OncoOVARIAN Dx

Non-invasive blood test useful to suggest a possible diagnosis in patients with suspected malignancy in the ovarians, reduce inappropriate diagnostic tests, days of hospitalization, as well as morbidity.
OVARIAN CANCER STATISTICS

Global
Ovarian Cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. A woman’s risk of getting Ovarian Cancer during her lifetime is about 1 in 75. Her lifetime chance of dying from Ovarian Cancer is about 1 in 100. (These statistics don’t count low malignant potential ovarian tumors.)

This cancer mainly develops in older women. About half of the women who are diagnosed with Ovarian Cancer are 63 years or older. It is more common in white women than African-American women.

The rate at which women are diagnosed with Ovarian Cancer has been slowly falling over the past 20 years.

Number of New Cases and Deaths per 100,000
The number of new cases of Ovarian Cancer was 11.7 per 100,000 women per year. The number of deaths was 7.4 per 100,000 women per year. These rates are age-adjusted and based on 2010-2014 cases and deaths.

Percent Surviving 5 Years
Based on data from SEER 18 2007-2013, only the 46.5% of patients being diagnosed with Ovarian Cancer will survive 5 years or more. Gray figures represent those who have died from Ovarian Cancer. Green figures represent those who have survived 5 years or more.

![46.5% Survival](image)

Lifetime Risk of Developing Cancer
Approximately 1.3 percent of women will be diagnosed with Ovarian Cancer at some point during their lifetime, based on 2012-2014 data.

Prevalence of this Cancer
In 2014, there were an estimated 222,060 women living with Ovarian cancer in the United States.
**RISK FACTORS**

- Age
- Obesity
- Reproductive history
- Birth control and fertility drugs
- Gynecologic surgery
- Androgens
- Estrogen and hormone therapy
- Family history of Ovarian Cancer, Breast Cancer, or Colorectal Cancer
- PTEN tumor hamartoma syndrome
- Hereditary nonpolyposis Colonrectal Cancer

**SYMPTOMS & SIGNS**

- Bloating
- Pelvic or abdominal pain
- Trouble eating or feeling full quickly
- Urinary symptoms such as urgency (always feeling like you have to go) or frequency (having to go often)
- Fatigue
- Upset stomach
- Back pain
- Pain during sex
- Constipation
- Menstrual changes
- Abdominal swelling with weight loss
STATE OF THE ART IN OVARIAN CANCER DIAGNOSIS

Currently, there is no effective method of early detection of Ovarian Cancer. It is usually diagnosed in advanced stages and only half of women survive more than five years.

Most women with Ovarian Cancer have symptoms. However, these symptoms are often vague and can be attributed to less serious conditions such as indigestion, weight gain or the consequences of aging, which makes it really difficult diagnosis.

In this sense, when pathology is suspected, a physical examination is performed and then is followed — if palpation enlarged ovary or fluid in the abdomen (ascites)—, by different diagnostic procedures —such as Ultrasound (US), Computed Tomography (CT), Positron Emission Tomography (PET) or Magnetic Resonance Imaging (MRI)—.
OncoOVARIAN is based on a simple blood test that can detect Ovarian Cancer with 93.5% of sensibility and 94.3% of specificity.

OncoOVARIAN reduces —in a very significant way—, the number of false positives (FP) and false negatives (FN) typical of other diagnosis procedures.

OncoOVARIAN can reduce the number of unnecessary tissue biopsies that patients have to undergo when suspicious finding.

OncoOVARIAN has been performed with data from 4,520 consecutive patients, then fine-tuned by other research.
WHY CHOOSE BIOPROGNOS’ TEST?

- **Innovative**
  Based on the combined count of a panel consisting of 6 Serum Tumor Markers (AFP, β-hCG, CA 19.9, CA 125, CEA and HE4).

- **Non-invasive**
  First test based on a simple blood test.

- **Accurate**
  Very high diagnostic capabilities: 93.5% Sensitivity and 94.3% Specificity.

- **Cost-effective**
  Solution to help in Ovarian Cancer diagnosis as well as confirmatory diagnostic —as an adjunct to suspicious image procedures findings, in order to reduce the number of unnecessary tissue biopsies that women have to undergo—.

- **More complete**
  If Cancer, it also determines Epithelial Tumors, Germ Cell Tumors or Stromal Tumors of Sexual Cords.

- **Already validated**

FOR WHOM IS IT INTENDED?

- **High-risk patients** (women older than 40 years with Ovarian or Breast Cancer family history).

- **Women with previous image findings suspicious of Ovarian Cancer** that should be biopsied to verify malignancy.
USES AND PURPOSES

- Aid in diagnostic assessments for high-risk patients.
- Confirm or discard malignancy from results obtained previously with other tests —such as Ultrasound (US) or Computed Tomography (CT) Scan—, to avoid invasive, costly and unnecessary biopsies —as well as days of hospitalization—, to low-risk patients.
- Therapy monitoring (how the cancer is responding to treatment) and predict or monitor for recurrence (detecting a recurrence sooner than other methods).

INTERPRETATION OF RESULTS

Once the blood is analyzed and the Tumor Marker values are calculated, a final report with the probability of finding Ovarian Cancer is generated.

This report includes all patient information previously collected, results, comments —if available—, as well as conclusions. It also includes a comprehensive 3 level color score bar to facilitate test interpretation in an easy way, which can result in Negative, Low Positive and High Positive as follows:

![Score Bar]

The meaning of these segments of the score bar is:

- **High:** There is a high risk of Ovarian Cancer.
- **Moderate:** There is a certain chance of Ovarian Cancer that does not allow to exclude malignancy, so it is recommended to repeat the test in 4 weeks to obtain a serial determination and determine the final risk. Of every three individuals with “Moderate” result, 1 will present Ovarian Cancer.
- **Low:** There is a low risk of Ovarian Cancer and it is recommended to repeat the test in one year due to low risk of malignancy.
Improving clinical outcomes and quality of life