A Clinical Diagnostics Company
Using Proteomics, Metabolomics and BioIT

Brian Mansfield, Ph.D.
Vice President for Research and Development

Patterns for Life®

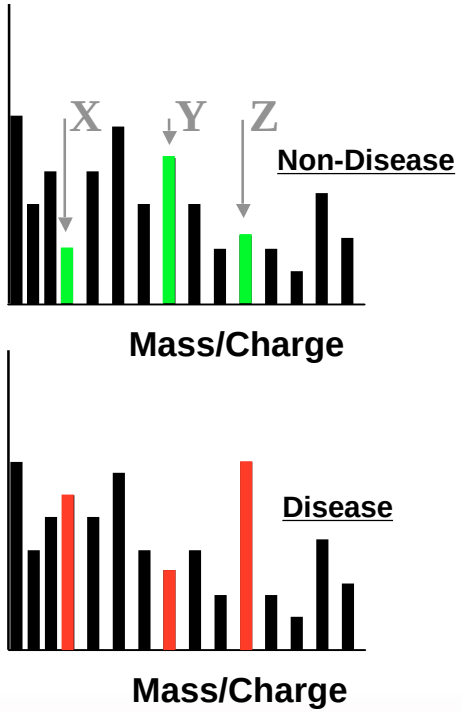
Our Central Premise

- Individual Biomarkers of disease are not the future
  - CEA, CA-125, PSA

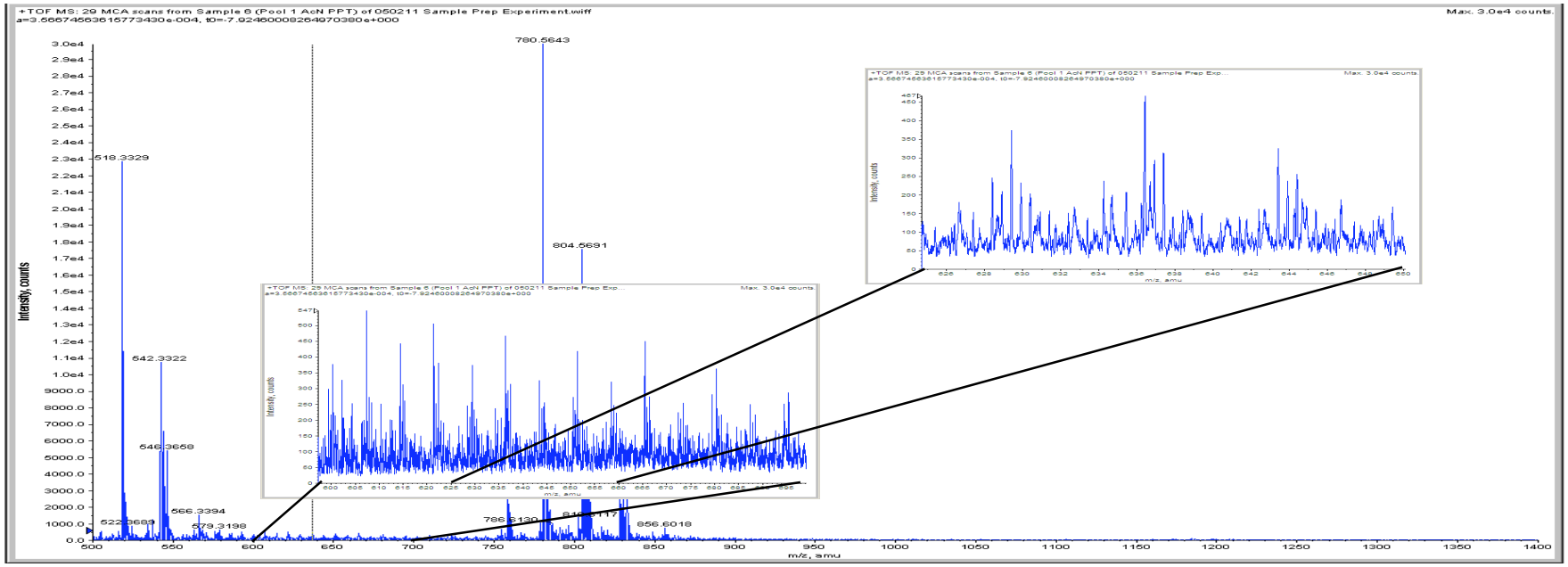
- The presence of disease is associated with many changes reflected in the circulating blood/serum
  - blood vessel growth, tissue architecture, immune response, local metabolic changes

