

For the  
well-being  
of your  
assay.

# Unique Glycovariant Assays for Early Diagnostics of Ovarian Cancer

05/2021



# Ovarian cancer

## Morbidity

One of the most common cancers among women

- 1.2 million women worldwide have ovarian cancer\*
- 239 000 new cases globally per year\*

## Mortality

The 5th most common cause of cancer-induced deaths

- 5-year survival rate 30-50%
- 152 000 deaths globally per year\*

## Diagnosis

Early detection essential for successful medical intervention

## Screening

Currently no screening method in clinical use

- Insufficient specificity and sensitivity of the conventional immunoassays

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# Current approach: CA125\*

## FDA

Approved by FDA for the diagnosis of ovarian cancer

## Non-specific

Increased levels also found in patients suffering from endometriosis, liver disease, and ovarian cysts

## Applications

Mainly used for follow-up and treatment monitoring due to poor specificity

## Weaknesses

Not applicable for screening or early-stage diagnostics of ovarian cancer

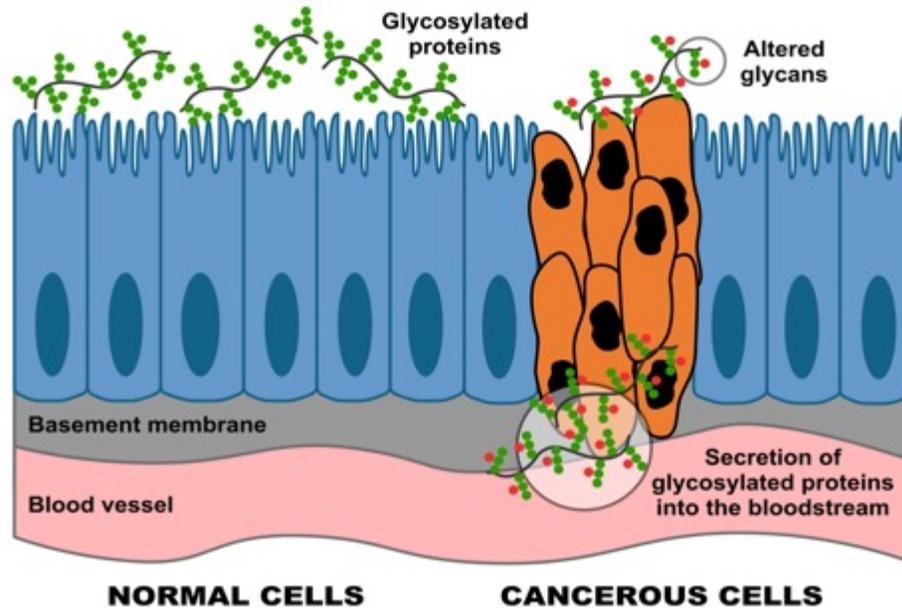
- Not suitable as the only diagnostic measure for ovarian cancer; surgery typically needed

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\*Cancer antigen 125, serum biomarker

