

Arizona Society of Pathologists 

Value of Pathologists in Current and Future Healthcare Practice

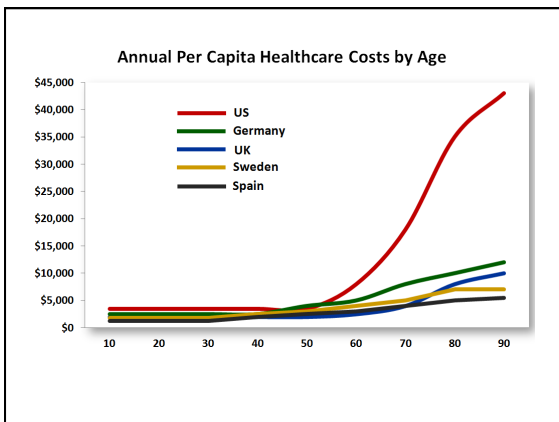
April 5, 2014

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Disclosures

I have no financial interest or other relationship with the manufacturer(s) of the product(s) or provider(s) of the service(s) that will be discussed in my presentation.

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 **In 2013, Healthcare Experienced Largest Drop in Job Growth Since 1990 and Hospitals Are Shedding Jobs; These Trends Are Likely to Mean Less Resources for Hospital Laboratories**

February 12, 2014

Market indicators support predictions of tougher financial times ahead for hospital-based clinical laboratories and pathology groups

Health Insurers Encourage Physicians to Help Patients Use Cost and Quality Data to Select Providers, Including Medical Laboratories

January 27, 2014

Employers and health insurers want more consumers use healthcare cost estimator tools and pride when choosing a hospital, physician, or clinical laboratory

Facing the Looming End of Fee-for-Service, Clinical Laboratories and Anatomic Pathology Groups Look for New Business Models

March 31, 2014

Falling finances at technical pathology laboratories may be the most immediate concern for many pathology group practices

Many [clinical laboratories](#) and [anatomic pathology](#) groups now recognize the new reality of the American healthcare system: less reimbursement for laboratory testing. On one hand, the fee-for-service prices for lab tests paid by government and private payers have been aggressively slashed.

On the other hand, all payers have become stubbornly resistant to issuing coverage guidelines and setting adequate prices for the flood of new [molecular assays](#) and [gene tests](#) coming to market.

More Bad News for Medical Labs and Pathology Groups

The bad news for labs doesn't stop there. Today, the majority of office-based physicians are now employees. Mostly hospitals and health systems now own their medical practices. These owners typically want their own clinical labs to do the testing in support of the office-based physician practices they own and operate.

Clinical Laboratory Industry Needs New Business Models

... two traits in common. First, they are stepping forward to engage referring physicians with a full range of information-rich lab testing services and consultations that help improve patient outcomes, while lowering the overall cost per healthcare encounter.

Second, these first-mover clinical labs and pathology groups recognize the value of collaboration and developing regional service networks. Yes, this is a strategy designed to mirror the creation of regionally based ACOs, medical homes, and integrated health systems in their communities.

THE DARK REPORT | www.darkreport.com | 3

Labs Push To Cut Costs As Budgets, Prices Shrink

► Repeated budget cuts and lower test prices are now forcing labs to aggressively cut costs

►► **CEO SUMMARY:** Cost-cutting is now the prime directive at progressive laboratories and laboratories in the United States. This is due to shrinking budgets and aggressive price-cutting by private payers. Even Obamacare is a factor, because of the Medicare Part B price cuts it mandates for five consecutive years. For this reason, proven ways laboratories can use to cut costs will be the main theme at the Lab Quality Confab that takes place on October 1-2, 2013.

By Robert L. Michel

The Dark Report | www.darkreport.com | 11

CEO SUMMARY: Described by its CEO as "an information company that happens to do laboratory testing," PeaceHealth Laboratories of Springfield, Oregon, is moving quickly to develop and deliver value-added services to its client physicians. The lab's goal is to help referring doctors achieve improved patient outcomes.

... helps as within the lab. It also creates new ways for us to support physicians, patients, and providers in our service areas.

... Tapping the data warehouse to deliver value to client physicians

PeaceHealth Lab Helps Docs With Info to Improve Outcomes

Report Cards Benefit primarily for payors

... groups, clinics, and laboratories in Oregon, Washington, and Alaska.

