Managing information flow in the molecular diagnostics laboratory

~The oncology perspective & adventures with Soft Computing

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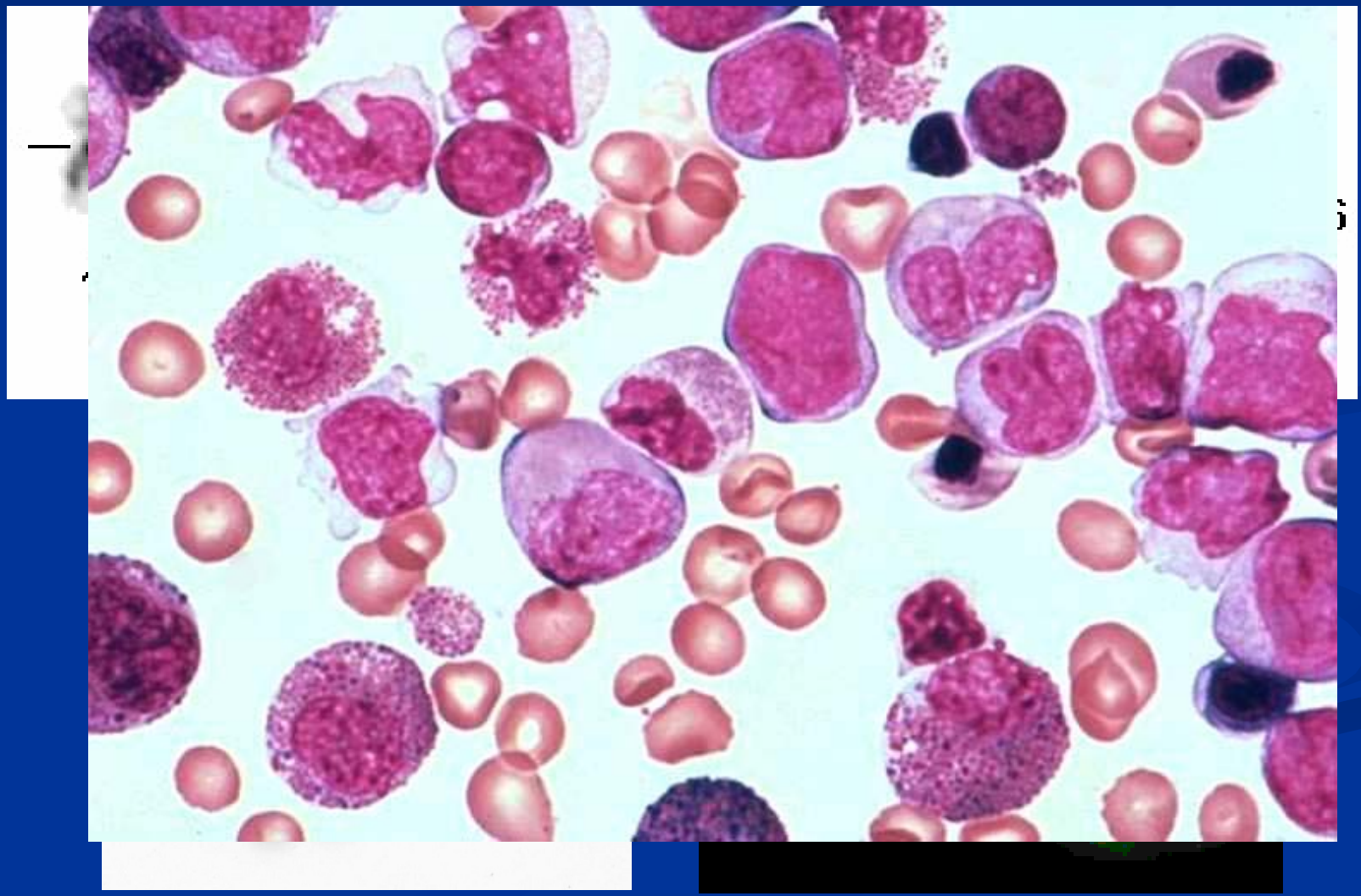
Disclosures:
Agilent
Ambion Diagnostics (Asuragen)
Biotage
Novartis
SCC