- Subtle changes in ***relative expression ratios*** of proteins/peptides/metabolites accurately reflect the disease and the body's systemic response (>3)

- "Invisible" patterns in complex data streams characterize biological state



The Challenge



Profile serum components, using Mass Spectrometry
- or other techniques *e.g.* NMR, FAIMS, GC-MS,..

Profiles are complex - >64,000 features

What is the right combination of which features?

Exact searches of all combinations are massive, not feasible

Our Solution

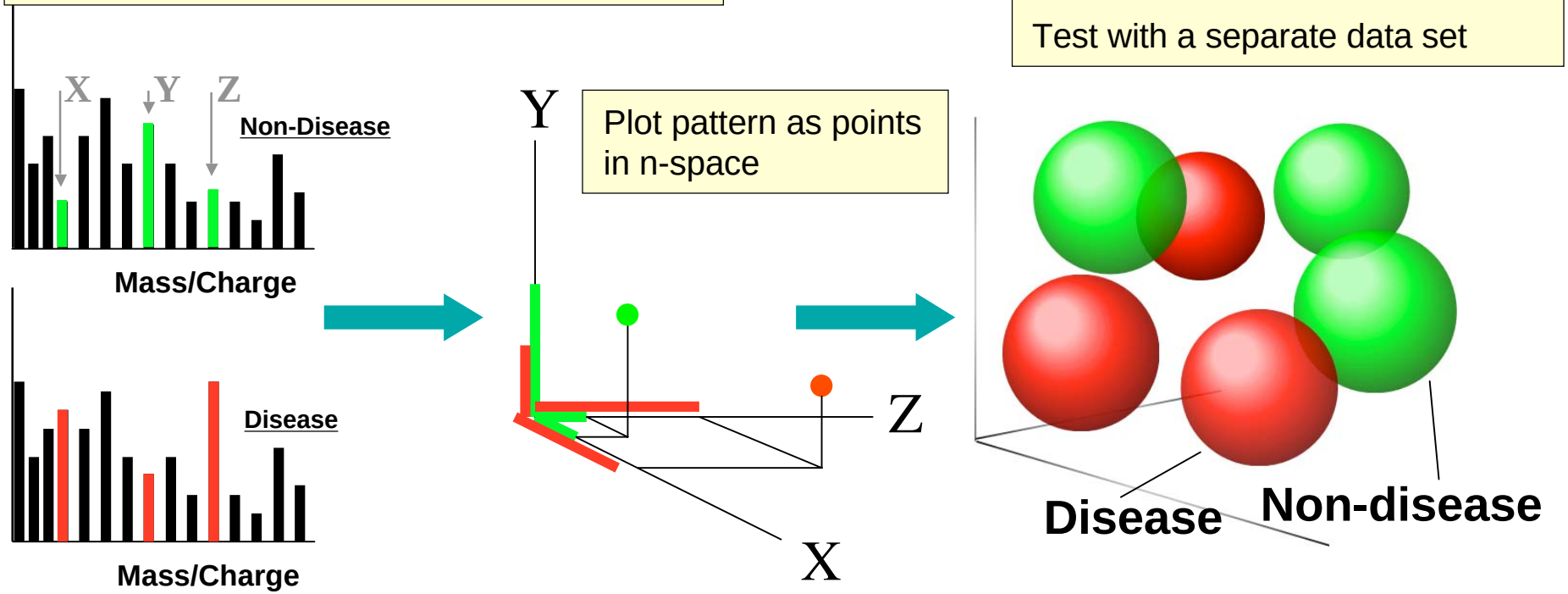
ProteomeQuest®

Lead Cluster Map - Genetic Algortihm

Select mass spec features to define a pattern

Build clusters of points in in-space

Test with a separate data set



A genetic algorithm iterates this process, evolutionarily selecting a set of features that can optimally discriminate disease states

The process is done in massive, parallel computations

Multiple runs scan 3, 4, 5…. Feature combinations to find the optimal number of features to monitor

CORRELOGIC®

Correlogic Systems, Inc.

