Cutting-edge ovarian cancer detection with novel GLYVAR™ Ovarian assays – superior performance over conventional CA125

DIAGNOSIS OF OVARIAN CANCER

Ovarian Cancer is a Common Malignancy

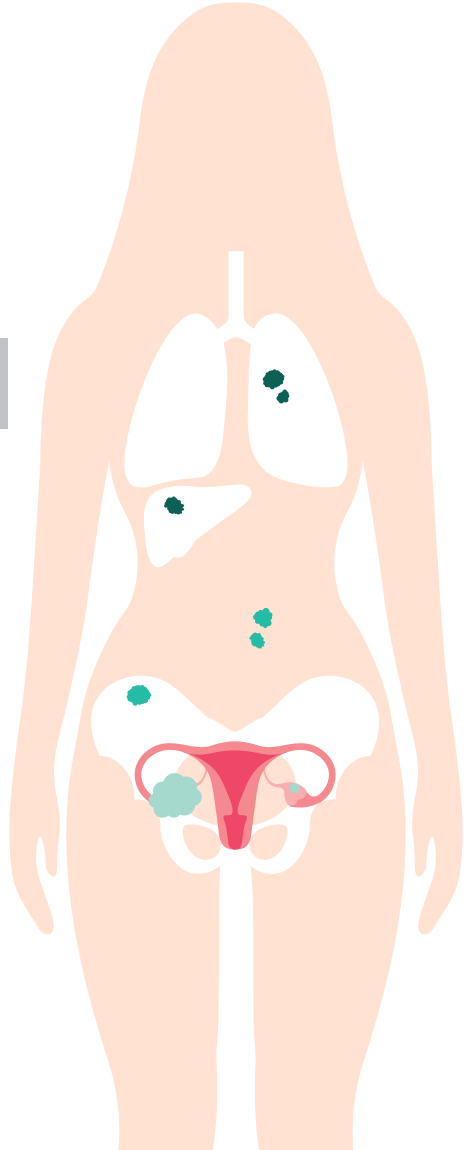
>320 000 New cases Diagnosed Annually	**>200 000** Deaths in 2022	5-year Survival Rate **50.9%**

WHO's GLOBOCAN 2022 estimates that ovarian cancer **incidence will rise 55.2% to >500 000 new cases by 2050**

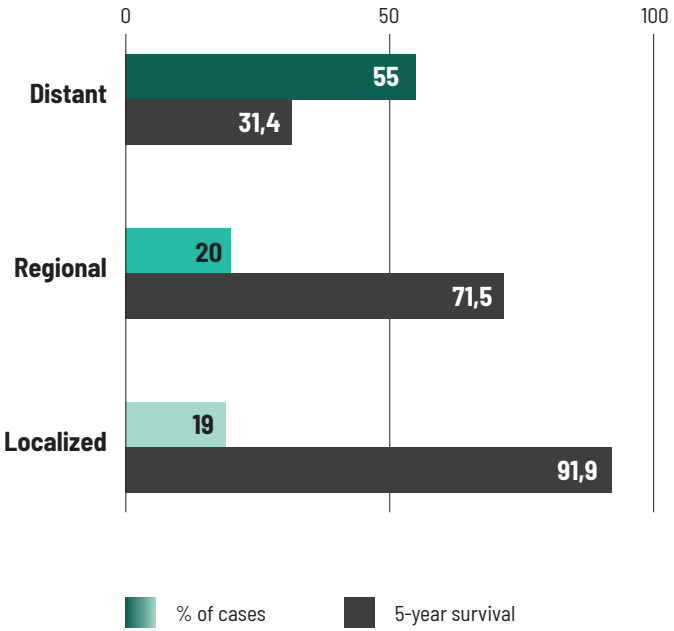
Current ovarian cancer diagnosis

Initial	Confirmation
Ultrasound + **CA125 blood test** Not specific enough for diagnosis	Imaging (CT scan/MRI) + Laparoscopy/ Laparotomy

CA125 test, is not sensitive or accurate enough, making clinicians dependent on invasive procedures. The only de initive way to determine if a patient has ovarian cancer is through laparoscopy.