AML-M4Eo: inv16 (CBFb:MYH11)

Old school molecular diagnostics



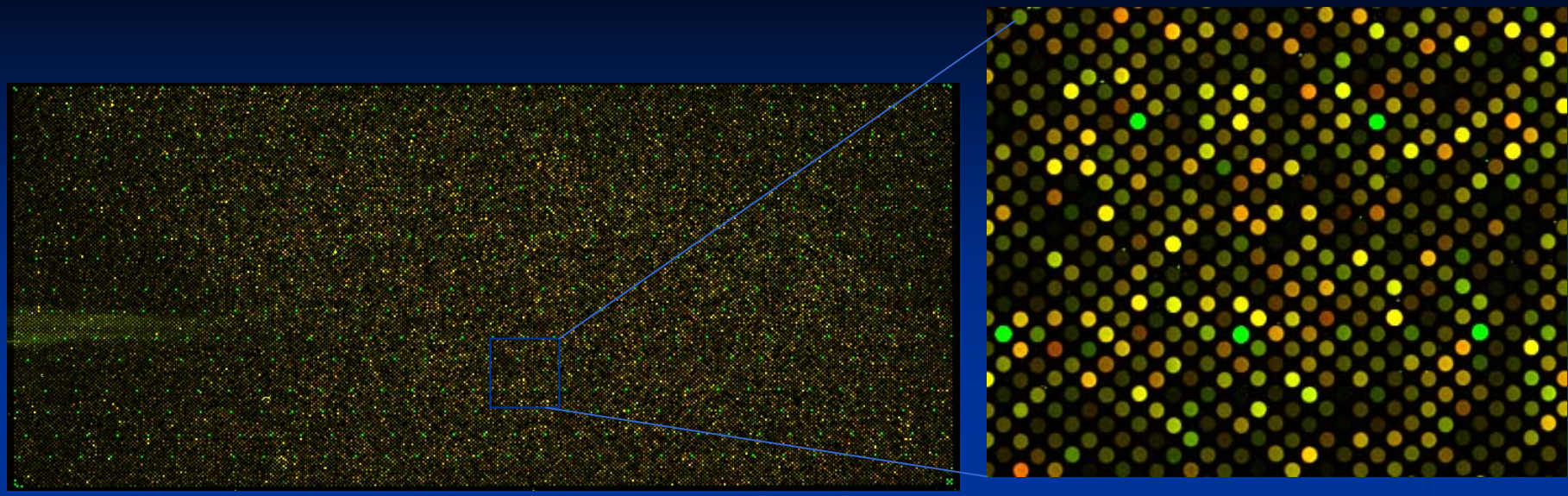
Not so simple anymore…
Goals of molecular testing in oncology

- **Germline testing**
  - *Cancer risk prediction (inherited susceptibility)*
  - *Pharmacogenetics (polymorphisms in drug metabolizing genes)*
- **Diagnostic assays**
- **Prognostic assays**
- **Diagnostic and prognostic assays**
- **Diagnostic and minimal residual disease monitoring**
- **Therapeutic response predictors**
  - *Pharamacogenomics (how an individual tumor might respond)*