Core Products / Services

Pattern / Model Discovery:

- **ProteomeQuest®**
  - Pattern discovery & pattern recognition algorithms,
  - Software and lab processes for the creation of computational, disease state “Models”

Clinical Deployment of a Diagnostic Model:

- **ProteomeDx®**
  - System software
  - Related lab processes for the deployment and use of the computational models

Correlogic's Ovarian Cancer Research

- Collaboration with FDA/NCI Clinical Proteomics Program
- Identify serum profiles that are diagnostic of Ovarian Cancer

Proof of Principle:

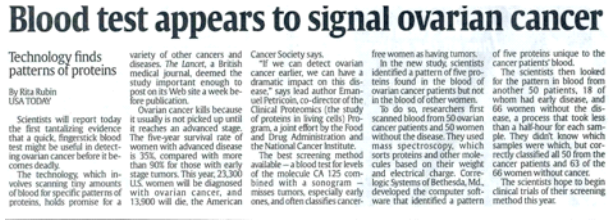
- Ground breaking study published in The Lancet (2002)
  - SELDI-MS
  - Identified a diagnostic pattern (Model) composed of 5 features
  - 100% sensitivity (CI 95% 93-100)
  - 95% specificity (CI 95% 87-99)
  - PPV 94% (CI 84-99)


Test Finds Ovarian Cancer Early

Bethesda Firm's Invention Could Provide Reliable Screening

USA TODAY

NO. 1 IN THE USA


Blood test appears to signal ovarian cancer

Technology finds patterns of proteins

By Rita Rubin
USA TODAY


Scientists Report Initial Success With a Blood Test for Ovarian Cancer

A gain in the effort for early detection of a disease often diagnosed too late.

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Correlogic Systems, Inc.

- ***Incorporated in May 2000***
  - Peter J. Levine, Esq. President/CEO
  - Ben A. Hitt, Ph.D. Chief Scientist/CTO Emeritus
- ***Privately held:***
  - several private investors
  - two corporate investors
    - Quest Diagnostics Inc.
    - Mitsui & Company, Ltd
- ***Located in:***
  - Rockville (1405 Research Boulevard, Suite 220, MD 20850)
- ***16 Full time employees*** (an additional 3 part-time)
  - 8 Ph.D.
  - 4 M.S.
  - software development, database development, computational modelling, Mathematics, Biochemistry, Molecular Genetics, Physical Chemistry, Clinical Monitoring, Legal

Widely Applicable

Proof of Principle for detection of:

- Prostate Cancer (sensitivity 100%, specificity 67%)
- Breast Cancer (performance 80-90%)
- Murine invasive ductal pancreatic cancer
- State of remission of Wegener's Granulomatosis

Environmental Contamination Models:

- Low level *bacillus* spore detection/classification (anthrax vs enviromental background)
- Identify pathogenic bacterial strains from closely related non-pathogenic strains

Publications:

- 10 peer-reviewed publications on the use of the technology


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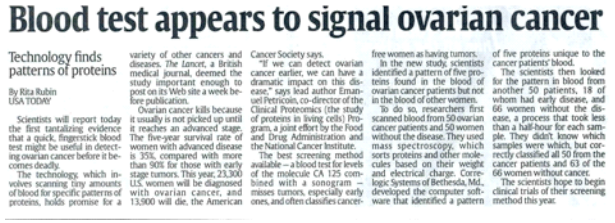

Blood test appears to signal ovarian cancer

Technology finds patterns of proteins

By Rita Rubin
USA TODAY

Scientists will report today the first tantalizing evidence that a quick, fingerstick blood test might be useful in detecting ovarian cancer before it becomes deadly.

