Antibody-based Diagnostics

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2017.02.27 Translation Medicine Symposium
What Would We Do Without Immunoassays?

- ELISA
- Immunocytochemistry
- Western Blot
- Immunohistochemistry
Basic Principles of Immunoassays

Must wash to remove unbound, active signal
Basic Principles of Immunoassays

Un-removed, active signal gives high background
Target Engaged Complementation (TEC)

Binding activates reporter signal

Inactive protein fragments are fused to antibodies

Binding to antigen enables fragments to form active protein
Basic Principles of “TEC”

Binding activates signal; no washing required.
Single-step detection of soluble antigen (HER2)

Detection in 100% Human Serum

Quantified HER2 levels < 1 ng/mL

Current HER2 assay has a cut-off of 15 ng/mL as criteria (Herceptest ®)
Defining TEC assay value and finding people who care…Round 1

“Novel” Idea

Predefined Application

Comparable to Gold Standard
Defining TEC assay value and finding people who care...Round 2
Get smart people to tell you what the want/need

Actual white-board from strategy session with ARUP
- HCI
- ARUP
- Various Research Labs

- Sources for Antibodies
  - Data Base
  - Commercial
  - In House Development

- Define “Improvement”
  - Faster
  - Cheaper
  - More Sensitive
  - Unmet need
Customizable to soluble or cell-surface proteins

Total Assay Time ~30-60 min

Homogeneous assay eliminates multiple steps
Streamlined TEC assay value proposition

- Versatile: Customizable to soluble or cell-surface proteins
- Rapid: Total Assay Time ~30-60 min
- Single-step: Homogeneous assay eliminates multiple steps

Seek Funding
Lessons learned

- Good academic ideas might not be good commercial ideas
- Get to the clinic and identify the nail, then work on your hammer
- Disclose early – way before you think you should
ARUP Collaborators ARUP
- Noriko Kusukawa, Ph.D. – VP New Tech
- Julio Delgado, M.D., M.S. – CMO

TVC
- Leena Bhoite, Ph.D. – Tech Manager

Research Assistant Professor/Post Docs
- Andy Dixon, Ph.D.
- Brett “Bump” Baumgartner, Ph.D. (former)
- Hsiao-nung Chen, Ph.D.

Graduate Students
- Jessica McCombs – UNCF/Merck Fellow
- Sun Jin Kim
- Keith Arlotta
- Chad Adamovich (Pharm.D.)

GPEN (6 month exchange)
- Sylvia Krippner
- Bjorn ter Mors