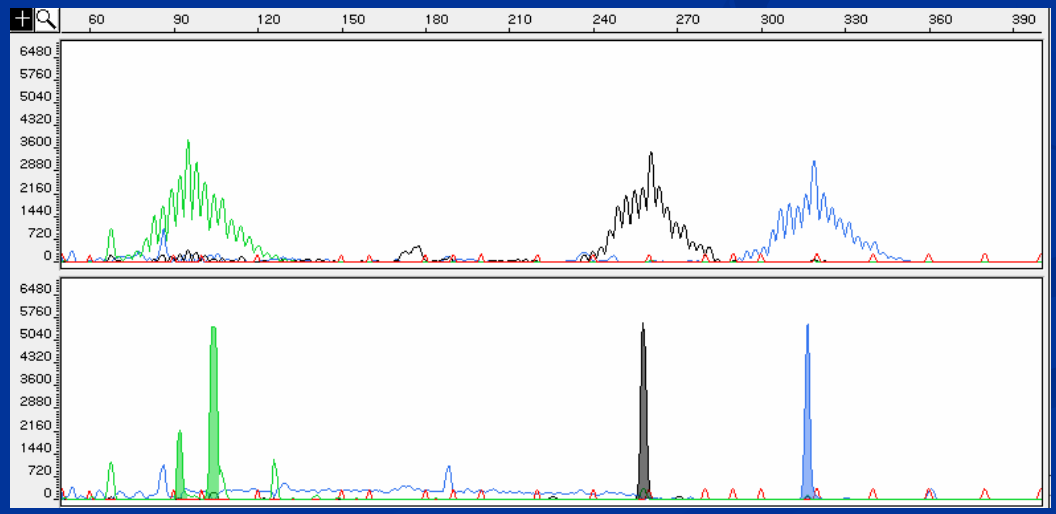
Always changing…

M. D. Anderson molecular oncology test panel

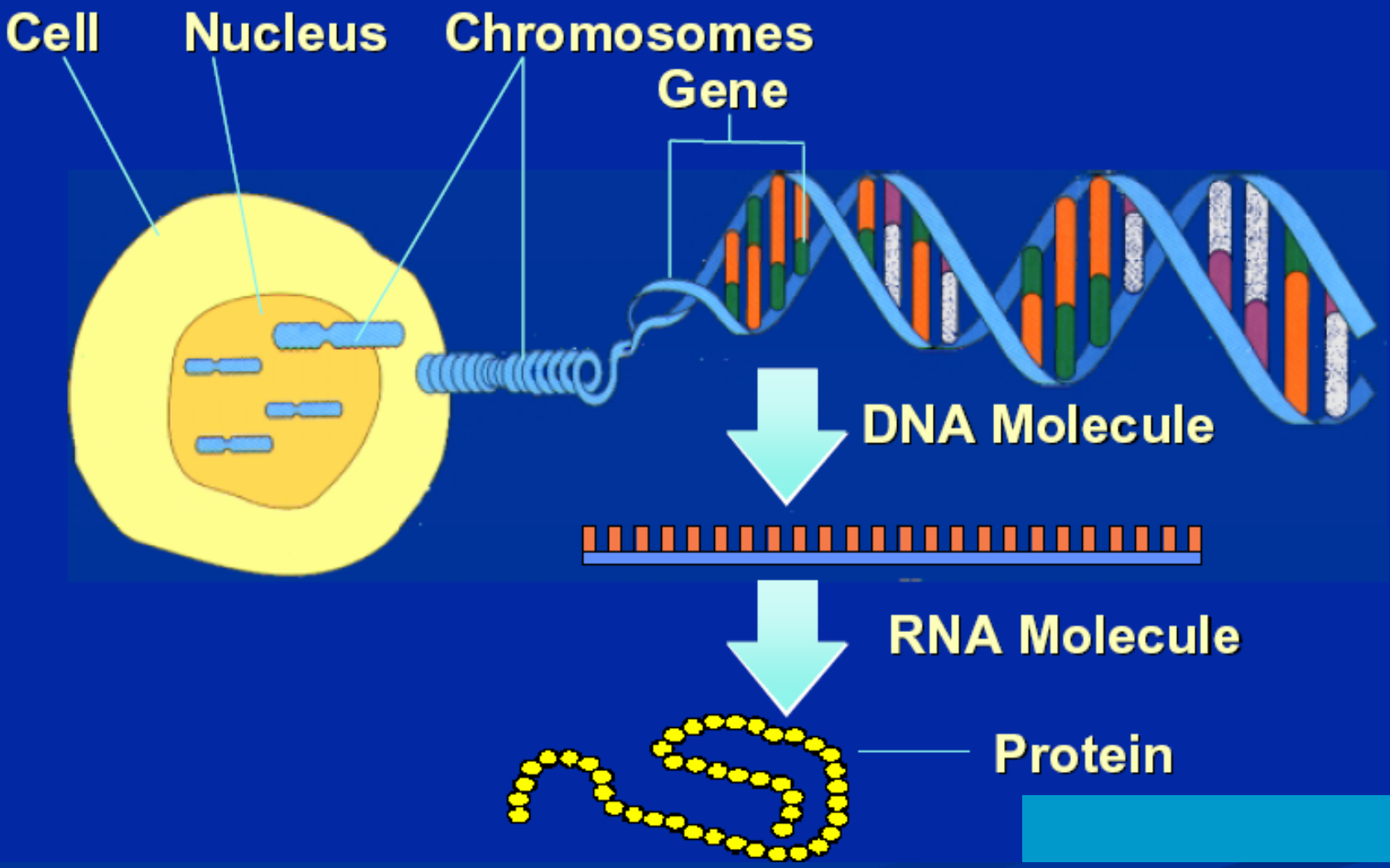
- Leukemia
  - AML1-ETO/t(8;21), RNA-PCR & quant
  - BCR-ABL, quantitative PCR & competitive PCR
  - BCR-ABL, mutational analysis, sequencing
  - BCR-ABL MUTATION, QUANT
  - CBFb-MYH11/inv16, RNA-PCR & quant
  - FIP1L1-PDGFR (hypereosinophilic syndrome/mast cell disease), RNA-PCR
  - FLT3 mutational analysis, PCR
  - JAK2 mutational analysis, quant sequencing
  - PML-RARA/t(15;17), RNA-PCR & quant
  - Somatic hypermutation analysis, IGH/CLL, sequencing
  - KIT mutational screening (mast cell disease/leukemia)
  - Acute leukemia translocation panels
- Lymphoma
  - BCL1/cyclin D1/t(11;14), PCR
  - BCL2/t(14;18), quantitative PCR
  - IgH Gene rearrangement, PCR
  - NPM-ALK/t(2;5) (ALCL), PCR
  - T-cell clonality (TCR-gamma), PCR
  - T-cell receptor beta spectrotyping
- Solid tumors
  - 18q LOH (colon cancer), PCR
  - BRAF mutational analysis (mel,GI, lung), sequencing
  - EGFR mutational analysis (lung), sequencing
  - 1p19q LOH (glioma), quantitative PCR
  - Microsatellite instability (GI, Gyn), PCR
  - MLH1 methylation, PCR (hereditary colon)
  - KRAS mutational analysis (mel,GI, lung), sequencing
  - KIT mutation (sarcoma)
  - MGMT methylation, PCR (gliomas)
  - UGT1A1 polymorphism
- Transplant
  - Chimerism analysis (post-transplant), with lineage-specific cell sorting for T and Myeloid cells, Post Transplant
  - Microchimersism analysis
  - HLA-A, B, C, DR/DQ/DP
  - KIR genotyping