The technology, which involves scanning tiny amounts of blood for specific patterns of proteins, holds promise for a variety of other cancers and diseases. *The Lancet*, a British medical journal, deemed the study important enough to post on its Web site a week before publication.

Ovarian cancer kills because it usually is not picked up until it reaches an advanced stage. The five-year survival rate of women with advanced disease is 35%, compared with more than 90% for those with early stage tumors. This year, 23,300 U.S. women will be diagnosed with ovarian cancer, and 13,900 will die, the American Cancer Society says.

"If we can detect ovarian cancer earlier, we can have a dramatic impact on this disease," says lead author Emanuel Petricoin, co-director of the Clinical Proteomics (the study of proteins in living cells) Program, a joint effort by the Food and Drug Administration and the National Cancer Institute.

The best screening method available — a blood test for levels of the molecule CA 125 combined with a sonogram — misses tumors, especially early ones, and often classifies cancer-free women as having tumors.

In the new study, scientists identified a pattern of five proteins found in the blood of ovarian cancer patients but not in the blood of other women.

To do so, researchers first scanned blood from 50 ovarian cancer patients and 50 women without the disease. They used mass spectroscopy, which sorts proteins and other molecules based on their weight and electrical charge. Correlogic Systems of Bethesda, Md., developed the computer software that identified a pattern of five proteins unique to the cancer patients' blood.

The scientists then looked for the pattern in blood from another 50 patients, 18 of whom had early disease, and 66 women without the disease, a process that took less than a half-hour for each sample. They didn't know which samples were which, but correctly classified all 50 from the cancer patients and 63 of the 66 women without cancer.

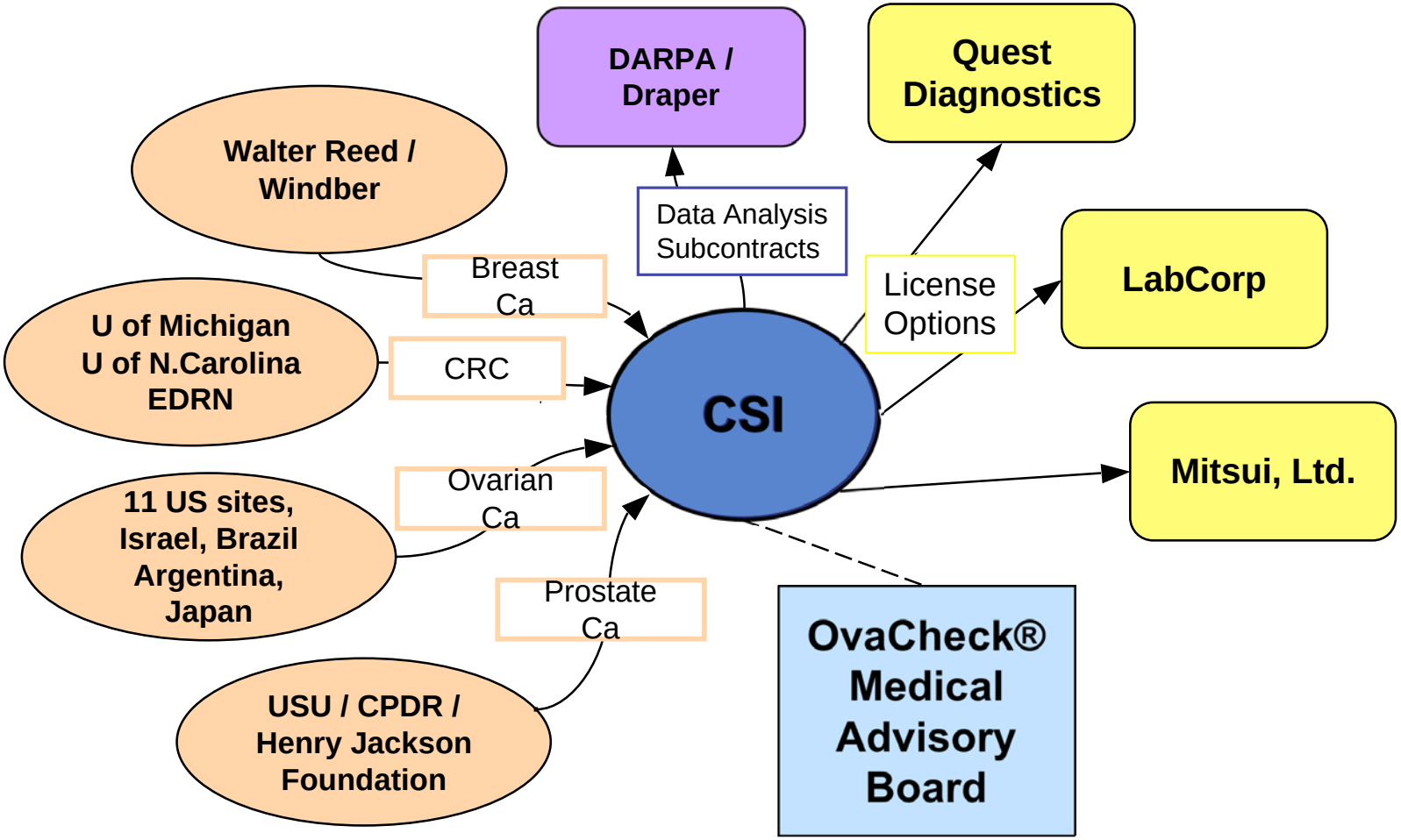
The scientists hope to begin clinical trials of their screening method this year.