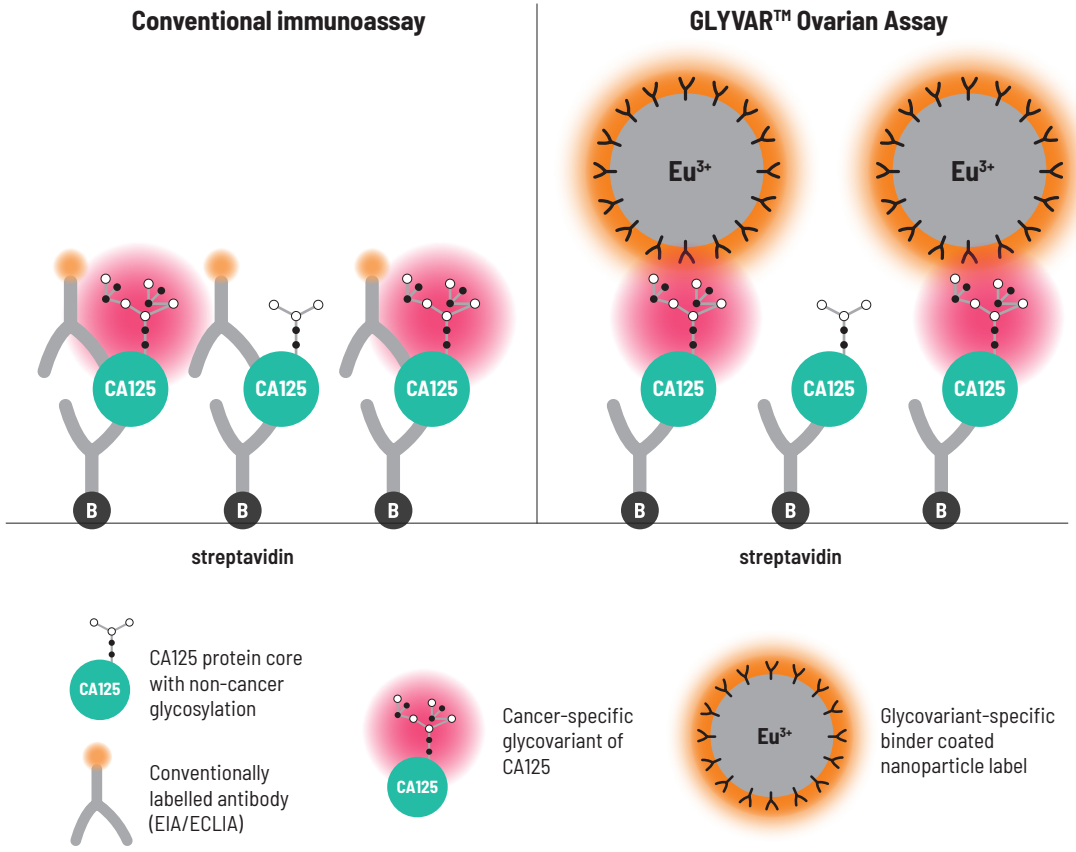
Percent of cases and 5-year survival by stage at diagnosis



Data Source: NIH, SEER 22 (Excluding IL/MA) 2014–2020, All Races, Females by SEER Combined Summary Stage

GLYVAR™ OVARIAN – ASSAY PRINCIPLE

- GLYVAR™ Ovarian I and II tests detect cancer specific glycan structures on the surface of a known protein marker CA125.
- Nanoparticle based, quantitative non-competitive immunoassay performed in 96-well plate.
- Enables very sensitive and cancer-specific assays.
- Signal measurement with time-resolved fluorometer.
- Now available as Research Use Only (RUO).



GLYVAR™ Ovarian I and II have a different binder coated on the nanoparticles and they detect separate glycovariants on the surface of CA125 protein core.

BENEFITS OF UNIOGEN GLYCOVARIANT ASSAYS

Comparison to conventional CA125-assay	GLYVAR Ovarian Test
~75 % more early stage ovarian cancer patients diagnosed[1]	✓
Three times more ovarian cancer patients correctly diagnosed when CA125 is borderline or marginally elevated[2]	✓

- Improved specificity due to detection of cancer specific glycan structures
- Superior sensitivity through particle- based labels
- Initial clinical validity confirmed
- Strong IP protection

[1] Sensitivity at 95% specificity.
[2] Patients with CA125 concentration (30-300 U/ml), which is a challenging group for differential diagnosis between benign and malignant ovarian tumors.

IP & COLLABORATION

Early-stage studies strongly indicate that the glycosylation-based approach improves the detection of several other cancers. In addition to the ovarian cancer, Uniogen holds intellectual property for colorectal, bladder, pancreatic, breast and prostate cancer assays (lung cancer assay IP in preparation).

At Uniogen we are open for discussions about different forms of collaboration.

REFERENCES

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3. Salminen et al., 2020 Gyn Onc, A longitudinal analysis of CA125 glycoforms in the monitoring and follow up of high grade serous ovarian cancer.
4. Bayoumy et al., 2020 Commun Biol, Glycovariant-based lateral flow immunoassay to detect ovarian cancer-associated serum CA125.
5. Gidwani et al., 2020 Mol Aspects Med, Nanoparticle-aided glycovariant assays to bridge biomarker performance and ctDNA results.
6. Jain et al., 2022 Int J Cancer, Diagnostic potential of nanoparticle aided assays for MUC16 and MUC1 glycovariants in ovarian cancer.