Types of molecular information



PCR FISH RT-PCR Southern blot SNP typing



SKY MS-MS CGH CISH

ELISA cDNA array Sanger sequencing G- banding

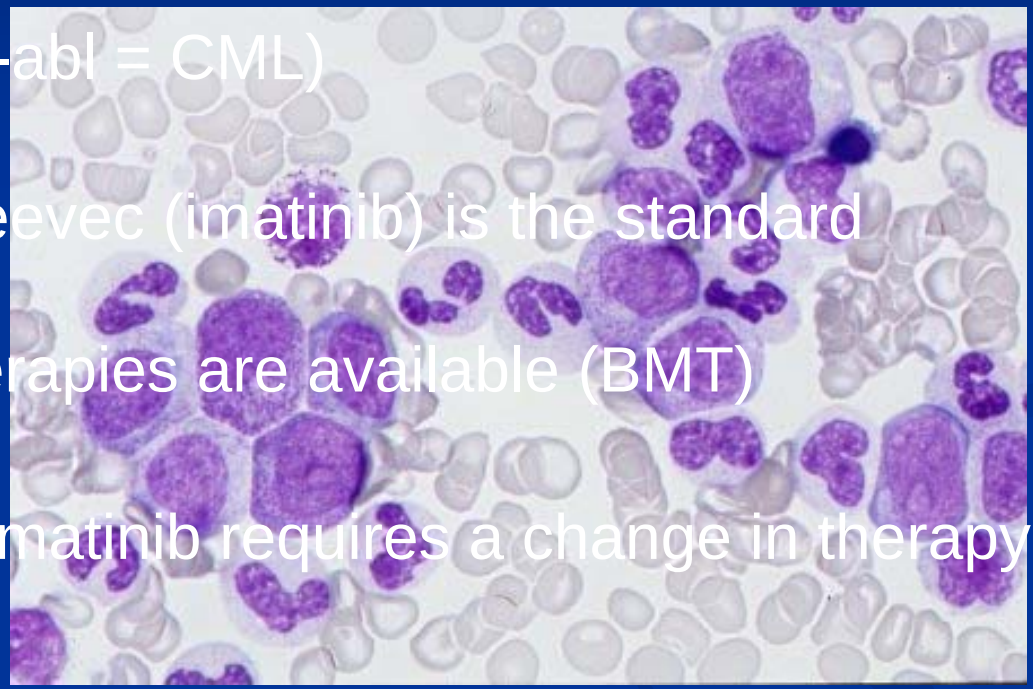
The model disease: Chronic myelogenous leukemia (CML)