Scientists Report Initial Success With a Blood Test for Ovarian Cancer

By DENISE GRADY

A gain in the effort for early detection of a disease often diagnosed too late.

Key Relationships



Intellectual Property

Pending and issued patents cover:

Our Core Concept:

Hidden Patterns identification methods

- Issued in US (No. 6,925,389) 2 August 2005
- Issued in South Africa

Our Algorithm:

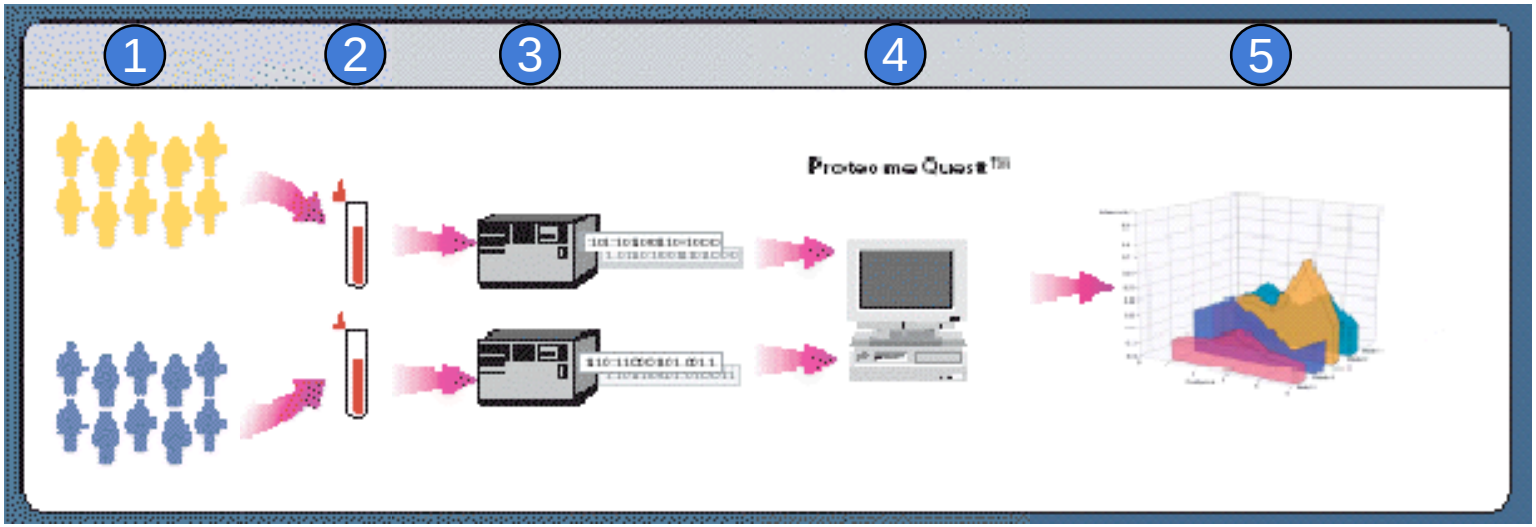
Knowledge Discovery Engine (KDE)