... There are 40 pathologists in four pathology groups that work with our labora-

Sharing Pathology's Value With Health Care Executives

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Our executives don't want to know.

Life in The Laboratory

The better a laboratory operates, the more it looks like a commodity.

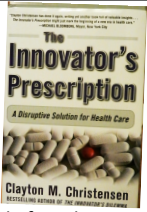
- We adapt and provide whatever services are necessary, but there is a lot behind it.
- Troubles come when demands outstrip capabilities.



The Pressure is Intense on Everyone

- All of medicine is being pressured to do more with less.
 - It is not possible to succeed simply by working harder.
 - After a point, pressure produces only anxiety and frustration.
- Our opportunity is to help others do more with less.**

**Killer Apps
Disrupt Industries**



- Originally**
 - A computer program that people found so valuable that they would buy an expensive new computer system just to get the program.
- For us**
 - A pathology/laboratory medicine offering that people demand more of and are willing to pay.

What Makes a Killer App




- People will pay a premium price, digest all kinds of instructions and change lots of habits in order to get a job done better and faster that **they have been trying to do**.
- The graveyard of failed products is full of things that people *should* have wanted – if only they could have been convinced those things were good for them.
- The home-run products in are concepts that help people more affordably, effortlessly, swiftly and effectively do tasks they already had been trying to do.




The convergence of social and economic factors together with advances in medical science and informatics presages a “Golden Era of Diagnostics”.

“In the future, diagnostics will become quite profitable relative to therapeutics because the value of defining and solving the right problem is immense.” (Clayton Christensen)

Value of Laboratory Data



60-70% of all critical, patient care decisions are impacted by laboratory results.




Laboratory results contribute as much as 94% of the objective data in a clinical record.

Regan M. Forsman R. Disease Management 2006;9(2):122-130

COST OF LABORATORIES only ~ 2% of healthcare costs.

**So why are they picking on us?
2% savings will not do much.**

Yes, but **“they drive all the rest”** (SEAPC Meeting, Don Bradley, Blue Cross Medical Director of North Carolina)



In the coming era of medicine, the most valuable physicians could be pathologists and clinical scientists who can influence practice patterns of other physicians.

Not a Surprise for Pathologists: Study Determines Doctors Fail to Follow Up on as Many as 60% Clinical Laboratory Test Results

November 12, 2012

Researchers looked at how physicians in ambulatory settings followed up on the results of medical laboratory tests

The Washington Post

[Back to previous page](#)

Medical tests are pointless when results don't reach the doctor or the patient

Humana and Norton Healthcare's Pilot ACO Triggered Both Increased Utilization of Clinical Laboratory Tests and Improved Patient Outcomes

June 13, 2012

Clinical laboratory managers and pathologists will want to develop strategies for adding value under ACO model

Lab Tests 101

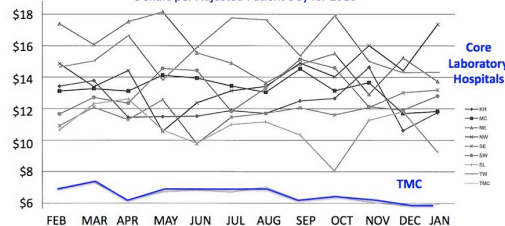


- The problem is not too many lab tests.
- The problem is information overload and arcane procedures of ordering and reporting that produce confusion and inability to interpret them or follow up appropriately.
- Our opportunity is to help others with these things.

Four Areas of Opportunity

1. When time of complex testing and interpretation is critical.
 - Microbiology
 - Heart failure surgery
2. Help physicians identify, justify, order, find and interpreting laboratory work ups.
 - Institute consultative algorithmic workups.
3. Advanced testing of tissue samples (molecular, proteomic, etc.)
 - Oncology
 - Transplantation
4. Test Coordination in Population Health
 - Diabetes

System Antibiotic Utilization
Dollars per Adjusted Patient Day for 2010



- TMC has the sickest patients.
- Equipment, reagents and procedures are standardized across the system
- 273,467 adjusted patient days at TMC.
 - Savings on antibiotics, \$2,000,000 - \$3,000,000
- Millions more savings on ICU time, LOS, etc.