Molecular definition (bcr-abl = CML)

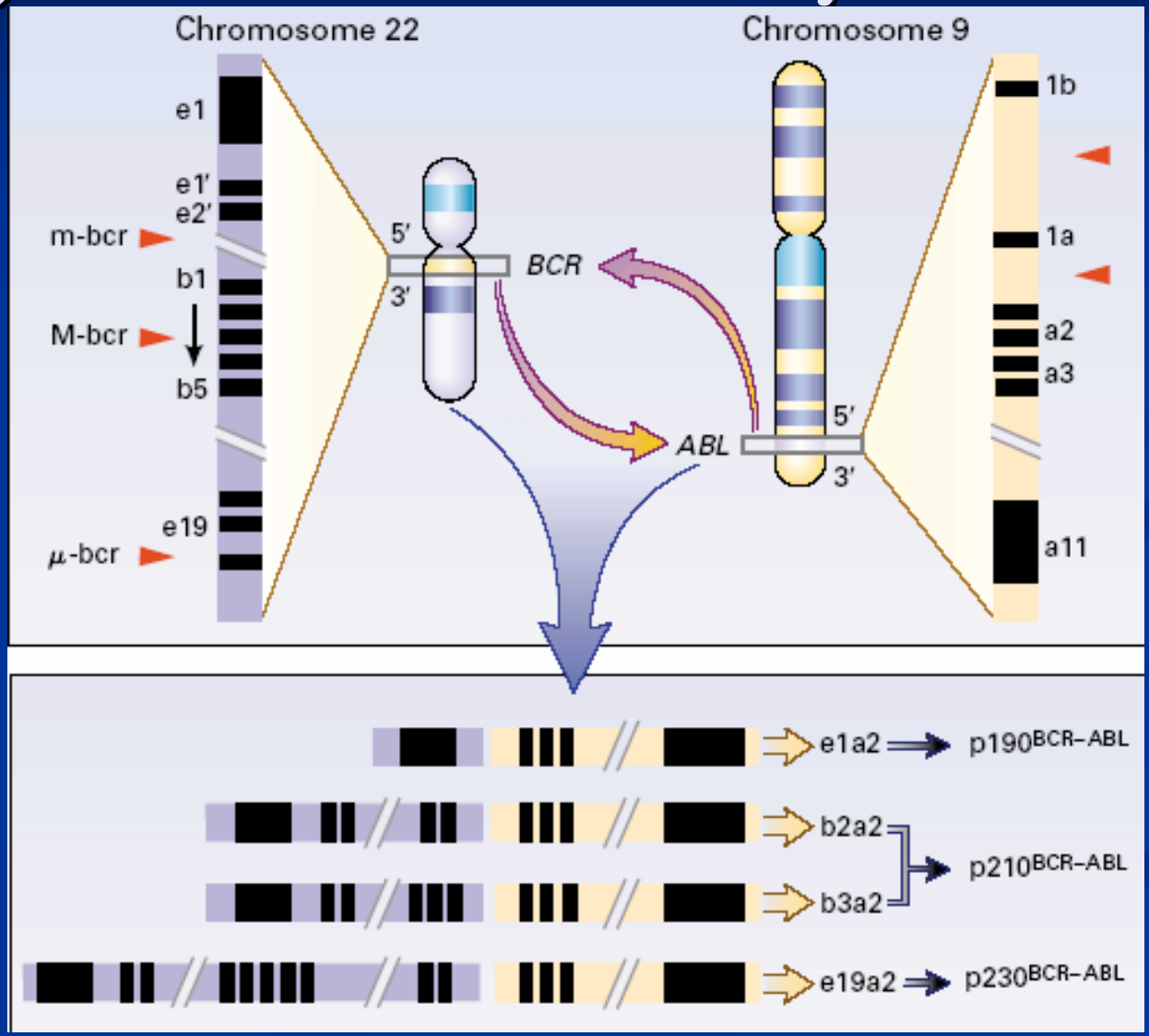
Monotherapy with Gleevec (imatinib) is the standard

