

Financial Management: Cost Analysis in the Molecular Pathology Laboratory

John Gibson
**Supervisor, Microbiology and
Molecular Pathology**

Goals

- Review growth history in molecular testing
- Identify sources of lab cost
- Calculate test cost per test

Historical Perspective

- **1859 – Charles Darwin**
 - Publishes *On the Origin of Species*
- **1866 – Gregor Mendel**
 - Establishes basic laws of inheritance
- **1869 – J Friedrich Miescher**
 - Extracts DNA from nucleus of cells

Historical Perspective

- **1953 – Watson & Crick**
 - Molecules form double-helix
 - Mechanism of DNA replication
- **1956 – Kornberg**
 - DNA Polymerase
- **1966 – Nirenberg & Khorana**
 - Universal Genetic Code

Historical Perspective

- **1970 – Temin and Baltimore**
 - Reverse Transcriptase
- **1972 – Smith**
 - Restriction Enzymes
- **1977 – Maxim & Gilbert and Sanger**
 - DNA Sequencing

Historical Perspective

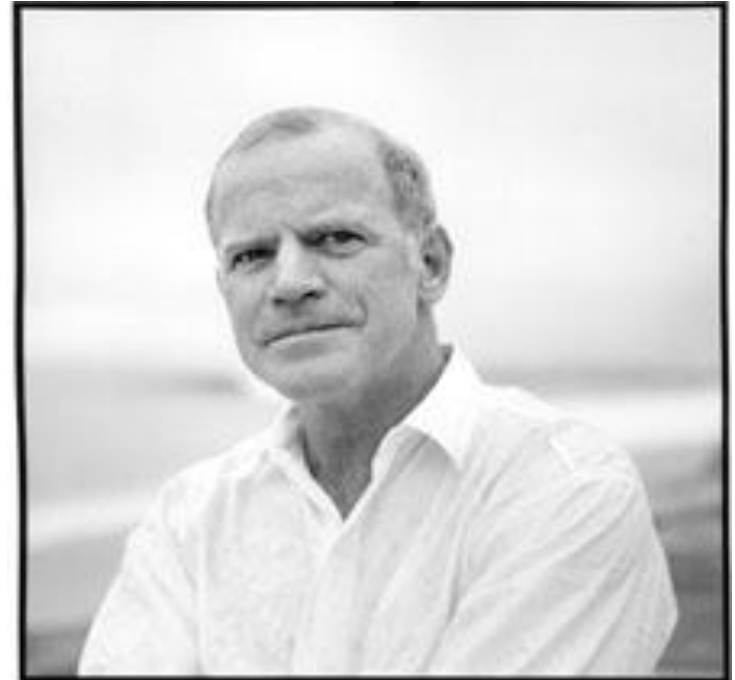


Other Milestones of 1977

Historical Perspective

1983 - Kary Mullis

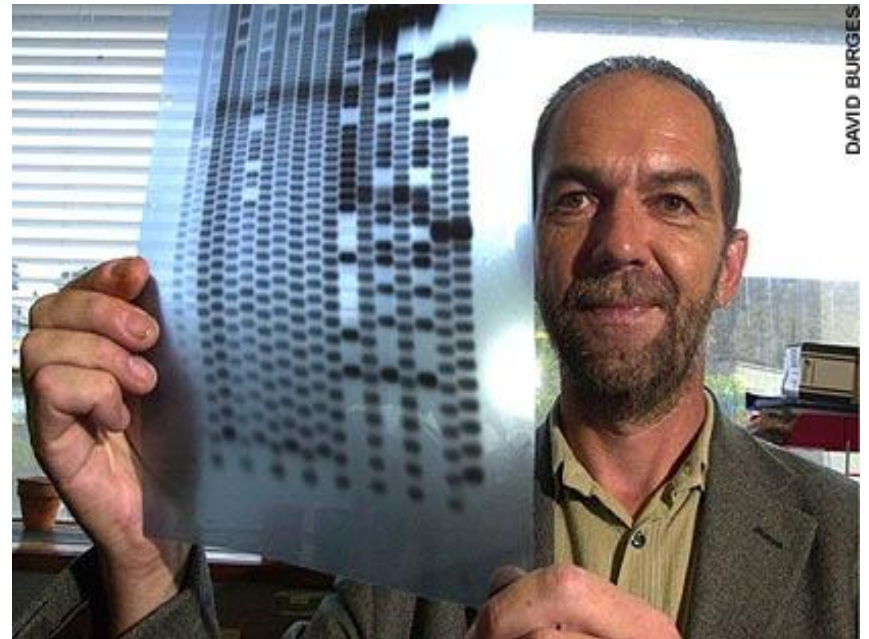
- Conceived and helped develop the first site-specific, cyclic NA amplification chemistry.
- **Polymerase Chain Reaction (PCR)**