Declining Nationwide Demand for Blood Products Is a Positive Trend for Hospitals and Their Medical Laboratories

March 7, 2014

Pathologists and blood bankers in many hospitals are finding it easier to manage costs because, for a variety of reasons, utilization of blood and blood products has declined in recent years

Blood Management

- **Preventing** a blood transfusion to the patient who doesn't need one
- **Right** blood product, at the **right** time, in the **right** dose, to the **right** patient.

Improves patient outcomes
 Conserves limited blood resource
 Reduces cost of care
 Helps satisfy regulatory requirements



Blood Usage Project

Goals

- Collect data on blood component usage at MHH-TMC
- Evidence-based education is the KEY
 - Set up clinician-driven algorithms
 - Set up periodic retrospective order reviews and educational materials
 - Set up monthly outcome reviews
- Real-time order review
 - Set up real-time order reviews
 - Offer consultation to outliers
- Prospective outcome research to support the project
- Management scorecards to track improvement outcomes

Blood Products Usage by All / Specified DRGs
 Memorial Hermann - TMC
 October, 2010

Facility	# Patients Received Transfusion	Avg Units Received per Patient	Red Cells and LR Red Cell	Random Apheresis, and Other Adhesive Platelet	Fresh Frzn Pls and Cryo Poor FFP	Cryoprecip
MHH HERMANN	406	7.2	1,832	323	504	460
% Change vs September	+18.4%	-10.9%	+4.9%	-8.8%	-6.5%	+43.8%

DRGs with Top Ten Transfusions by Product Category *

Blood Products	DRG	Units	% Change vs Last Month	Patients	% Change vs Last Month	Avg Units Per Pt	% Change vs Last Month
Red Cells	003 ECMO or trach w MV 96+ hrs or PDX exc face, mouth & neck w maj O.R.	350	-	24	-	12.9	-
	927 Other O.R. procedures for multiple significant trauma w MCC	136	-	11	-	12.6	-
	237 Major cardiovascular procedures w MCC or thoracic aortic aneurysm repair	68	-	11	-	6.2	-
	956 Limb reattachment, hip & femur proc for multiple significant trauma	61	-	10	-	6.1	-
	981 Extensive O.R. procedure unrelated to principal diagnosis w MCC	43	-	5	-	8.6	-
	425 Pancreas, liver & shunt procedures w MCC	39	-	4	-	9.8	-
	442 Wnd debrid & skin graft exc hand, for musculo-skelet tra w MCC	27	-	6	-	5.4	-
	464 Wnd debrid & skin graft exc hand, for musculo-skelet tra w CC	27	-	6	-	4.5	-
	219 Cardiac valve & oth maj cardiothoracic proc w/o card cath w MCC	26	-	4	-	6.5	-
	233 Coronary bypass w cardiac cath w MCC	26	-	3	-	8.7	-
Totals		765		83		9.2	

Blood Products	DRG	Units	% Change vs Last Month	Patients	% Change vs Last Month	Avg Units Per Pt	% Change vs Last Month
Platelet	003 ECMO or trach w MV 96+ hrs or PDX exc face, mouth & neck w maj O.R.	110	-	11	-	10.0	-
	579 Other skin, subcut tiss & breast proc w MCC	24	-	1	-	24.0	-
	237 Major cardiovascular procedures w MCC or thoracic aortic aneurysm repair	18	-	4	-	4.5	-
	426 Pancreas, liver & shunt procedures w CC	17	-	1	-	17.0	-
	025 Craniotomy & endovascular intracranial procedures w MCC	15	-	3	-	5.0	-
	957 Other O.R. procedures for multiple significant trauma w MCC	11	-	3	-	3.7	-
	219 Cardiac valve & oth maj cardiothoracic proc w/o card cath w MCC	10	-	4	-	2.5	-
	969 HV w extensive O.R. procedure w MCC	9	-	1	-	9.0	-
	082 Traumatic stupor & coma, coma >1 hr w MCC	7	-	1	-	7.0	-
	625 Thyroid, parathyroid & thyroglossal procedures w MCC	7	-	1	-	7.0	-
Totals		228		30		7.6	
FFP	003 ECMO or trach w MV 96+ hrs or PDX exc face, mouth & neck w maj O.R.	93	-	13	-	7.2	-
	927 Other O.R. procedures for multiple significant trauma w MCC	64	-	12	-	5.3	-
	870 Septicemia or severe sepsis w MV 96+ hours	25	-	3	-	8.3	-
	426 Pancreas, liver & shunt procedures w MCC	22	-	3	-	7.3	-
	441 Disorders of liver except malign, cirr,alci heps w MCC	20	-	2	-	10.0	-
	183 Major chest procedures w MCC	19	-	2	-	9.5	-
	025 Craniotomy & endovascular intracranial procedures w MCC	18	-	6	-	3.0	-
	219 Cardiac valve & oth maj cardiothoracic proc w/o card cath w MCC	17	-	4	-	4.3	-
	237 Major cardiovascular procedures w MCC or thoracic aortic aneurysm repair	16	-	5	-	3.2	-
	981 Extensive O.R. procedure unrelated to principal diagnosis w MCC	14	-	2	-	7.0	-
Totals		308		52		5.9	



