



**DIAGNOSE AND TREAT WITH ANTIBODIES  
THAT RECOGNIZE NATIVE HUMAN PROTEIN  
EPITOPES IN BLOOD AND TISSUE**



# EXECUTIVE SUMMARY

Oncologists reviewing blood and tissue test results face the same problems: Is the test result accurate and reliable, or is it a false negative or false positive? Will the test accurately monitor therapeutic efficacy?

Every patient diagnosed with and treated for cancer faces the same concerns: Are there any non-invasive tests to diagnose cancer and monitor cancer progression? Will the cancer return?

An ideal solution for these problems meets these requirements:

- **Accurate detection- avoid false negatives and false positives**
- **Enable testing on both blood and tissue for accurate diagnosis**
- **Testing is non- or minimally- invasive**

ADxRx has a platform technology that produces diagnostic products that are purpose-built to meet these exacting requirements.

# IS THE TEST RESULT ACCURATE?

All the clinical laboratories performing blood and tissue tests rely on biologicals such as antibodies that are commercially available, FDA-approved, or registered and officially recommended by healthcare organizations. The majority of the commercially available antibodies developed do not represent the actual conformation, native epitopes of the biomarker proteins as they are present in human body.

This problem affects blood and tissue cancer diagnosis, and in order to avoid false negative and false positive test results, clinical laboratories need antibodies that:

- **Recognize native epitopes of proteins**
- **Recognize the protein in both blood and tissue samples to truly diagnose the disease**

Most of the detection antibodies do not meet the above criteria and produce false negative and positive test results.

# ARE THERE NON-INVASIVE TESTS?

Every patient that has been diagnosed and treated for cancer faces the same problem: Are there any non-invasive tests to diagnose the disease? Will the disease come back?

Most of the diagnostic tests are not only invasive and expensive but also some cause exposure to radiation.

Naturally, we prefer non-invasive diagnostic tests, such as biomarkers detection (tumor markers) or blood tests (liquid biopsy). One example of a minimally invasive companion diagnostic is screening for HER2 levels in blood to assess the effectiveness of trastuzumab (Herceptin) therapy in treating HER2-positive breast cancer.

Due to the limited number of available blood tests and most importantly the issue of false negatives and false positives diagnostic test results, we have one choice which is invasive diagnostic tests.

# THERE IS AN URGENT NEED FOR BLOOD TESTS TO MONITOR THERAPY AND RECURRENCE

Some antibodies perform in tissues, and some antibodies perform in blood samples.

For example, after the tumor is surgically removed, tissue samples are sent to a pathology laboratory for tissue staining (IHC) in order to diagnose the disease and guide therapy.

Optimally, there would be a blood test that would monitor therapeutic efficacy, as well as, disease state. Blood tests (liquid biopsies) are done using antibodies, and they are non-invasive, less stressful and more cost-effective compared to invasive diagnostic tools.

The problem is the absence of antibodies that perform both in tissues and blood samples. The advantage of this type of antibody is that the patient is monitored with the very same antibody before and after the surgery to monitor the disease status.

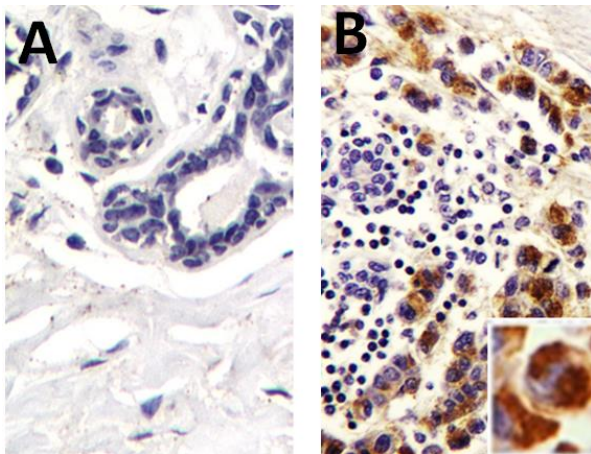
# What an **IDEAL SOLUTION** LOOKS LIKE

- **Perform in both blood and tissue to truly diagnose the disease**
- **Improve accuracy to avoid false negatives and false positives**
- **Available as a non-invasive diagnostic test**
- **Antibody recognizes natural conformation, and native epitopes of proteins**
- **Guide therapeutic selection**
- **Monitor the therapy (companion diagnostics)**

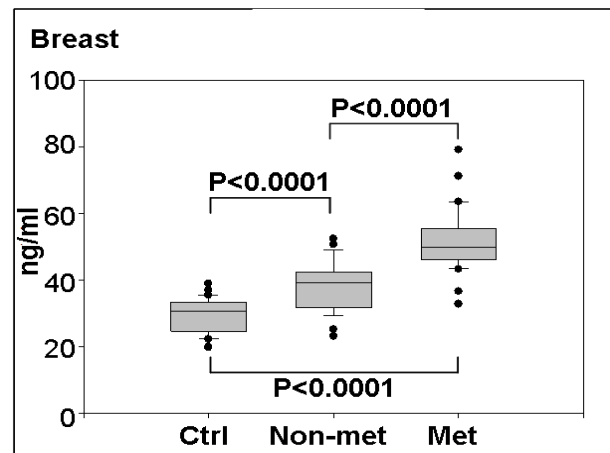


# AN IDEAL SOLUTION LOOKS LIKE

As an example, a monoclonal antibody developed for soluble and circulating form of FilaminA by Dr. Alper and is patented by Thermo Fisher Scientific, is an example for an ideal antibody that performs both in tissue and blood samples.