Historical Perspective

1984 - Alec Jeffreys

- Introduces DNA fingerprinting
- **1986**: First Molecular HLA Test (DQA1)



Historical Perspective

1988–1992: Molecular ID

(Subsection of the Virology lab)

- HIV
- HSV
- VZV
- CMV
- EBV
- HHV-6
- Parvo
- C. trachomatis
- N. gonorrhoeae
- C. pneumoniae

Staff: Technical Director, 4 Technologists & 1 MLT

Historical Perspective

Molecular Pathology Laboratory

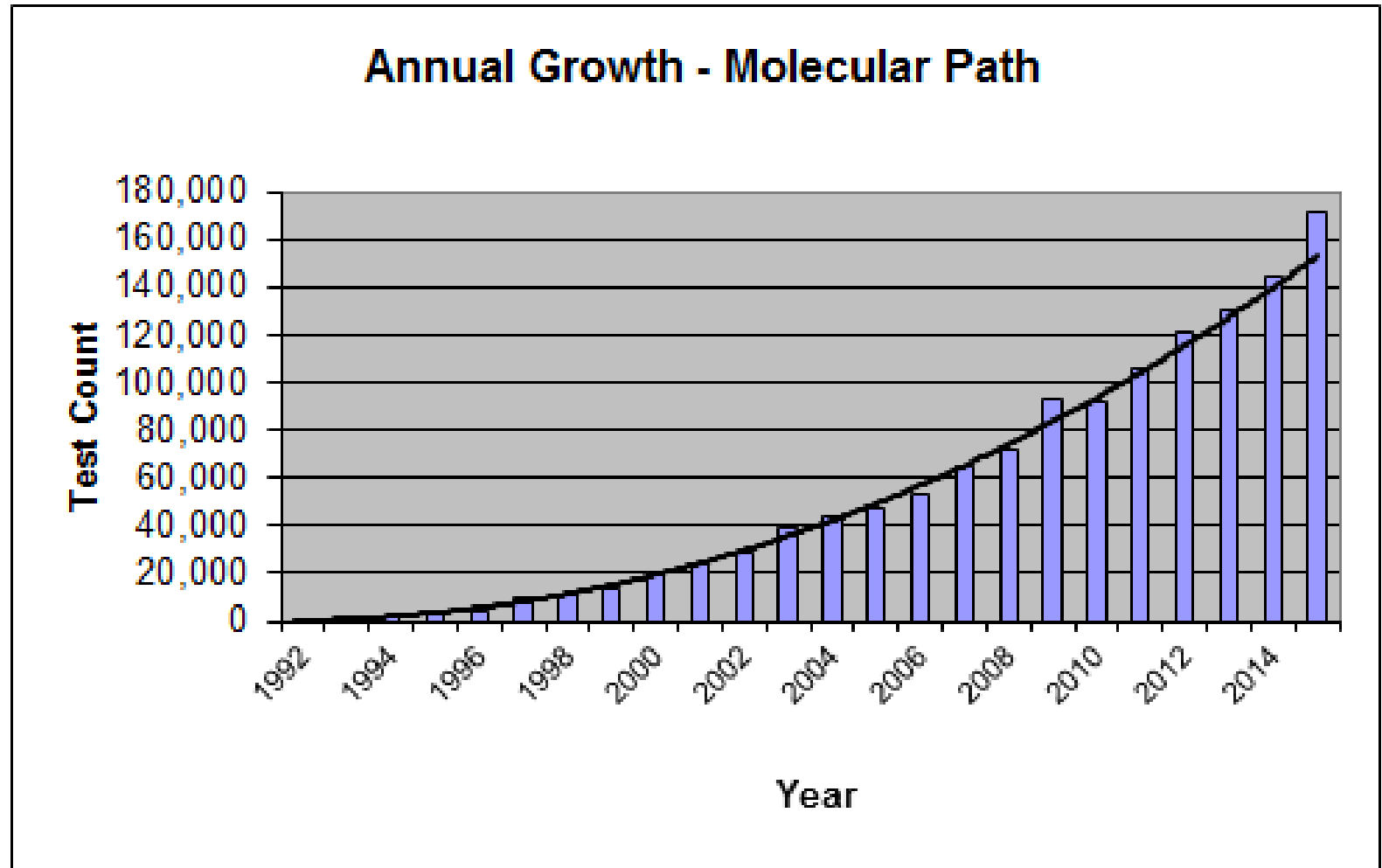
Staff: Medical and Technical Directors & 2 Technologists

