www.campusbiomedicohospital.com/prosigna

INFORMATION AND RESERVATIONS

Monday to Friday, hours 8:00 - 19:00

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Academic Medical Center Hospital Accreditation
Quality and Safety for our Patients

LABORATORY OF MOLECULAR DIAGNOSTICS

ANATOMIC PATHOLOGY DEPARTMENT

Email: molecolab.anatomiapatologica@unicampus.it

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PROSIGNA™ TEST

Undergo Chemotherapy Only When Necessary

POLICLINICO UNIVERSITARIO CAMPUS BIO-MEDICO
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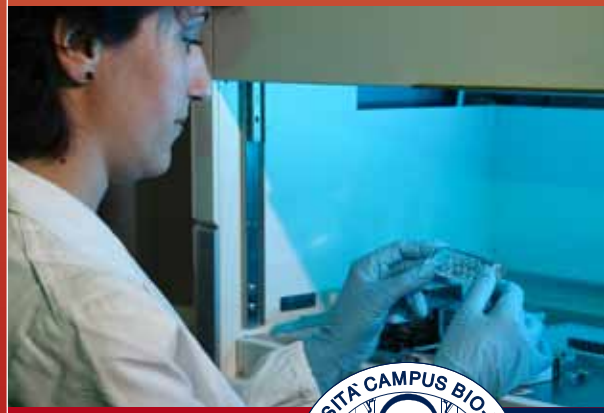

UNIVERSITÀ CAMPUS BIO-MEDICO DI ROMA

POLICLINICO UNIVERSITARIO

PROSIGNA™ TEST

Undergo Chemotherapy Only When Necessary

WHY CHOOSE PROSIGNA™ TEST

Following surgery for the removal of breast cancer, the oncologist evaluates the opportunity to submit the patient for chemotherapy. This assessment is normally done on the basis of clinical/pathological factors (lymph node status, tumor size and grade, patient's age, etc.) and immunohistochemical factors (markers of cell proliferation, expression of hormone receptors, *etc.*).

The **Prosigna™** kit provides prognostic indicators and additional information for the oncologist and is useful to identify cases in which chemotherapy can be avoided. Prosigna™ is the only test performed on the national level, which therefore precludes sending samples abroad. It makes use of the analysis of gene expression to identify patients with tumors with low probability of recurrence within 10 years after surgery. In this way, it provides additional information to the clinical/pathological and immunohistochemical factors useful to the physician to identify patients who may avoid chemotherapy following surgery and provide personalized treatment options. The study NEMESI (BMC Cancer, 2012), conducted by Italian researchers, has shown that chemotherapy, along with its side effects, could be avoided in 25% of cases.

Who is the Prosigna™ Test Designed For?

The Prosigna™ Test is intended for all women who have been operated on for breast cancer (quadrantectomy / mastectomy) with the following characteristics:

- Diagnosed in postmenopausal phase
- Invasive breast cancer (lobular histology, ductal or mixed)
- Hormone receptor positive
- Locoregional lymph nodes; negative or positive (1 to 3)

HOW IT WORKS

Prosigna™ is a genetic test (CE / IVD - FDA) that relies on the analysis system NanoString nCounter® DX to evaluate the expression profile of a group of 50 genes implicated in the progression of breast cancer. Prosigna™ is the only test that can simultaneously classify genetic breast cancers and assess simultaneously the category of risk of tumor recurrence at 10 years for women undergoing breast cancer surgery. The risk of relapse is expressed as a numerical score from 0 to 100, in order to define three risk categories (low, intermediate and high).
The genetic classification of the tumor allows for more accurate guidance on choosing the best individual treatment for each patient and providing an indication of the prognosis.

THOSE TO UNDERGO THE TEST

Scientific Referrals - The Prosigna™ Test is conducted in the Laboratory of the Anatomic Pathology Department at the Campus Bio-Medico University Hospital, directed by Dr. Anna Crescenzi. Referring physician for the service is Dr. Giuseppe Perrone. More information on the Department are available on:
www.campusbiomedicohospital.com/prosigna.

Booking the Test - To undergo Prosigna™ testing, a prescription is required from an oncologist. Because the test cannot be performed as part of the National Health Service, one only needs a prescription from a physician on official letterhead ("red" prescriptions not necessary).

Delivery of Material/Results and Execution of the Test - On the date of the test, you must present yourself at the main service desk of the Campus Bio-Medico University Hospital (Via Álvaro del Portillo, 200 - Rome - Trigoria, Floor -1, 1 ATM; a reservation number is not necessary) with the following material:

1) Histological Sample In the event that the surgical removal of the tumor occurred at the Campus Bio-Medico University Hospital, the histological sample is already deposited in our laboratory. Otherwise, the patient will have to get a hold of the histological specimen prior to the day of the test by submitting to their respective hospital the following request:

Block of paraffin-embedded tissue of infiltrated carcinoma (the material received will be returned after the execution of the examination). Alternatively, organize the inclusion of at least 6 tumor histological sections from 10 microns thick, each on a standard covered glass slide (non-polarized and without sealant) used for collecting sterile distilled water in disposable containers (e.g. petri dish). Prepare sections from the paraffin embedded tissue of infiltrating carcinoma and primitive, in which the neoplasm is prevalent, compared to healthy tissue. Provide a section of the corresponding hematoxylin and eosin;

2) A certified copy of the histological report on the material sent;

3) A prescription for Prosigna™ testing (prescription should be on official letterhead, signed by the physician and include corresponding telephone numbers)

Reporting Time - Results are available within 15 working days from the fixed day of the test.

Costs - Prosigna™ is a prognostic test with European certification and offers no reimbursement by the National Health Service. The cost of the test for the patient is 3.000 Euros.