- Issued in US (No. 7,096,206) 22 August 2006
- Issued in Singapore and South Africa
- Allowed in Eurasia

Associated Technology:

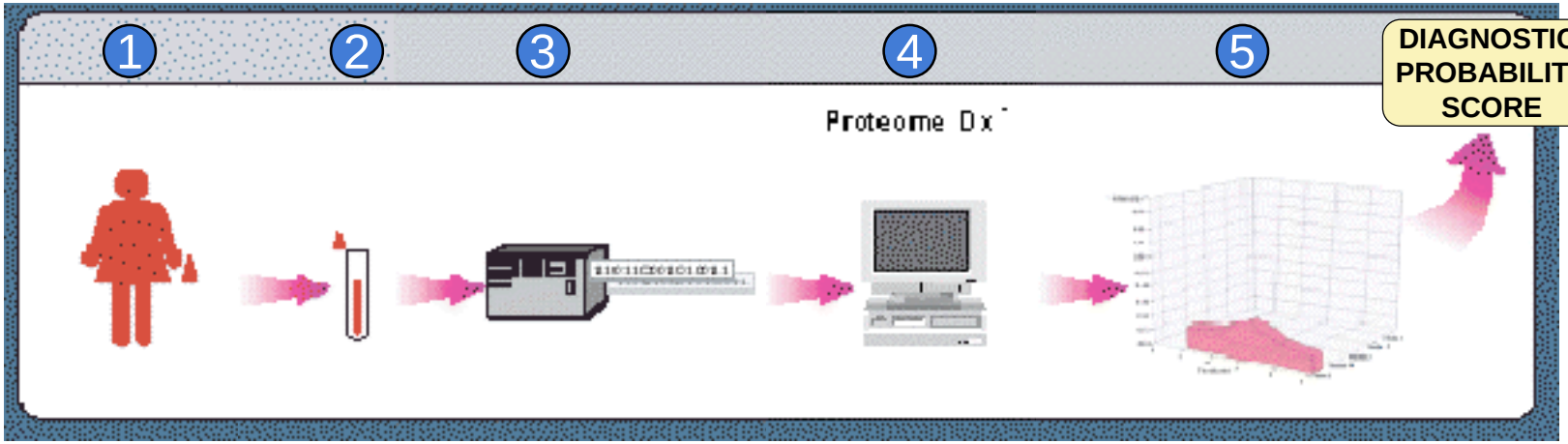
- specific disease models
- sample preparation and quality control
- remote data processing
- equipment optimization techniques

