# Thomsen-Friedenreich (TF) Antigen in Nipple Aspirate Fluid: Biomarker for Breast Cancer Detection

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Why TF Antigen?

- TF is a carcinoma-associated carbohydrate antigen expressed on > 85% of carcinomas.
- Relative expression of this antigen on human carcinomas correlates with carcinoma aggressiveness
- TF immunodeterminant group is Gal-β1-3GalNAc-
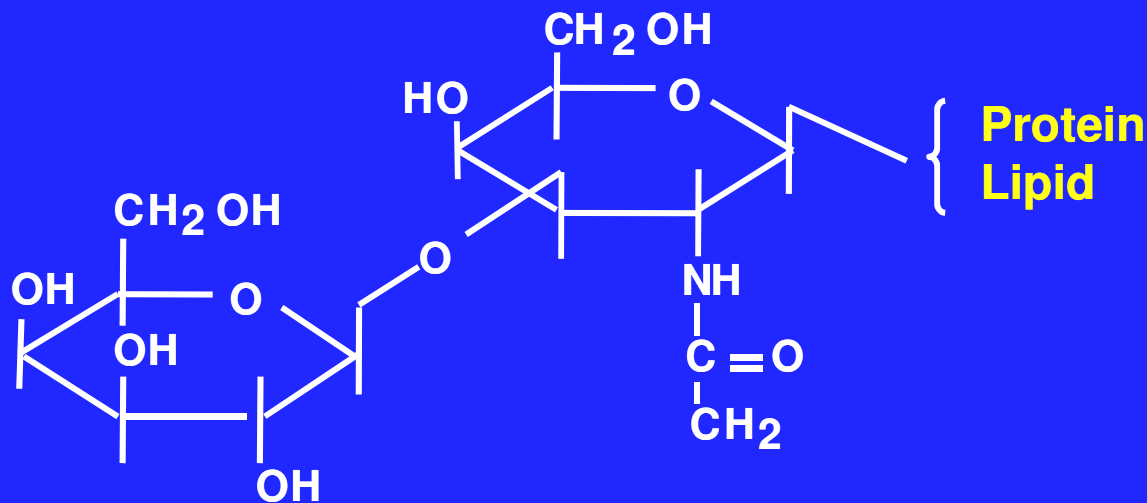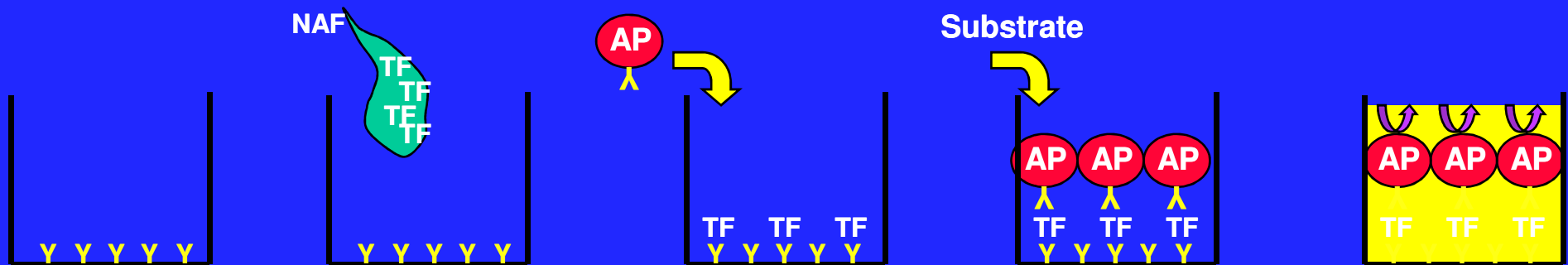
Breast Cancer and NAF

- **Currently available breast cancer screening tools miss up to 40% of early breast cancers.**

- **An ideal cancer diagnostic procedure is noninvasive, reliable, and repeatable.**

- **Screening breast nipple aspirate fluid (NAF) for cancer biomarker fulfills all three criteria.**

Nipple Aspirate Fluid (NAF)

- **Can be obtained noninvasively**

- **Contains a small number of cells**

- **Contains relatively high levels of proteins and lipids secreted from ductal and lobular epithelia**

- **NAF is obtained using a modified breast pump without significant side effects**

- **Have been able to collect NAF in over 99% of both pre- and postmenopausal subjects**

- **NAF is collected in capillary tubes and stored at -80 °C until use.**

TF Clinical Study

A prospective study to evaluate the presence of TF antigen in the nipple aspirate fluid (NAF) from the breasts of women that require a biopsy and assess if this antigen is a useful biomarker for non-invasive breast cancer detection