<u>Year</u>	<u>Test Volume</u>
● 1992	307
● 1993	550
● 1994	1,747
● 1995	3,604
● 1996	4,472

Historical Perspective

Test	Year Offered
BCR gene rearrangement	1991
B/T cell gene rearrangement	1992
Bcl-2 gene rearrangement	1992
DNA Bank	1992
Fragile X Syndrome	1992
Her-2/neu gene amplification	1993
HCV qualitative	1994
Chlamydia trachomatis	1994
Factor V Leiden	1995
Neisseria gonorrhoeae	1996

Historical Perspective



Molecular Dx at WBH in 2015

Labs performing molecular based tests

<u>Section</u>	~ <u>Annual Volume</u>
– Molecular Pathology	175,000
– Microbiology	35,000
– Blood Bank – HLA	
– AP – Advanced Diagnostics	600
– Cytogenetics	

Validations: How often?

Molecular Validations 2012

- JAK2 Quant (Jan, 2012)
- BCR Quant on 7500 with IS (Feb, 2012)
- Whole Blood extractions on EasyMag (Feb, 2012)
- HBV CAP-Taq (Mar, 2012)
- FV, Pt, MTHFR Invader-Plus IVD (Apr, 2012)
- CYP2C19 Genotyping for Plavix Response (May 2012)
- HIV v2.0 (Aug, 2012)
- APO E by Allelic Exclusion (Aug, 2012)
- Ct/Ng from Thin Prep (Aug 2012)

Validations: How often?

Molecular Validations 2013

- PCA3 Gene Expression GenProbe TMA IVD (Jan 2013)
- CMV DNA Quantitation CAP-Taq IVD (Feb 2013)
- CYP2C9/VKOR1 Genotyping - GenMark e-Sensor (Jun 2013)
- HCV Quant v2.0 (expanded LOD) CAP-Taq IVD (Jun 2013)
- CLL IgVH Sequencing directly from PCR product (Aug 2013)
- HCV Genotyping - GenMark e-Sensor (Sep 2013)
- Mycoplasma pneumonia by NAAT – Meridian (Dec 2013)
- Respiratory Virus Panel – GenMark e-Sensor (Dec 2013)
- N. gonorrhoeae Confirmation – Cepheid GenXpert (Dec 2013)
- CSF Enterovirus by RT-PCR – Cepheid GenXpert (Dec 2013)

Validations: How often?

