urine
- Validated for the diagnosis and monitoring of patients with non-muscle-invasive bladder cancer (NMIBC)

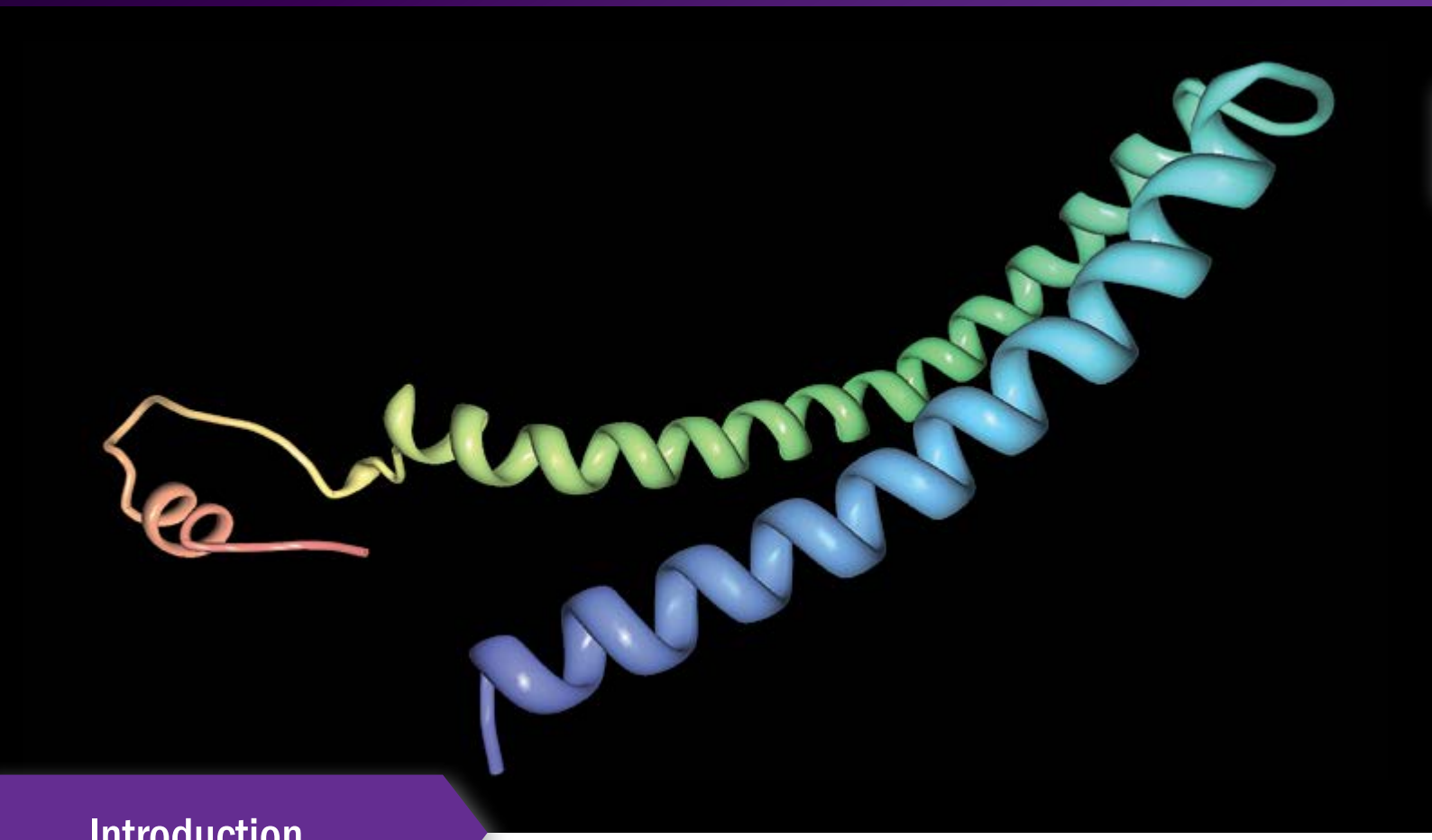


**ONCOLOGY**

**NEURAL TISSUE MARKERS**

BioVendor
Research
and Diagnostic Products

# HUMAN SYNUCLEIN GAMMA ELISA



## Introduction

Synucleins are small, highly conserved, soluble proteins expressed primarily in neural tissue and in certain tumors. The synuclein family consists of three members: α-, β-, and γ-synuclein present only in vertebrates [1].

