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Cancer Progress 2012

**BIOMARKERS, COMPANION DIAGNOSTICS
AND ENABLING TECHNOLOGIES AND
SERVICES FOR PERSONALIZED MEDICINE**

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Themes for cancer drug development

- Companion molecular diagnostics fast becoming standard for cancer therapeutics, because we can and we should
 - IHC, FISH and allele-specific PCR today
 - NGS coming very soon
- Molecular analysis of blood will be standard
 - Circulating tumor cells, circulating free DNA, proteomics etc
 - Contains actionable information
 - Readily accessed longitudinally

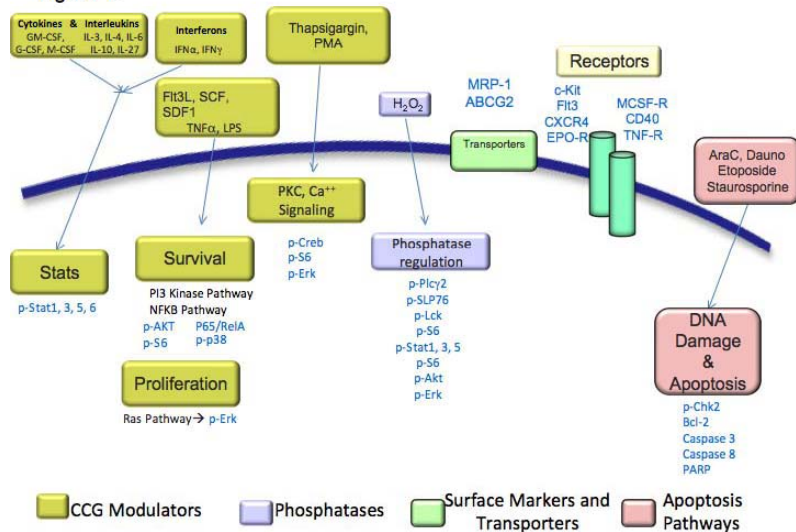
But

- Making deals between drug developers and CDx companies can be challenging – incentives for pricing, IP, access quite distinct
- How to ensure test quality in the clinic – If IHC struggles to be standardized, what of NGS?

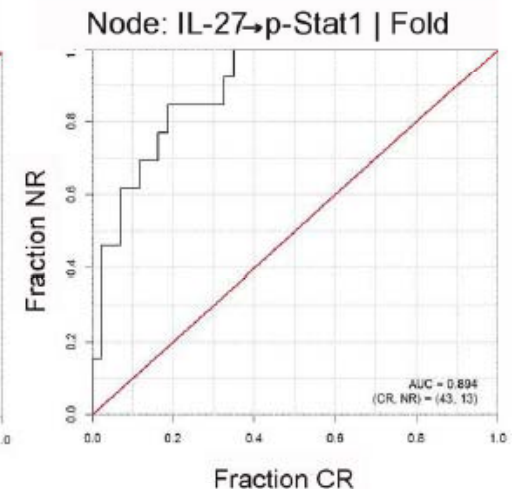
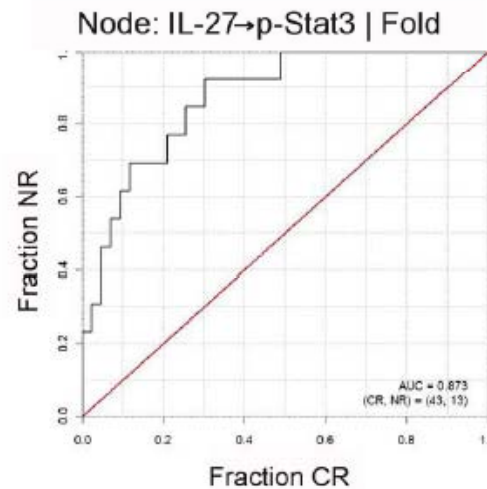
Circulating hematologic tumor cells



Figure 1.



Age Alone		Node Alone		Model			
AUC	p-Value	AUC	Node (Metric)	AUC	p-Val (AUC = .5)	p-Value Node	p-Value Age
0.65	0.001	0.66	IL-27 → p-Stat1 Fold	0.89	< .001	0.012	0.001
0.65	0.001	0.71	IL-27 → p-Stat3 Fold	0.87	< .001	0.019	0.001



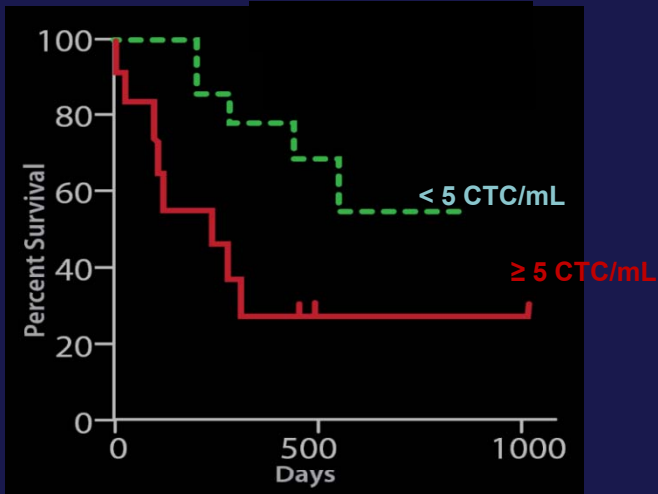
Source: Kornblau et al (2010) Clin Can Res

Confidential



Circulating solid tumor cells

Overall Survival of NSCLC patients



*PTEN null
CTC from
prostate cancer
patient*



www.epicsciences.com

Source: Epic Sciences, San Diego, CA



Drug-CDx co-development challenging today, but may ease over time

	Drug developer	CDx developer
Sample used	Routine clinical sample - blood >FFPE>frozen	Typically tissue
Test performed	Locally (kit)	Typically centrally, e.g. CLIA LDT
Turnaround	Days	May be weeks for complex tests
Multiple tests on one sample	Strongly preferred (also by clinician) – eases sample collection	Not typically possible
Exclusivity	Test exclusivity to their drug	Wants use by all members of drug class
Price	Cheap or free	Value-based (high)
Test evolution	Migrate to cheaper, simpler platform	Maintain high value platform