Molecular Validations 2014

- **SOFT MU-2 LIVE (Mar 2014)**
- **HPV DNA Test on Roche 4800 – (Mar 2014)**
- **Enterovirus by NAA – Validation of NP's (Jul 2014)**
- **B. pertussis by NAAT – Meridian (Aug 2014)**
- **RVP Expanded Targets - (Nov 2014)**
- **CALR Mutation Analysis - (Nov 2014)**
- **HCV Qualitative Detection by CAP-Taq – (Nov 2014)**
- **DNA Extraction from Salyva – (Dec 2014)**

Validations: How often?

Molecular Validations 2015

- MTb Detection by NAA on Cepheid GeneXpert (Mar 2015)
- **SOFT MU-2 LIVE (Mar 2014)**
- Group A Strep Detection by NAA on 7500 (May 2015)
- JAK2 Exon 12 Mutation Detection (July 2015)

Why add a new test?

- Adding new tests
 - Clinical necessity
 - Availability of new technology or clinically relevant target
 - Perceived value to the organization

Why change an existing test?

- Change a target or methodology
 - **Process improvement**
 - Decrease TAT
 - Add automation
 - Improve Sensitivity, specificity, LOD, range, etc
 - **Manufacturing issues**
 - Product revision
 - Equipment / software changes
 - Quality assurance issues
 - Product discontinuation

Financial Analysis....

Cost

Financial Analysis....

- **Cost Analysis** is the examination of factors that influence the cost of performing an individual procedure.
- Does NOT typically include the cost of evaluating, validating or verifying the new test
(These costs are evaluated in annual budget performance review of the section)

Why do a cost study?

- Existing tests
 - Understand and monitor the cost of service
 - Monitor trends to forecast budget needs
 - Use as a metric for process improvement
 - Set fees for clients/patients
- New tests or Methodologies
 - Select the most appropriate tests for evaluation

When to do a cost study?

- Before the decision has been made to make a change.
- Before evaluating new protocols, reagents or equipment.
- At least annually for existing assays.

Expense Categories

- Overhead
- Indirect Costs
- Direct Costs

Overhead

- Administration
- Building/ facilities/ utilities
- Client services
- Client supplies
- Couriers/ logistics
- Human resources
- Information Systems
- Telephone Services
- Finance Department
- Marketing/ Sales Department

These are considered “fixed” costs and **not** generally included in a labs cost analysis.

Indirect Costs

- Supervisor salary
- QC and QC personnel
- Expenses for proficiency testing program
- Instrument lease and expenses
- Equipment purchase
- Personnel
- Test validation / verification costs

These **are** generally considered in the labs cost analysis
Typically estimated and factored in as a percentage

Direct Costs

- Cost of reagents and consumable supplies, calibrators and controls.
- Hands-on labor to perform the assay including daily instrument set-up.
- Cost of repeat and confirmatory testing.

These **are** figured into the labs cost analysis.
Calculated by quantitative measurement.

Financial Analysis....

Revenue... ??

Other Considerations

- Government – Insurance - Patient
- Payer Mix
- Inpatient – Outpatient – Outreach
- CPT - DRG

Reimbursement

CMS

- The Centers for Medicare & Medicaid Services (CMS) is an agency within the US Department of Health & Human Services responsible for oversight of:
 - Medicare & Medicaid
 - Children's Health Insurance Program (CHIP)
 - HIPPA
 - EHR
 - Meaningful Use
 - **DRG and CPT Coding**

Reimbursement

DRG codes

- Diagnostic Related Group
 - a statistical system of classifying any inpatient stay into groups for the purposes of payment.
- Factors used to calculate:
 - Severity
 - Risk of mortality
 - Prognosis
 - Treatment difficulty
 - Need for intervention
 - Resource intensity

Reimbursement

CPT codes

- Current Procedural Terminology (CPT) is a code set that is used to report medical procedures and services to entities such as physicians, health insurance companies and accreditation organizations.
- CPT is used in conjunction with ICD-9/10 numerical diagnostic coding during the electronic medical billing process.