Synuclein-γ (SNCG) is a human gene localized at 10q23.20-23.3. SNCG cDNA is about 5 kb in length and comprised of five exons that translate into a 17 kDa cytoplasmic protein consisting of 127 amino acids [2].

Synuclein-γ (SNCG) is implicated in many biochemical functions, but its exact role is not completely understood. As this aggregation-prone protein is highly expressed in healthy neuronal cells its involvement in the neurodegenerative diseases has been extensively studied [3]. Some publication suggest that γ-synuclein may change its intracellular localization in response to stress and make appropriate alterations in the gene expression pattern [4]. SNCG can function like chaperone protein and stimulates hormone-responsive mammary tumorigenesis [5]. The abnormal expression and elevated levels of γ-synuclein protein has been demonstrated in many different malignant diseases [6, 7].

Recently, a clinical study showed that the multi-marker test combining cytology and urinary levels of midkine and synuclein-γ can improve the detection of bladder cancer during the primary diagnostics and also during monitoring of patients with non-muscle-invasive bladder cancer [8].

# QUANTITATIVE DETERMINATION OF HUMAN SYNUCLEIN GAMMA

## BioVendor Human Synuclein Gamma ELISA (RD191397200CS)

## Intended use

The RD191397200CS Human Synuclein Gamma ELISA is a sandwich enzyme immunoassay for the quantitative measurement of human synuclein gamma (SNCG).

- It is intended for research use only
- The total assay time is less than 3 hours
- The kit measures human synuclein gamma in serum, plasma (EDTA, citrate, heparin) and urine
- Assay format is 96 wells
- Standard is human native protein
- Components of the kit are provided ready to use, concentrated or lyophilized

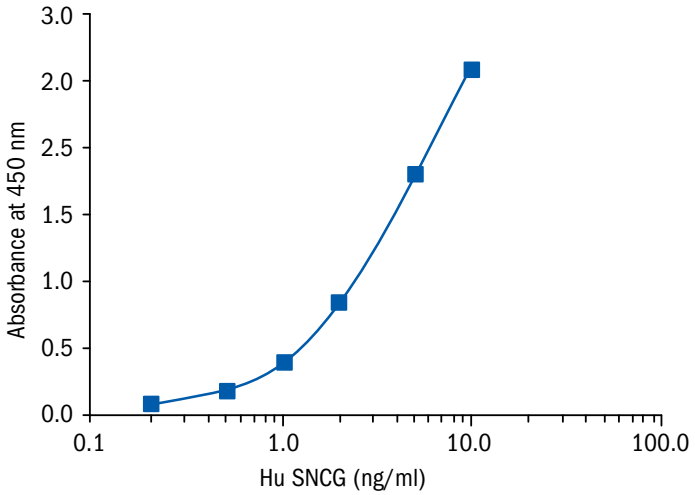
## Clinical application

- Oncology
- Neural tissue markers

## Test principle

In the BioVendor Human Synuclein Gamma ELISA, standards and samples are incubated in microplate wells pre-coated with anti-human SNCG antibody. After 60 minutes incubation and washing, biotin-labelled polyclonal anti-human SNCG antibody is added and incubated with captured SNCG for 60 minutes. After another washing, streptavidin-horseradish peroxidase conjugate is added. After 30 minutes incubation and the last washing step, the remaining conjugate is allowed to react with the substrate solution (TMB). The reaction is stopped by addition of acidic solution and absorbance of the resulting yellow product is measured. The absorbance is proportional to the concentration of SNCG. A standard curve is constructed by plotting absorbance values against concentrations of standards, and concentrations of unknown samples are determined using this standard curve.

| HUMAN SYNUCLEIN GAMMA ELISA<br>CAT. NO.: RD191397200CS | |
|---|---|
| Assay format | Sandwich ELISA, Biotin-labelled antibody, 96 wells/kit |
| Samples | Serum, plasma (EDTA, citrate, heparin) and urine |
| Standards | 0.2 to 10 ng/ml |
| Limit of detection | 20 pg/ml |



