

Ortho Clinical Diagnostics (OCD) Background

- IVD lines of business
 - Transfusion Medicine
 - Donor Screening
 - Clinical Laboratories
 - Veridex, LLC
- Novel Medical Content
- Veridex, LLC
 - High-value IVD Oncology products
 - CellSearch®
 - GeneSearch®
- OCD's Broader Novel Medical Content Focus
 - Oncology
 - Cardiovascular Disease
 - Metabolic Disease
 - Reproductive Health

Why Aren't There More Novel Diagnostic Tests??

- Disconnect in Marker Discovery platforms - usable versus useful
 - Mature platforms - Gene Expression & Genomics
 - Broadly applicable platforms - Proteomics & Metabolomics
- Need markers that will work in the real-world
 - Population selection for marker discovery, verification, and validation
 - Resolution of sample handling issues (processing / shipping / storage)
- Gold Standards can be flawed, in flux, or both
 - Diagnosis of diabetes (fasting glucose, OGTT, HbA1c)
 - Tissue pathology for lymph node metastasis
- New diagnostic tests have many hurdles to clinical adoption
 - Regulatory oversight (increasing rigor - IVDMA, Home Brews, ASRs)
 - Incorporation into clinical guidelines & re-imburement
 - Demonstrate improved patient outcomes
 - Developing channels for reaching and educating the physician
- Is a new biomarker necessary? What is the major unmet need?
- How big is the opportunity relative to risk & cost