Other (curative) therapies are available (BMT)

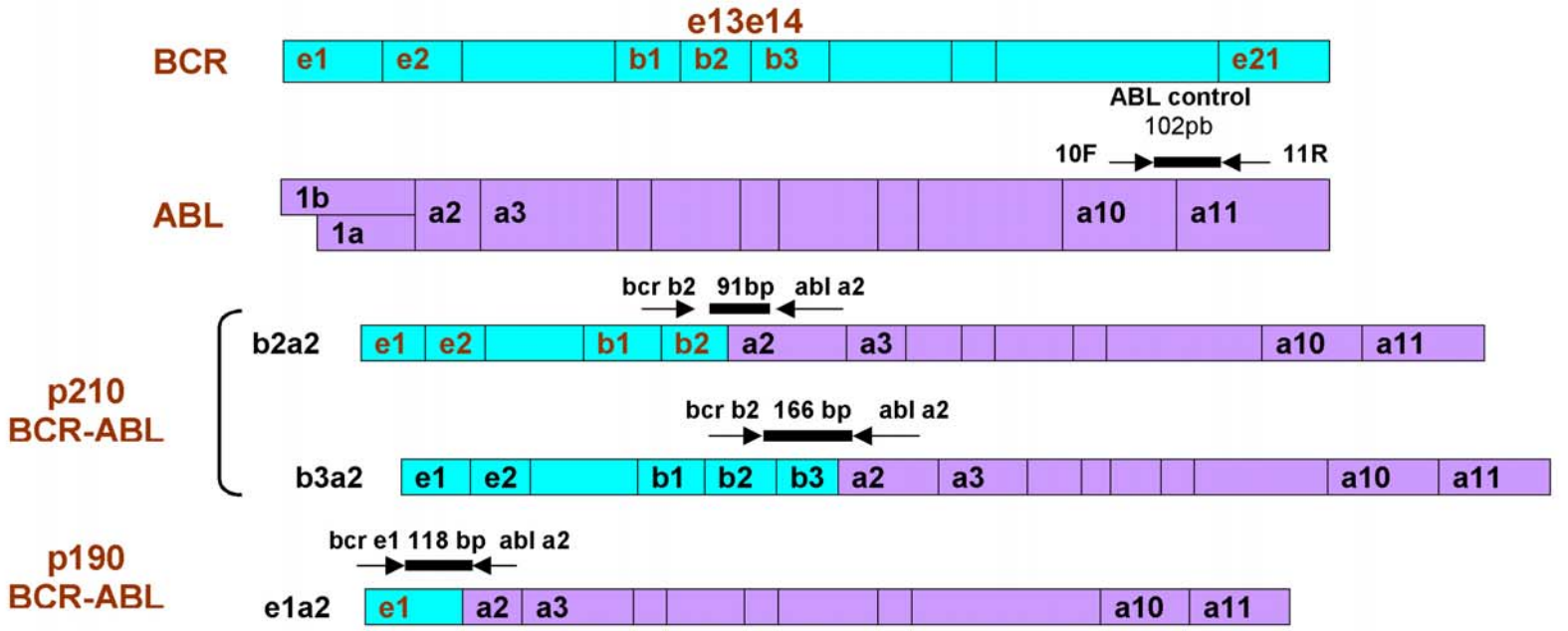
Resistance to imatinib requires a change in therapy