Reimbursement

CPT 2013

87512	Gardnerella vaginalis, quantification
87515	hepatitis B virus, direct probe technique
87516	hepatitis B virus, amplified probe technique
87517	hepatitis B virus, quantification
87520	hepatitis C, direct probe technique
87521	hepatitis C, reverse transcription and amplified probe technique

Financial Analysis....

COST per Report

Cost Analysis

- Basic Information to gather:
 - Approximate test volume
 - Run frequency
 - Ave batch size
 - Estimated annual test growth
 - Equipment required
 - Technology options
 - Shared technology / platform

Cost Analysis

- Additional Information to gather:
 - Equipment, Instrumentation, Software Cost
 - If purchased – lease – “Reagent rental”
 - Service contract cost
 - Kit and/or Reagent Cost
 - Differs depending on equipment contract
 - Consumables Costs
 - Controls cost/run
 - CPT Coding and Reimbursement (Payer mix)

Cost Analysis

Direct Cost - Labor

- Manufacturer's estimates are generally low
- Must consider productive vs non-productive "away" time
- Include all necessary labor
 - Specimen pick-up
 - Accessioning / log-in
 - In lab processing and storage
 - Run review and result entry
 - Supervisor or Pathologist review and sign-out

Cost Analysis – Other Considerations

- **QC / QA / QI**
 - Review the CAP Molecular Pathology Checklist
 - Validation
 - Proficiency
 - Competency
 - Contamination Surveillance & Control

Cost Analysis – Direct Costs

VZV Cost analysis - May 2013			
EZ Mag Extraction			\$8.88
	Cost	Rxn / Kt	Cost/rxn
Lightcycler capillary	\$330.00	480	\$0.69
10uL tip	\$59.50	960	\$0.06
100uL tip	\$59.50	960	\$0.06
DI water	\$3.00	33333	\$0.00
Fastart Kit	\$715.50	440	\$1.63
UNG	\$142.00	200	\$0.71
VZV Forward Primer	\$15.00	100	\$0.15
VZV Reverse Primer	\$15.00	100	\$0.15
VZV 640 Probe	\$360.00	48	\$7.50
VZV FI Probe	\$120.00	48	\$2.50
Reagent / Consumable cost per rxn			\$22.33
	Total		
QC: Pos + Neg	2 Rxns		
	Cost/Hr	Hr	Total
Labor	30	1	\$30.00

Cost Analysis – Impact of Batch Size

- VZV by PCR

# Pts	# Cntrls	Rxns	Rgnt Cost per Rxn	Total Rgnt Cost	Labor Cost	Total	Per
1	2	3	\$22.33	\$66.98	\$30.00	\$96.98	\$96.98
3	2	5	\$22.33	\$111.64	\$10.00	\$121.64	\$40.55
5	2	7	\$22.33	\$156.29	\$6.00	\$162.29	\$32.46
7	2	9	\$22.33	\$200.95	\$4.29	\$205.23	\$29.32
9	2	11	\$22.33	\$245.60	\$3.33	\$248.94	\$27.66
11	2	13	\$22.33	\$290.26	\$2.73	\$292.99	\$26.64
13	2	15	\$22.33	\$334.92	\$2.31	\$337.22	\$25.94
15	2	17	\$22.33	\$379.57	\$2.00	\$381.57	\$25.44

Cost Analysis – Equipment Purchase

- Entero by PCR
 - ~300 tests per year

Equipment:	(Cepheid Quote #QA13506 of 9/17/12)	Purchase price
GenExpert IV R2 2 Module Config w/Desktop PC		40796.00
b/w Printer		250.00
UPS		995.00
2 x 10 rxn install kits	"@ \$648.60 / ea"	1297.20
	Total	\$ 43,338.20
* Equip Purchase cost / report		
Amortized over 5 yr at 10% annual growth		\$ 28.38