**Filamin-A** expression is increased in patients with metastatic breast cancer (**B**) compared to the adjacent normal breast (**A**) from the same patient using Alper-p280 anti-FilaminA monoclonal antibody (209 No.13). Tissue samples are from NCI/NIH.



Box plot analysis representing levels of the 280kd form of **Filamin-A** in plasma detected by the Alper-p280 anti-FilaminA monoclonal antibody (209 No.13) and measured by ELISA in plasma from healthy individuals, patients with either non-metastatic or metastatic breast cancer. Plasma samples are from Harvard.

# WHAT IS ADXR?

ADxRx is committed to making a difference in patients' lives through the development of cancer diagnostic tests, companion diagnostic and monitoring tests, and anti-cancer antibody therapies.

## Company Initiatives are:

- **Collaborate with drug development and diagnostic companies on the development of effective diagnostic tools using unique biomarkers and monoclonal antibodies**
- **Current internal collaboration initiative with Thermo Fisher Scientific for diagnosis of metastatic breast cancer**
- **Early Diagnosis of pancreatic cancer initiative (biomarker panel)**

Dr. Özge Alper, Ph.D. is the Founder of ADxRx. She is a world-class scientist and experienced entrepreneur and sole inventor of twelve patents with more than ten pending patent applications. Dr. Alper has developed 18 novel antibodies against cancer tissues. Her work was the first to identify the soluble, circulating form of HER protein and received an International award. Dr. Alper's work was also first to show the soluble, circulating form of FilaminA.

## Dr. Alper's patents:

MONOCLONAL ANTIBODIES AGAINST PCBP-1 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST HER2 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST HER2 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST HER2 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST PCBP-1 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST PCBP-1 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST GMF-B ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST GMF-B ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST ALPHA-ACTININ-4 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST PCBP-1 ANTIGENS, AND USES THEREFOR  
MONOCLONAL ANTIBODIES AGAINST SEROTRANSFERRIN ANTIGENS, AND USES THEREFOR  
METHODS AND COMPOSITION FOR DAIGNOSING NEOPLASTIC DISEASE

U.S. Patent No.: 8,703,441 Issued 04-22-2014  
U.S. Patent No.: 8,349,585 Issued 01-08-2013  
U.S. Patent No.: 8,753,829 Issued 06-17-2014  
U.S. Patent No.: 8,722,362 Issued 05-13-2014  
U.S. Patent No.: 8,540,991 Issued 09-24-2013  
U.S. Patent No.: 8,609,096 Issued 12-17-2013  
U.S. Patent No.: 8,519,104 Issued 08-27-2013  
U.S. Patent No.: 9,040,043 Issued 05-26-2015  
U.S. Patent No.: 9,040,018 Issued 05-26-2015  
U.S. Patent No.: 9,448,239 Issued 09-20-2016  
U.S. Patent No.: 9,663,567 Issued 05-30-2017  
U.S. 20080293162A1 Issued 03-23-2006

Dr. Alper's publications are available at [pubmed](https://www.ncbi.nlm.nih.gov/pubmed/) (<https://www.ncbi.nlm.nih.gov/pubmed/>)



# CONCLUSIONS

ADxRx produces high quality monoclonal antibodies that recognize human protein epitopes in their native configuration. These antibodies represent an enormous advantage over other antibodies produced with other methods.

ADxRx antibodies detect circulating biomarkers in only one microliter of serum or plasma. These unique antibodies perform with the same quality in all immunoassays: IHC, ELISA, Nanosensor devices, Circulating tumor cells, Flow Cytometry, as well as in R&D applications such as Western blot and Immunoprecipitations.

ADxRx antibodies can be used in multiple diagnostic tests:

- **ELISA testing for early diagnosis**
- **IHC staining of FFPE and frozen tissue for diagnosis and guiding therapy**
- **Circulating tumor cell staining for diagnosing and monitoring metastasis**



# ABOUT THE COMPANY

ADxRx, LLC, founded in 2017 and based in Maryland, USA, develops in vitro diagnostic (IVD) tests focused on early detection, companion diagnostics, monitoring therapy by isolating biomarkers and development of monoclonal antibodies that are applicable in every immunoassay including blood and tissue with high sensitivity and specificity. For more information, visit [www.adrx.com](http://www.adrx.com)