CML = Philadelphia chromosome = t(9;22) = chimeric bcr-abl tyrosine kinase



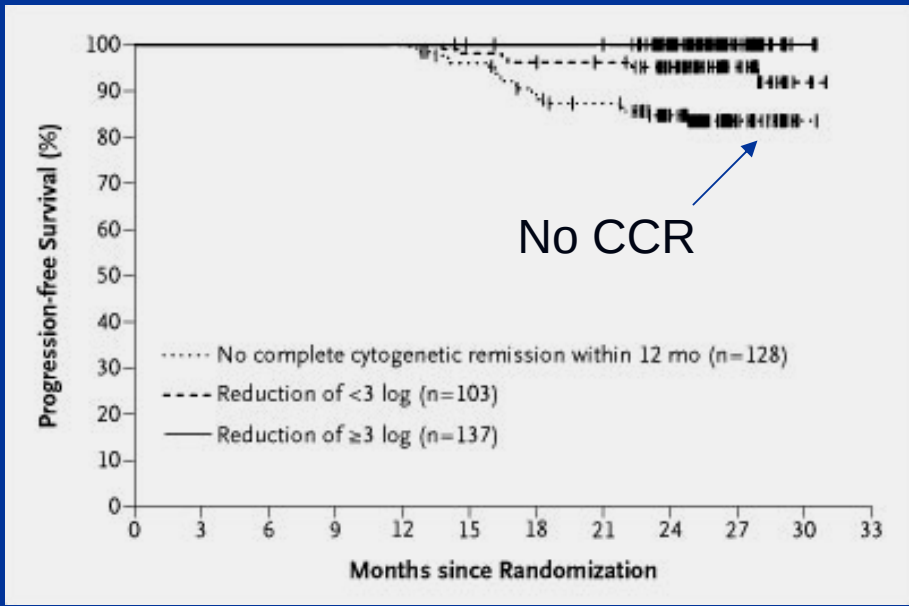
Quantitative RT-PCR for bcr-abl



1. Single tube assay (10 ml PB, 3 ml BM aspirate)
2. Samples run in duplicate
3. TaqMan probe detection (1;100,000 lower limit)
4. Post-PCR sizing to detect transcript type

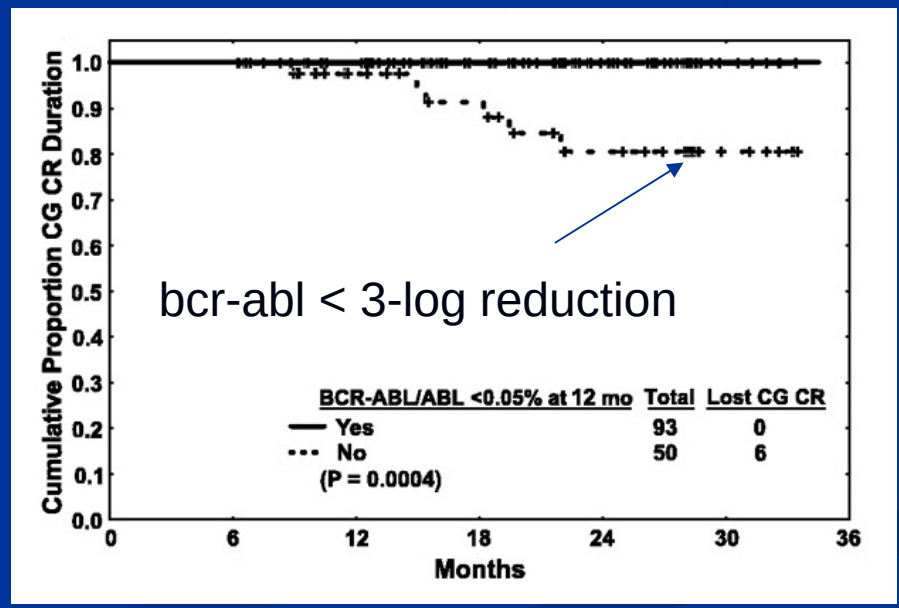
Molecular monitoring to assess effects of imatinib

- Failure to achieve 3-log or 4-log fold reduction from **baseline** in bcr-abl transcript levels within 6 months, as assessed by quantitative reverse transcription PCR (RT-qPCR), identified those at risk for resistant disease