# Advantage 1:

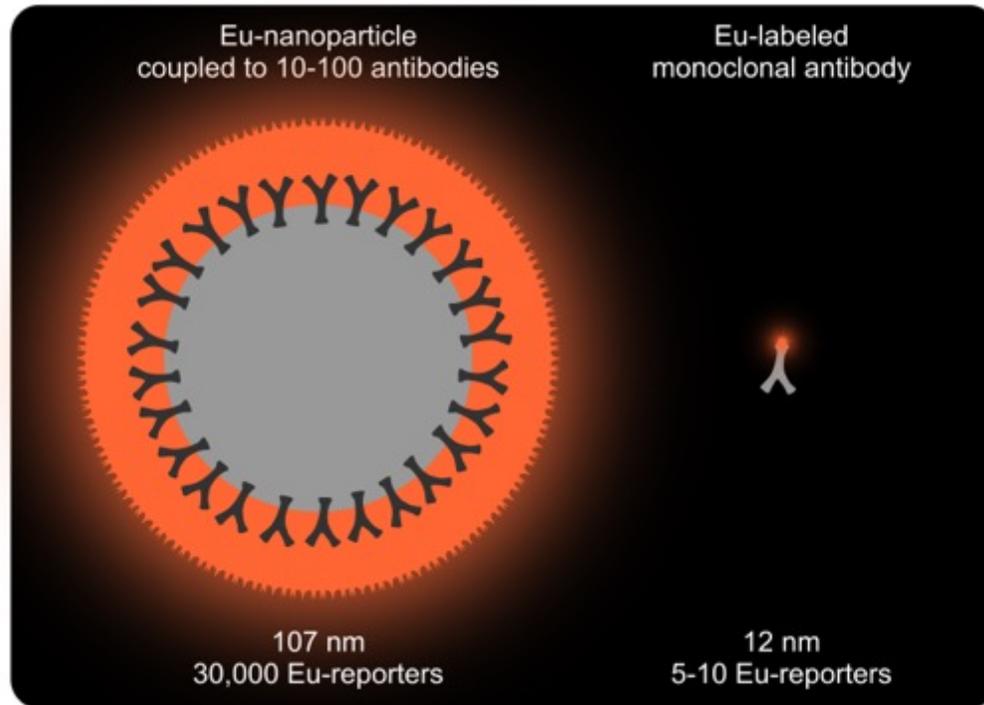
## Lectins increase **specificity**



- Lectins are proteins binding to carbohydrates
  - Exist in plants, animals, bacteria and viruses
  - Exhibit diverse biological functions: regulatory, signaling, immune system, recognition of cells and proteins
  - Specifically recognize altered glycans
- Low affinity and consequent poor sensitivity have previously limited the use of lectins in assays

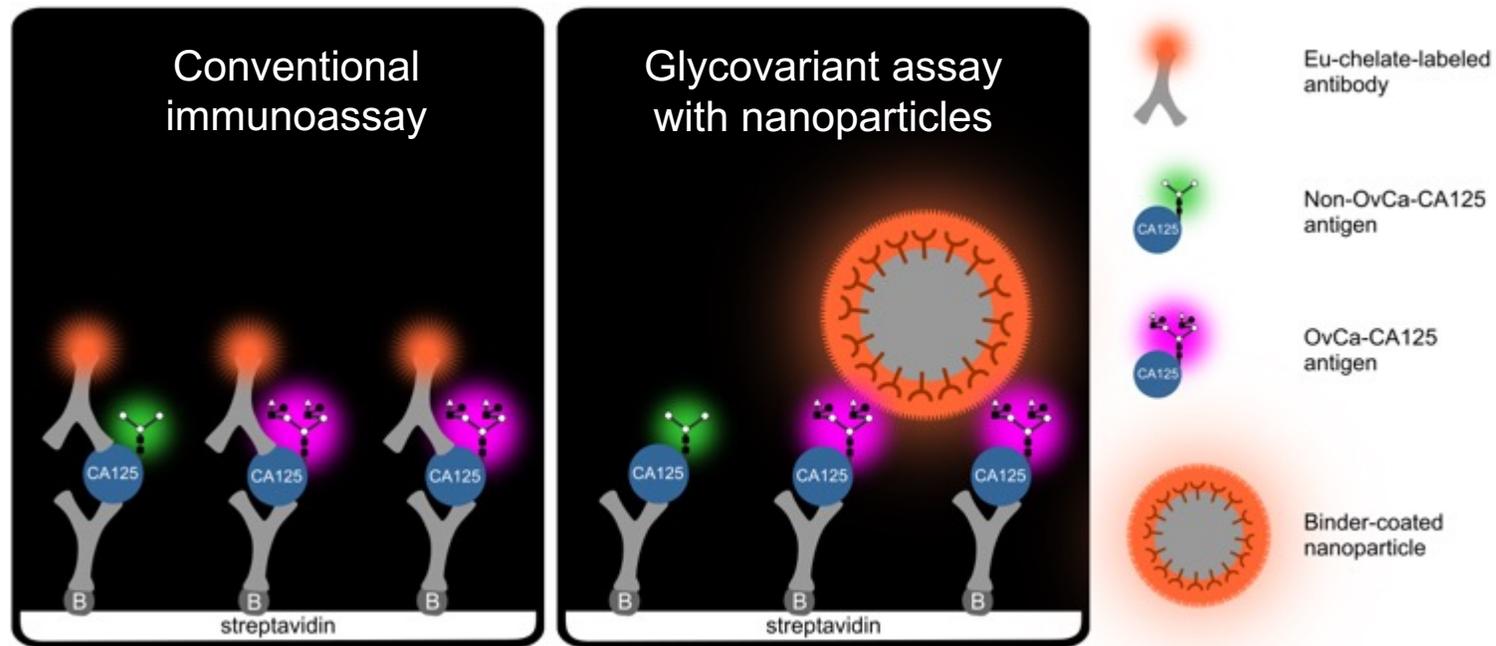
# Advantage 2:

## Nanoparticles increase **sensitivity**



- Specific activity of the label is high as one nanoparticle gives very high signal
- One particle carries high amount of binder molecules
  - Avidity effect improves functional binding affinity
- Up to 275-fold sensitivity compared to standard biomarker assays

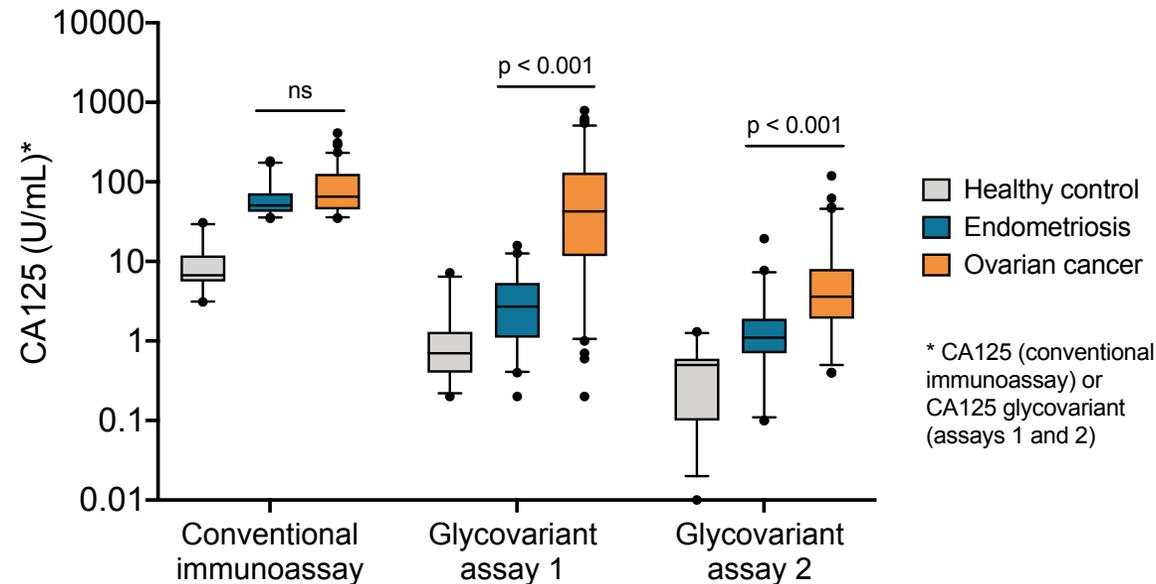
# Combining the **advantages:** Unique glycovariant assays



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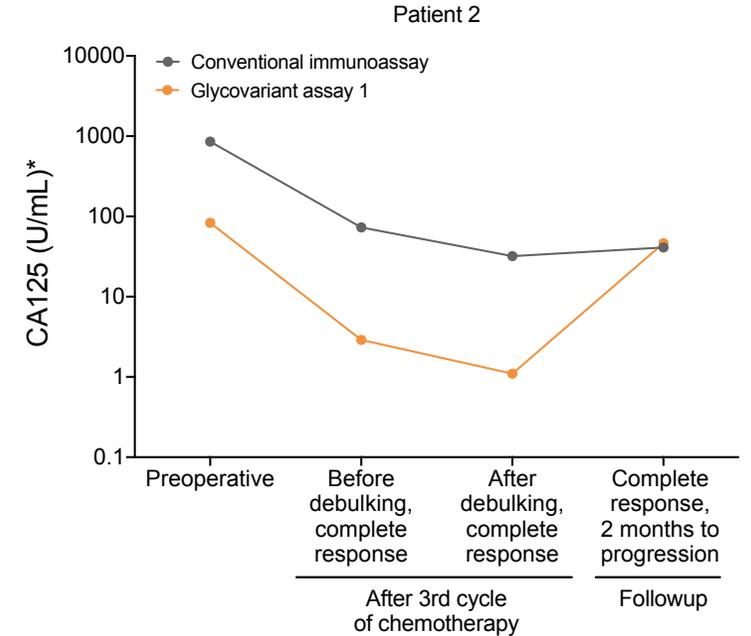
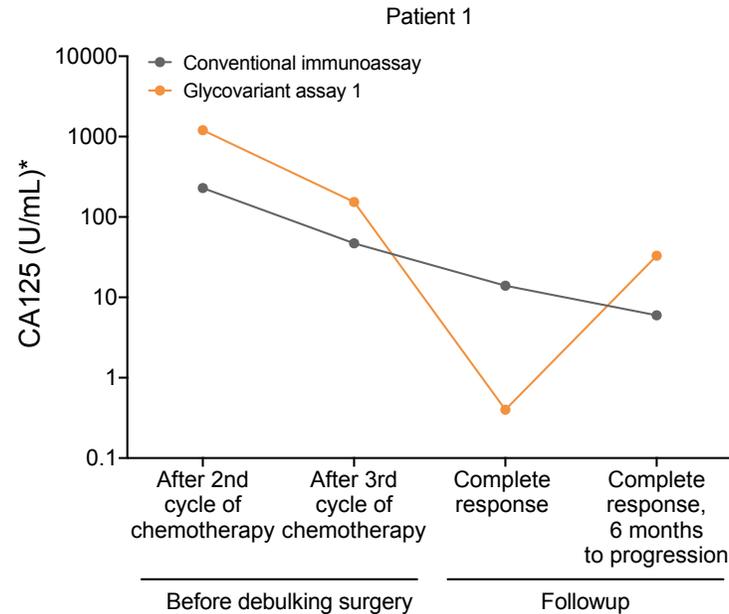
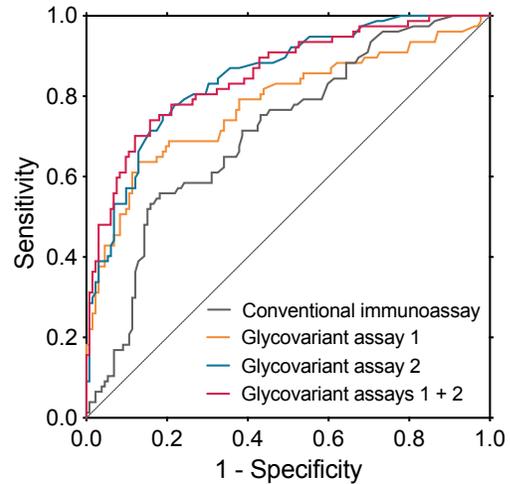
Glycoprotein recognition combined with nanoparticle-based detection → highly sensitive assays with improved specificity for early diagnosis of cancer