Building a Model for Disease Detection



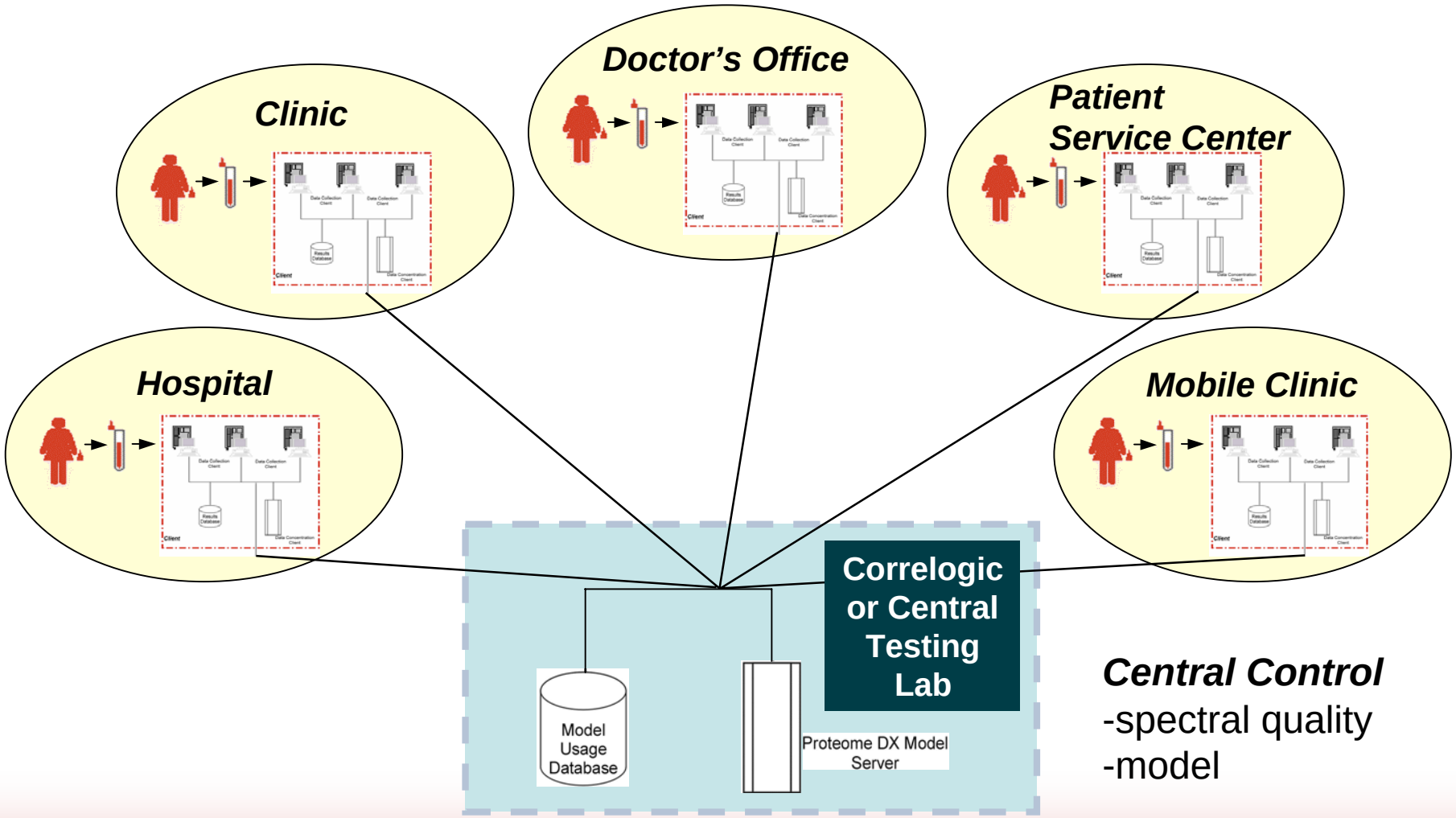
1. Select patients with disease and subjects without the disease
2. Obtain serum samples
3. Run samples through mass spec to generate spectra files
4. Use **Proteome Quest®** to analyze the spectra files and build models that can discriminate between disease and non-disease states
5. Select a model for diagnosis deployment

Using the Model to Test Patients



1. Physician orders test
2. Physician or patient service center collects serum and forwards the sample to central clinical diagnostic laboratory
3. At clinical laboratory, samples are run through mass spec to generate spectra files
4. For each sample, **ProteomeDx®** extracts the pattern for the mass spectral feature set defined by the previously created diagnostic model. Data is transmitted to the model server.
5. **ProteomeDx®** scores the pattern against the disease diagnostic model and returns a diagnostic probability score to the physician

ProteomeDx®
Point of Care Applicability



Central Control
-spectral quality
-model

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Future:

- Breast Cancer
- Colorectal Cancer
- Prostate Cancer
- Other Diseases
- Technology equally applicable to many alternative data sources - microarray, sequence data, etc.

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