Intraoperative coagulation-based hemotherapy protocol decreases overall blood utilization with left ventricular assist device implantation

Elena Nedelcu, Igor D. Gregoric, Rajko Radovanovic, Kerry Webb, Yu Bai, Kimberly L. Klein, Biswajit Kar, Pranav Loyalka, Ovidiu Moise, Manish Patel, Nghia D. Nguyen

- Bleeding complications and blood transfusion administration are associated with increased morbidity and mortality after major cardiac surgery.
- We developed an intraoperative algorithm for transfusion support using integrated analysis of functional hemostatic assay results and transfusion triggers.
- No significant post-operative bleeding was observed and there was no need for factor VIIa administration for the first 17 patients.
- The cumulative transfusion rate of our patients was 15.4 units, much lower than the previously published transfusion rates of 37 or 91.3 units.

Getting Paid

1. Hospital energetically works to control blood utilization, but refuses to pay pathologists since they can not conveniently measure benefits.
2. Hospital pays well for taking care of high risk of bleeding patients because surgeons demand it and the service is profitable.

Four Areas of Opportunity

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Emerging role of pathologists in ACO's and patient centered medical homes.

Restructuring Outpatient Laboratory Medicine .

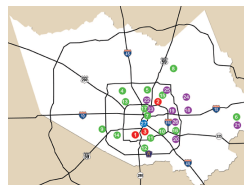
Evidence Based PreConsult Evaluations
Evidence Based Algorithmic Diagnostic Workups

Marylee Kott MD
Lei Chen MD
Semyon Risin MD, PhD
Robert L Hunter MD, PhD

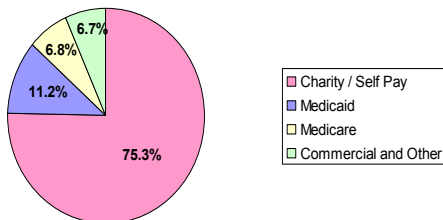


Harris County Hospital District

- 3rd Largest County in the US
- 7500 FTE
- \$1.2 Billion budget (property taxes)
- 3 Hospitals
- 2 Medical Schools
- 44 Site Ambulatory Network
 - >1,000,000 visits annually
 - 10,000 consult / month
 - 10,000 call for appointments per week



HCHD Outpatient Payor Mix



How did we get where we are?

Medicare medical necessity rules were designed to prevent fraud, not to promote efficiency.

- The necessity of justifying every test on every patient is a
 - Huge time waster.
 - Places extraordinary demands on the knowledge of physicians that result in inappropriate tests, consultations, delays and errors.
- Why not produce actionable information, not just numbers?
Order laboratory workups like we order clinical consultations and biopsy examinations?
- HCHD has a bundled payment structure well suited to pioneer better ways of doing things.

Primary Care Physicians Conversations

- **QUESTION:** What would you like differently from laboratories?
 - Faster turnaround time
 - More point-of-care
- **OK, tell me about your day. What are your time wasters?**
- **Laboratory workups.**
 - Test results trickle in over 2 weeks so I must look for them several times, collate them, call the patient back for follow up tests and start over.
 - I frequently order 'everything' to save time.
- **Consults:**
 - I scheduled a patient for a consult in the liver clinic.
 - Six weeks later, he came back with a note that his liver function tests did not qualify him for the clinic.
 - I referred a young woman to the rheumatology clinic for suspicion of Lupus.
 - Six months later, when she finally got an appointment, she had kidney failure.
- Half of my hospitalized patients have AML. They all get a remission, then relapse and die. Help me do better.