## Precision

Intra-assay (Within-Run) (n=8)

| Sample | Mean (ng/ml) | SD (ng/ml) | CV (%) |
|---|---|---|---|
| Serum *) | 1.38 | 0.12 | 8.7 |
| Urine **) | 1.16 | 0.09 | 7.8 |

## Spiking recovery

Serum or urine samples were spiked with different amounts of human SNCG and assayed.

| Sample | Observed (ng/ml) | Expected (ng/ml) | Recovery O/E (%) |
|---|---|---|---|
| Serum *) | 1.38 | - | - |
| | 2.13 | 2.38 | 89.5 |
| | 3.22 | 3.38 | 95.2 |
| | 5.18 | 5.38 | 96.3 |
| Urine **) | 1.16 | - | - |
| | 1.92 | 2.16 | 88.9 |
| | 2.96 | 3.16 | 93.7 |
| | 4.75 | 5.16 | 92.1 |

## Linearity

Serum or urine samples were serially diluted with Dilution Buffer and assayed.

| Sample | Dilution | Observed (ng/ml) | Expected (ng/ml) | Recovery O/E (%) |
|---|---|---|---|---|
| Serum *) | - | 1.44 | - | - |
| | 2x | 0.69 | 0.72 | 95.8 |
| | 4x | 0.33 | 0.36 | 91.7 |
| | 8x | 0.13 | 0.16 | 81.3 |
| Urine **) | - | 1.00 | - | - |
| | 2x | 0.47 | 0.50 | 94.0 |
| | 4x | 0.28 | 0.25 | 112.0 |
| | 8x | 0.14 | 0.12 | 115.2 |

*) Sample from patient with craniotrauma

**) Sample from patient with bladder cancer

## Summary of protocol

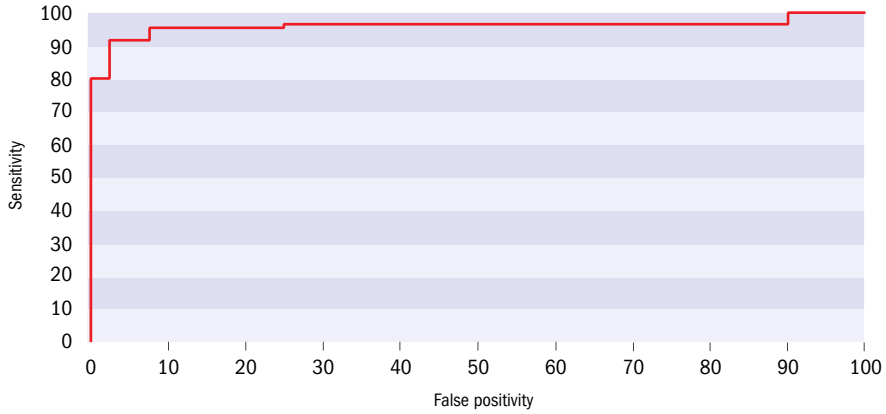
- Reconstitute Master Standard and prepare set of Standards
- Dilute samples (3x)
- Add 100 µl Standards and samples
- Incubate at RT for 1 hour/300 rpm
- Wash plate 3 times
- Add 100 µl Biotin Labelled Antibody
- Incubate at RT for 1 hour/300 rpm
- Wash plate 3 times
- Add 100 µl Streptavidin-HRP Conjugate
- Incubate at RT for 30 min/300 rpm
- Wash plate 5 times
- Add 100 µl Substrate Solution
- Incubate at RT for 10 min
- Add 100 µl stop solution
- Read absorbance and calculate results

# QUANTITATIVE DETERMINATION OF HUMAN SYNUCLEIN GAMMA

## Clinical Relevance

### Diagnosis and monitoring of patients with non-muscle-invasive bladder cancer (NMIBC)

Study group definition: 49 healthy controls, 61 patients with a history of NMIBC without current disease, and 114 patients with bladder cancer.




The results of the study showed that the multi-marker test combining cytology and urinary levels of midkine and synuclein gamma can improve the detection of bladder cancer during the primary diagnostics and also during monitoring of patients with NMIBC with clinical specificity 97.5% and sensitivity 91.8% as shown on ROC curve.

**Source:**

Soukup, V., et al., *Panel of Urinary Diagnostic Markers for Non-Invasive Detection of Primary and Recurrent Urothelial Urinary Bladder Carcinoma*. Urol Int, 2015. 95(1): p. 56-64.

## References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