Founded in 2000, XDx, Inc. is a molecular diagnostics company based in Brisbane, CA, USA.

XDx applies modern genomics technologies to the development of molecular diagnostic assays that translate a patient's immune status into clinically actionable information.
Molecular Diagnostic and Personalized Medicine

- Care is focused on late-stage treatment: pathology, severe clinical manifestations, organ dysfunction
- New Dx technologies offer the opportunity to reduce health care costs, patient morbidity and mortality

Figure 2. The development of chronic disease and opportunities for intervention.

Disease burden generally increases over time and is correlated with less reversibility and greater cost of intervention.

Courtesy of Dr. Snyderman
Heart Transplantation

- Patients receive a transplanted heart and are subjected to a life-long treatment of immunosuppression to avoid rejection.

- A regular assessment of risk for acute cellular rejection is used to adjust management strategy (e.g., immunosuppression).

- Patients undergo frequent invasive endomyocardial biopsies (30+ in 5 years):
  - 1/week Month 1
  - 1/month Year 1
  - 1/quarter Years 2-5
Endomyocardial Biopsy
AlloMap® Molecular Expression Testing

AlloMap® features:

• Tests for low probability of acute cellular rejection
• Uses a blood sample rather than heart tissue sample
• Measures expression of 20 genes by quantitative real-time PCR
• Reports a single score (0-40)
• Performed in XDx CLIA certified laboratory
• Cleared by FDA (IVDMIA class II) on Aug. 26th 2008
Invasive Monitoring Attenuation through Gene Expression

- 12 U.S. Heart Transplant Centers
- 600 Heart Transplant recipients enrolled and randomized into two arms
  - Biopsy Arm: Patients are managed with biopsies
  - AlloMap® Arm: Patients are managed with AlloMap®
- Goal of IMAGE study is to demonstrate the non-inferiority of clinical outcomes of heart transplant recipients managed with the AlloMap® test compared to endomyocardial biopsy
AlloMap® is objective (Physicians)
• 99% Negative Predictive Value

AlloMap® is non invasive (Patients)
• Simple blood draw

AlloMap® is cost efficient (Payers)
• List price: $3,200