Primary Care Physicians Conversations 2

- **Rheumatology Clinic**
 - 180 day wait for new appointments.
 - Over half of new patients do not have conditions that require rheumatologists for treatment.
 - Most of the rest are inadequately worked up at the time of their first appointment.
- **Why does it happen?**
 - The primary care physician frequently does not have time nor the knowledge to work the patients up optimally.
 - The specialists are bogged down with patients they can not help.
- **Conclusions**
 - Movement of patients and information among outpatient providers is frequently chaotic and wasteful.
 - Both primary care and specialist physicians have increasing demands to see more patients in less time.



What does the patient's treating physician want?

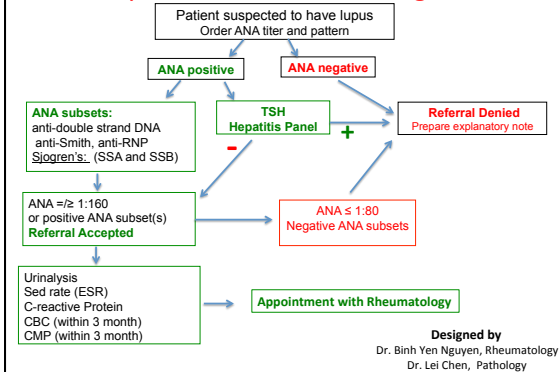
Help!

- Fast and accurate results
- Understandable and useful information
- Direction on therapy

The Deliverables

- **Evidence Based PreConsult Evaluations**
 - Evidence based laboratory workup of patients prior to specialty consultation in hematology, endocrinology, rheumatology, nephrology, etc.
 - Insure that referrals have the appropriate testing done ahead of time.
 - Help specialists see more patients that they can actually help.
 - **Reduce backlog for consultations.**
 - **Help the specialist see patients whom he/she can help.**
- **Evidence Based Algorithmic Diagnostic Workups**
 - Execute a testing algorithm to arrive at the best diagnosis with the fewest tests in the shortest time at the lowest cost.
 - Produce a narrative interpretation that provides actionable evidence based information in addition to numbers.
 - **Facilitates compliance with evidence based workups**
 - **Saves time and office visits for primary care physicians.**

LBJ Lupus/ANA Preconsult Algorithm



Activation of the Rheumatology Pilot Algorithm

- Ask IS to establish an orderable that contains specimen information and a large text box for the results.
- Identify a tech to manually order tests and execute the algorithm.
- Pathologist prepares narrative summary of testing and results that are pasted into the lab computer.
- Begin with patients who are waiting for initial rheumatology appointments.
- Collect data to improve processes and document efficacy.

Benefits

- **Help primary care physicians with diagnostic problems**
 - See patients faster with less anxiety
 - Increased patient satisfaction
- **Help specialty physicians see more patients who they can treat**
 - Less time to order tests, collect, collate and interpret results.
 - Fewer return office visits for diagnostic problems.
- **Reduce diagnostic errors that:**
 - Occur in as much as 15% of cases.*
 - Are responsible for twice as many adverse events as medication errors.**
 - 44% of the diagnostic errors were failure to order, report, process or follow up on results of tests or x-rays.
 - 70% of diagnostic errors have been attributed to**
 - Data gathering (pathology can help)
 - Data Synthesis (pathology can help)
 - Clinical knowledge (pathology can help)

* Diagnostic Errors in Acute Care" Pa Patien Saf advisory 2010 Sept;7(3):76-86.
**Creating a Value-Driven Laboratory: Opportunities in the New Marketplace. G2 Intelligence, 2012

How do we get paid? Clinical Pathology Consultations

A clinical pathology consultation is a service, including a written report, rendered by the pathologist in response to a request from an attending physician in relation to a test result(s) requiring additional medical interpretive judgment.

- 80500 Clinical pathology consultation: limited. without review of patient's history and medical records.
- 80502 comprehensive, for a complex diagnostic problem with review of patient's history and medical record.

