

# TM-B2

## A New Diagnostic Test for Breast Cancer

### What Is TM-B2 Blood Test?

TM-B2 is a blood test for breast cancer diagnosis. The test is based on Total Biochemical Infrared Analysis (TBIA) of the immune cells and the plasma using infrared spectroscopy and unique algorithm.

### How Does TM-B2 Relate to Breast Cancer?

The immune system (PBMCs), as well as plasma, are known to be affected by the presence of a tumor at all stages. T cells (and specifically regulatory T cell) as well as B cells, natural killers and platelets, are all participating in identifying or protecting tumor cells at different stages of its development. TM-B2 assay ‘observes’ characteristic biochemical changes in these blood cells and compose a ‘picture’ of cancer patients’ population vs benign and healthy. Plasma, together with PBMCs from the same blood sample, gives additional important relevant information about tumor presence.

### How Does The TM-B2 Assay Work & What Is Unique In TM-B2 Blood Test?

While most of the biomarkers assays lean on a single or multiple markers which are known to be directly related to the tumor, TM-B2 ‘observes’ the biochemical composition (e.g. proteins, lipids, nucleic-acids, carbohydrates) of the biological sample and learns patterns in the ‘biochemical picture’ of pre-cancer or cancer patients. Furthermore, the unique approach and utility of infrared spectroscopy allows using a single blood test to gain analysis of two different cancer related blood components – the PBMCs and the plasma.

### How Do You Use TM-B2 Blood Test?

Todos Medical Ltd, will provide a complete TM-B2 testing kit to a designated laboratory. The laboratory will then provide the kit to the physician at the location the actual blood screening is conducted. The lab then takes the blood sample and separates its components and the PBMCs and plasma are dried and analyzed by infrared spectrometer. The spectra of the blood components are then analyzed by TodoSpectra – a unique algorithm which is based on multiple clinical trials. The results are sent to the lab and the physician for clinical evaluation.

### TM-B2 Intended Use.

TM-B2 test is a biochemical test of peripheral blood mononuclear cells and plasma using infrared spectroscopy and computer analysis. It is indicated for women who meet the following criteria: Female subjects, aged 25 years and older, without a diagnosis of inflammatory or autoimmune disease and who were diagnosed as presenting with BI-RADS score of 3 or 4 (or equivalent). TM-B2 is to be used to further assess if a malignancy is present or not. TM-B2 test results should be used in conjunction with other common diagnostic tests as part of breast cancer screening and should not be used as stand-alone assay.

### What Is the Clinical Evidence for TM-B2 Test?

During the development of our technology TBIA, multiple clinical studies were conducted including hundreds of patients. The results of these studies were published in a distinct clinical peer reviewed journals such as BMC cancer <sup>1</sup> and Journal of Gastroenterology <sup>2</sup>. We are about to publish our latest results of the TM-B2 studies conducted in Israel and Singapore.

### Interpreting TM-B2 Results.

TM-B2 assay can supply complimentary information about patients how completed mammography and had ambiguous results or BI-RADS score of 3 or 4. The results of TM-B2 are for positive or negative for breast cancer with about 90% accuracy. Following your consideration of the entire clinical information, including TM-B2, you can conclude what procedure to do next – short term follow-up or breast biopsy or even additional tests for breast cancer.

### How Does It Improve Clinical Screening Results?

The common clinical practice today includes several steps for breast cancer screening including screening mammography starting from the age of 40 or 50, diagnostic mammography and ultrasound, and finally, biopsy. The results of BI-RADS 3 and 4 are ambiguous and needs additional evaluation. Furthermore, about 80% of the breast biopsy are negative – which is 80% false positive of mammography and/or ultrasound. TM-B2 is indicated to add the missing information and reduce the number of women that go through unnecessary breast biopsy. TM-B2 will save lives and reduce costs.

### Other Products Using TBIA Technology?

There are two additional tests. One is TM-B1 which is intended for breast cancer screening and the other is TM-C1 which is intended specifically for colorectal cancer screening.

### Where Do I Get More Information About The TM-B2 Test?

You are invited to contact Todos Medical by Email: [Info@todosmedical.com](mailto:Info@todosmedical.com), or visit our web site [www.Todosmedical.com](http://www.Todosmedical.com)



### Reference

1. Zelig, Udi, et al. "Early detection of breast cancer using total biochemical analysis of peripheral blood components: a preliminary study." BMC cancer 15.1 (2015): 408.
2. Barlev, Eyal, et al. "A novel method for screening colorectal cancer by infrared spectroscopy of peripheral blood mononuclear cells and plasma." Journal of gastroenterology 51.3 (2016): 214-221.