Median Values for TF
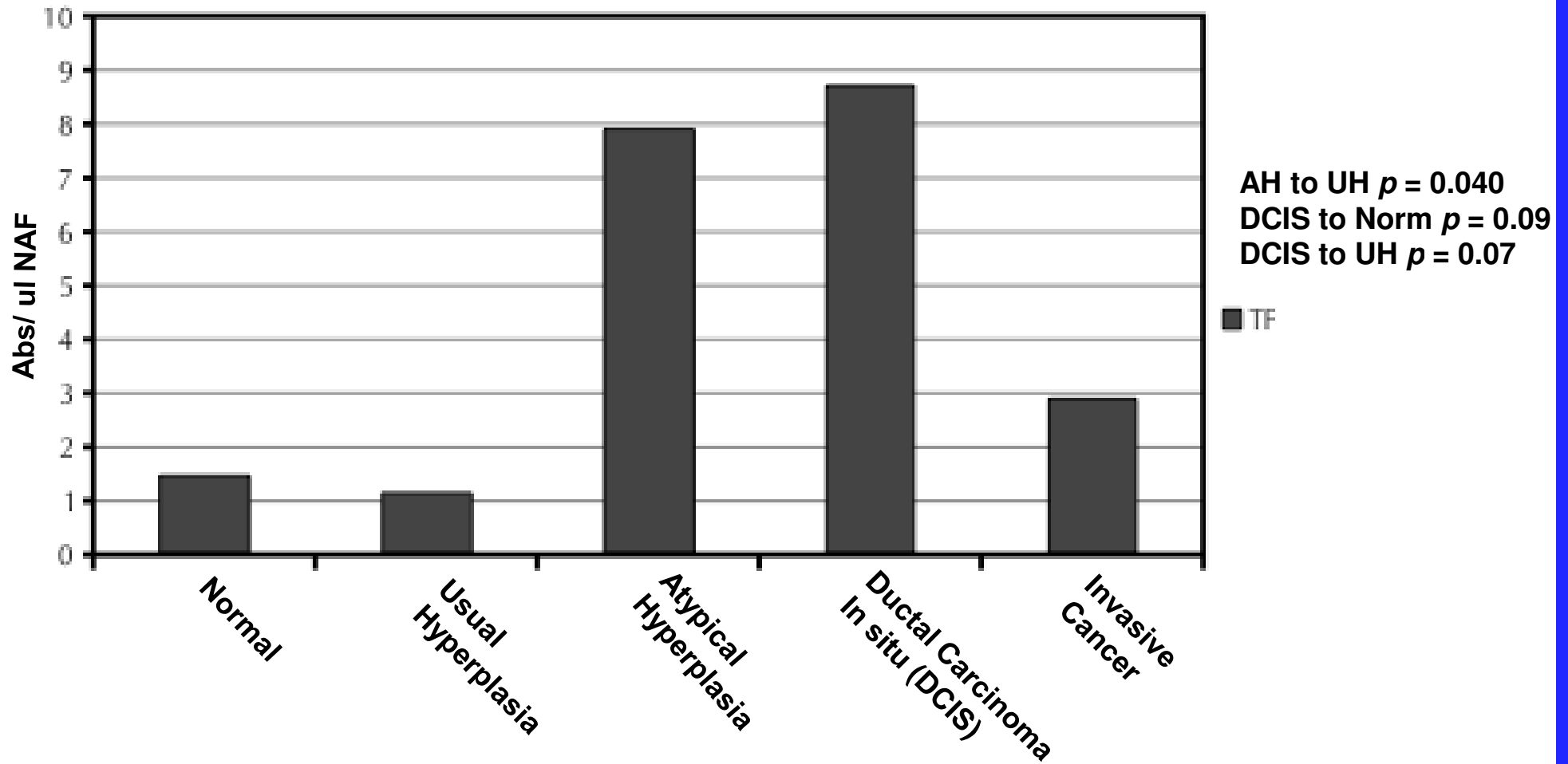
Conclusions

- TF appears to be useful for the development of a non-invasive diagnostic tool for breast cancer.

- Quantification of this glycoantigen in NAF should prove useful as an adjunct to mammography and physical examination to screen for the development of primary or recurrent breast cancer.

TECHNOLOGY COMMERCIALIZING

What is the nature of the technology?
Potential method for early breast cancer screening.

What is its distinct value or advantage?
Non-invasive, complementary with other screening methods, does not destroy the breast or impact other screening methods.

Who is the customer and why will he/she buy? What is the market?
Physicians: Current screening methods miss ~ 40% of early beast cancers.
40,000 women die of breast cancer each year.
Physicians would highly value a screening test that could be diagnostic.
~300,000 mammograms per year in the +50 age group

What is the nature of the opportunity…short, medium, and long view?
There is no diagnostic breast cancer screening test available. If we could validate this test we would be first in the market. Need to validate test and publish the results. The test will become standard in a women's yearly physical exam.

What competing technologies and providers exist?
Imaging (mammography) and Physical exam.

What are the relative advantages/disadvantages of the technology vs. existing and potential solutions?
Cheaper than imaging modalities. TF + cytology results from NAF are potentially diagnostic for breast cancer. Imaging and physical exam are not.

Who is currently involved and in what capacity?
Susan Deutscher, Ph.D. : Assay development and execution.
Edward Sauter, Ph.D. M.D. : Breast Surgeon, NAF expert; sample acquisition.
Tom Quinn, Ph.D. : Antigen and antibody biochemistry and structure.

What are the next logical milestones, how do they add value, and what are the requirements and obstacles to meeting them?
Larger sample size (500 patients); subset analysis, validation. Multi-center trial.
Securing multi-center trials and sample acquisition.

What is the current ownership of the technology/company?
MU

What is the current state of IP protection, and how protectable is the technology?
Patent application under review

What kind of team is required to take this to the next milestone?
Physician(s), nurse(s): collect NAF samples, provide physical exam & cytology.
Basic scientists: perform assays, analyze data, confirm internal controls.
Corporate partner: commercialization.

What rough expectations of validation?
Our goal is to get at least 500 patients from 2 or more centers for assay validation and subset analysis.

What could go wrong?
•Less than 500 patients.
•Findings may be different from the preliminary results.
•Reagent heterogeneity.