Fees 2011		
CPT	RVU	FEE
80500	0.52	\$17.74
80502	1.77	\$61.52

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GEN News Highlights: Jan 10, 2012

Ion Torrent Instrument Designed to Sequence the Human Genome for \$1,000 in One Day



The Ion Torrent Proton will be based on the same semiconductor sequencing technology as the PGM but will include upgraded electronics to handle genome-scale data.

Of course, huge amounts of data will be generated from sequencing an increasing number of human genomes. To deal with the resultant tens or hundreds of millions of data points, Ion Torrent is collaborating with Carnegie Mellon to develop open-source software to assist clinicians in interpreting genetic data.

Clinical Trials Find Success with Use of Next-Generation Gene Sequencing: Could Lead to More Precise Clinical Pathology Laboratory Tests

February 10, 2014

Pathologists and medical lab scientists may do more consults with interdisciplinary teams in connection with biomarker-based phase I clinical trial selection

Major Healthcare Systems Begin Building In-House Whole Human Genome Sequencing Capabilities, Creating New Opportunities for Pathologists

February 5, 2014

Partners HealthCare and Geisinger Health are among health systems making investments and developing the clinical utility of genome sequencing

Foundation Medicine Striving to Use Next-Generation Gene Sequencing to Enrich Diagnostic Value Offered to Physicians by Clinical Laboratories

March 10, 2014

Pathologists will want to understand how this innovative company is doing multi-gene analysis of patient tumors that includes information about therapeutics and clinical trials

FoundationOne
foundationone.com/

FoundationOne is a fully informative genomic profile that helps physicians make treatment decisions for patients with cancer by identifying the molecular growth ...

236 cancer-related genes
 ... 236 cancer-related genes (3,769 exons) plus 47 introns from 19 ...

Test Requisition Form
 Test Ordered* (CHECK ONE BOX), Associated Study ...

Order
 To order FoundationOne or FoundationOne Heme for a ...

Learn More
 Learn more about the Interactive Cancer Explorer, FAQs: Patients ...
[More results from foundationone.com »](http://foundationone.com)

About the test
 About The Test, Foundation Medicine Test: FoundationOne ...

Genes listed. FoundationOne...
 ... in each of the genes listed. FoundationOne Heme is ...

Foundation One Heme™

FoundationOne Heme includes tests for genomic alterations in each of the genes listed. FoundationOne Heme is designed to interrogate the entire coding sequence of 405 genes, selected introns of 31 genes involved in rearrangements and utilizes RNA sequencing to interrogate 265 genes known to be somatically altered in human hematologic malignancies, sarcomas and pediatric cancers based on recent scientific and clinical literature. Reported alterations may indicate response or lack of response to validated targets for therapy (approved or in clinical trials), or may be unambiguous drivers of oncogenesis based on reported scientific knowledge.

DNA Gene List: Entire Coding Sequence (Base Substitutions, Indels, Copy Number Alterations)

ABL1	ACTB	AKT1	AKT2	AKT3	ALK	AMER1 (FAM1123B or WTX)	APC
APH1A	AR	ARAF	ARRFP1	ARHGAP26 (GIMF)	ARID1A	ARID2	ASMTL
ASXL1	ATM	ATR	ATRX	AURKA	AURKB	AXIN1	AXL
B2M	BAP1	BARD1	BCL10	BCL11B	BCL2	BCL2L2	BCL6
BCL7A	BCOR	BCORL1	BIRC3	BLM	BRAF	BRCA1	BRCA2
BRD4	BRIP1 (BACH1)	BRSK1	BTG2 (BTK)	BTLA	c11orf50 (EMY1)	CAD	CARD11
CBF1B	CBL	CCND1	CCND2	CCND3	CCNE1	CCTB	CCZ2
CD274 (PDL1)	CD36	CD58	CD70	CD79A	CD79B	CDC73	CDH1
CDK12	CDK4	CDK6	CDK8	CDKN1B	CDKN2A	CDKN2B	CDKN2C
CEBPA	CHD2	CHEK1	CHEK2	CIC	CIT1	CKS1B	CPS1