# Benefit over competing approaches (1)



- Excellent clinical performance compared to the conventional CA125 immunoassay in serum
  - The glycovariant assays distinguish ovarian cancer from endometriosis significantly better than the conventional assay

# Benefit over competing approaches (2)



\* CA125 (conventional immunoassay) or CA125 glycovariant (assay 1)

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- Better sensitivity and specificity compared to the conventional CA125 immunoassay
- The progression of ovarian cancer can be detected several months earlier

# How Kaivogen brings added value?

## Assays

### New assay development

- Monitoring the recurrence of cancer or response to cancer therapy in parallel with conventional CA125 immunoassay
- Detection of recurrence possibly months earlier

## Monitoring

### Screening studies for high-risk patients

- Selected patients screened (BRCA-positive, family history or other hereditary factors)
- Clinical suspicion (adnexal mass, symptoms)

## Reagents

### Reagents for a service laboratory

- Assays compatible with AutoDelfia system
- Availability of clinical data needed for CE marking
- Faster commercialization of CE-marked kit

## Screening

### Ovarian cancer screening

- Collaboration projects to develop assays for ovarian cancer screening

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# Benefits of collaborating with Kaivogen

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## IPR

Protected by two patents

- Lectin-based diagnostics of cancer (WO2018011474A1)
- Diagnostics of gynecological diseases, especially epithelial ovarian cancer (WO2017005974A1)

## Sales

Sales of research use only (RUO) reagents will begin in Q3/2021 at latest

- Estimated annual turn-over 100 000 – 300 000 €

## Goals

To reach 1% market share within 3 years after CE marking (est. 2022\*)

- Monitoring of patients with ovarian cancer
- Estimated annual turn-over 3,5 M€

## Future

Breakthrough year 2028\*

- Monitoring of patients with ovarian cancer and screening / diagnosing ovarian cancer
- Estimated annual turn-over 60 M€ (9% of current US market estimate)

\*Forward-looking statement

# Summary

- Kaivogen has acquired exclusive rights to **unique glycovariant assays for cancer diagnostics** from the University of Turku.
- The assay technology is based on **nanoparticles** coated with great number of binders, lectins or antibodies. This approach provides improved assay sensitivity.
- Due to the number of binders on an individual nanoparticle, the affinity of the coated particle is much higher compared to individual binders. This results in a **substantial increase in both sensitivity and specificity**.
- The first promising application is the **early detection** of ovarian cancer but eventual extension to **population screening** provides significant sales potential.
- Promising preliminary results for the **detection of other cancer types** have been obtained.

## Contact information



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