Cost Analysis – Service Contracts

Cost Analysis for Cepheid Enterovirus - **EXCLUDING Labor and Controls**

Cat #	Description	List Price	Rxns / Kit	Cost per Extr
GXEV-100N-10	Entero kit	\$ 690.00	10	\$ 69.00
Cost/Rpt (Excluding equipment, labor, controls or repeats)				\$ 69.00
Equipment purchase cost/Rpt *				\$ 28.38
Equipment Service cost/Rpt*				
	Cost	Rxns / Yr	\$ / Rpt	Cost / Rpt
Yr 1 Service	Warranty	250	\$ -	\$ 97.38
Yr 2 service	\$ 5,075.60	275	\$ 18.46	\$ 115.84
Yr 3 service	\$ 5,075.60	303	\$ 16.75	\$ 114.13
Yr 4 service	\$ 5,075.60	333	\$ 15.24	\$ 112.62
Yr 5 service	\$ 5,075.60	366	\$ 13.87	\$ 111.25

Cost Analysis - Example

PSA mRna Rack	Rack of 100 tubes (40 patients)		Tubes		PCA3 Rack	Rack of 100 tubes (40 patients)		Tubes
Calibrators	5	Triplicate	15		Calibrators	5	Triplicate	15
Controls	2	Duplicate	4		Controls	2	Duplicate	4
Specimens	40	Duplicate	80		Specimens	40	Duplicate	80
Total Tubes			99		Total Tubes			99
10% Out o	4				10% Out o	4		
Net Specir	36				Net Specir	36		

Cost Analysis - Example

A	B	C	D	E	F	G	H	I
Wm Beaumont Hospital - Molecular Pathology GenProbe ProgenSA PCA3 IVD Cost Analysis - 2012								
First Run of Kit		Total available Rxns →		200			# Rpts/Wk	\$/Rpt
							1	\$1,400
Sample	Number	# of Replicates	PSA	PCA3	Total Rxns		2	\$700
Patients / run	1	840	2	2	4		3	\$467
Calibrators / run	5	Triplicate	15	15	30		4	\$350
Controls / Run	2	Duplicate	4	4	8		5	\$250
				Total Rxns	42			
Second Run of Kit		Total available Rxns →		158				
Sample	Number	# of Replicates	PSA	PCA3	Total Rxns			
Patients / run	1	Duplicate	2	2	4			
Calibrators / run	5	Triplicate	15	15	30			
Controls / Run	2	Duplicate	4	4	8			
				Total Rxns	42			
Third Run of Kit		Total available Rxns →		116				
Sample	Number	# of Replicates	PSA	PCA3	Total Rxns			
Patients / run	1	Duplicate	2	2	4			
Calibrators / run	5	Triplicate	15	15	30			
Controls / Run	2	Duplicate	4	4	8			
				Total Rxns	42			
							Kit cost/report	
							\$1,400.00	

Cost Analysis - Example

Wm Beaumont Hospital - Molecular Pathology							
GenProbe ProgenSA PCA3 IVD Cost Analysis - 2012							
First Run of Kit		Total available Rxns →		200		# Rpts/Wk	\$/Rpt
Sample	Number	# of Replicates	PSA	PCA3	Total Rxns	1	\$1,400
Patients / run	3	840	6	6	12	2	\$700
Calibrators / run	5	Triplicate	15	15	30	3	\$467
Controls / Run	2	Duplicate	4	4	8	4	\$350
				Total Rxns	50	5	\$250
Second Run of Kit		Total available Rxns →		150			
Sample	Number	# of Replicates	PSA	PCA3	Total Rxns		
Patients / run	3	Duplicate	6	6	12		
Calibrators / run	5	Triplicate	15	15	30		
Controls / Run	2	Duplicate	4	4	8		
				Total Rxns	50		
Third Run of Kit		Total available Rxns →		100			
Sample	Number	# of Replicates	PSA	PCA3	Total Rxns		
Patients / run	3	Duplicate	6	6	12		
Calibrators / run	5	Triplicate	15	15	30		
Controls / Run	2	Duplicate	4	4	8		
				Total Rxns	50		
						Kit cost/report	
						\$466.67	

Questions

Thank you!