What the Competition Offers

Morphoproteomics
 Personalized Cancer Therapy from a slide

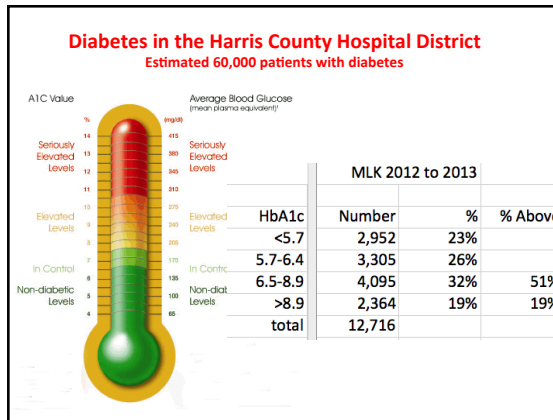
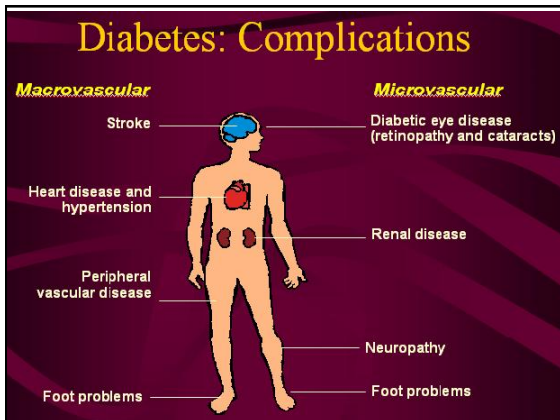
Morphoproteomics relies on immuno-histochemical probes to assess the state of activation of protein analytes through detection of their phosphorylation and/or compartmental translocation within the cells.

Dr. Robert Brown and team

Many talk about personalized therapy of cancer, We do it.

Four Areas of Opportunity

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DIABETES CARE MANAGEMENT

People with diabetes should receive medical care from a team that may include:

- Physicians, nurse practitioners, physician's assistants, nurses, dietitians, pharmacists, mental health professionals.
- HCHD problem includes laboratory logistics
 - 30% of HbA1c ordered tests are never drawn
 - Many others do not get to the physician and patient efficiently.

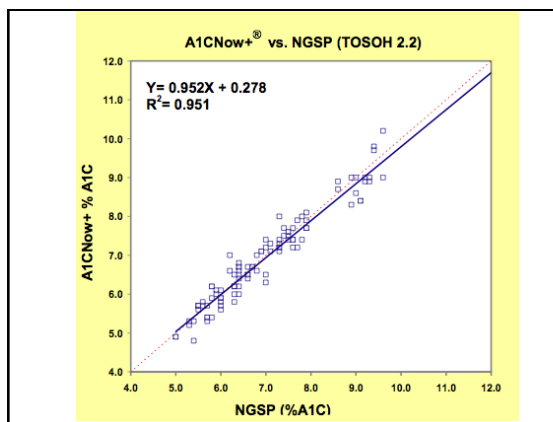
Groups of patients to be screened for DM

The challenge is to identify unsuspected disease

- All patients that walk-in the EC
- Patients over 45 years-old (as a first time visit to their PCPs)
- All pregnant women (OB/GYN consults; in their 1st or 2nd visit)

Physician must get results before seeing the patient

The DCA Vantage Analyzer is a point-of-care immunoassay analyzer for diabetes management for use in the physician office or lab, diabetes care clinic, or POC coordinated site. It provides quantitative test results for HbA1c in whole blood during the patient visit to help improve decision making. With a single urine sample, the analyzer also provides quantitative test results for low levels of Albumin, Creatinine and A:C Ratio in the physician office or clinic.



What will make us successful in the "Golden Age of Diagnostics"

- 1) Talk with responsible parties to find out what troubles them and devise a way to help.
 - Physicians
 - Hospital administrators
 - Clinic Directors
 - Payers
 - Patients
- 2) Master the discipline and tools of medical science and informatics to facilitate development of new services to satisfy emerging needs.
- 3) Find ways to document the value.



- **Don't look to solve problems.**
 - It will only dissipate your energy on secondary issues
- **Seek opportunities**
- **The greatest risk is to take no risks at all.**

Arizona Society of Pathologists



THANK YOU