IRIS Trial

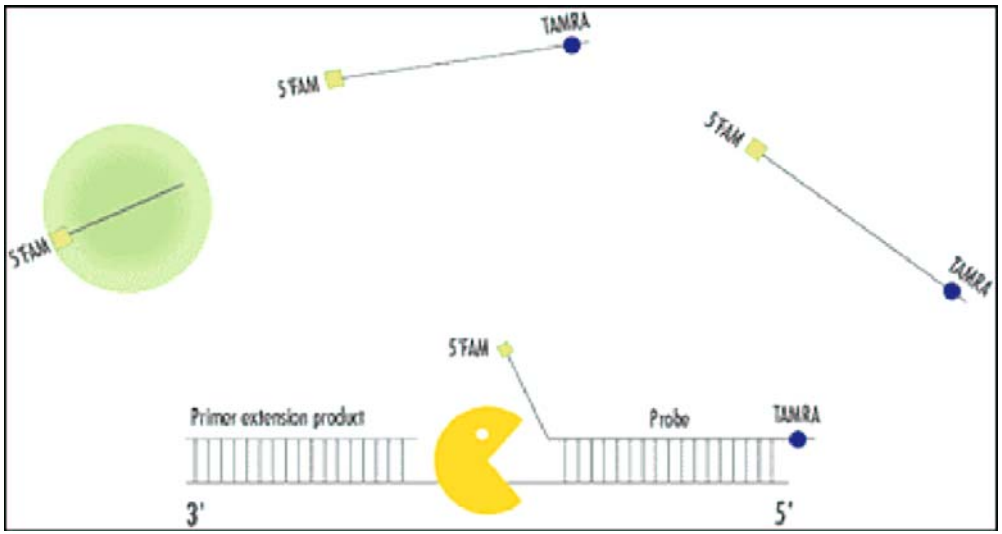
NEJM (2003) 349:1423



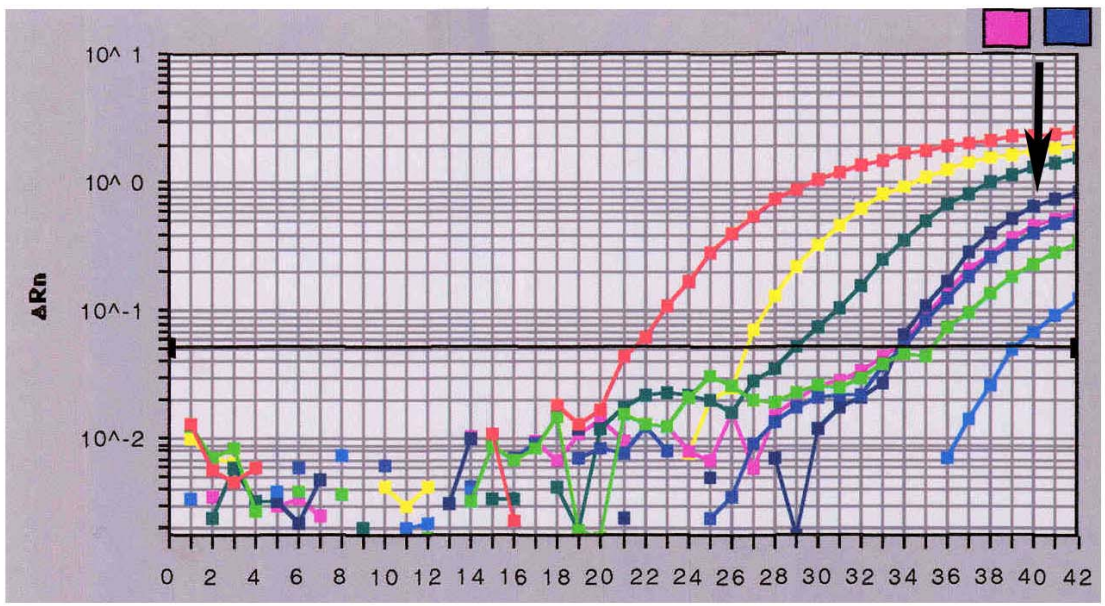
MD Anderson cumulative experience

Clin Cancer Res (2005) 11:3425

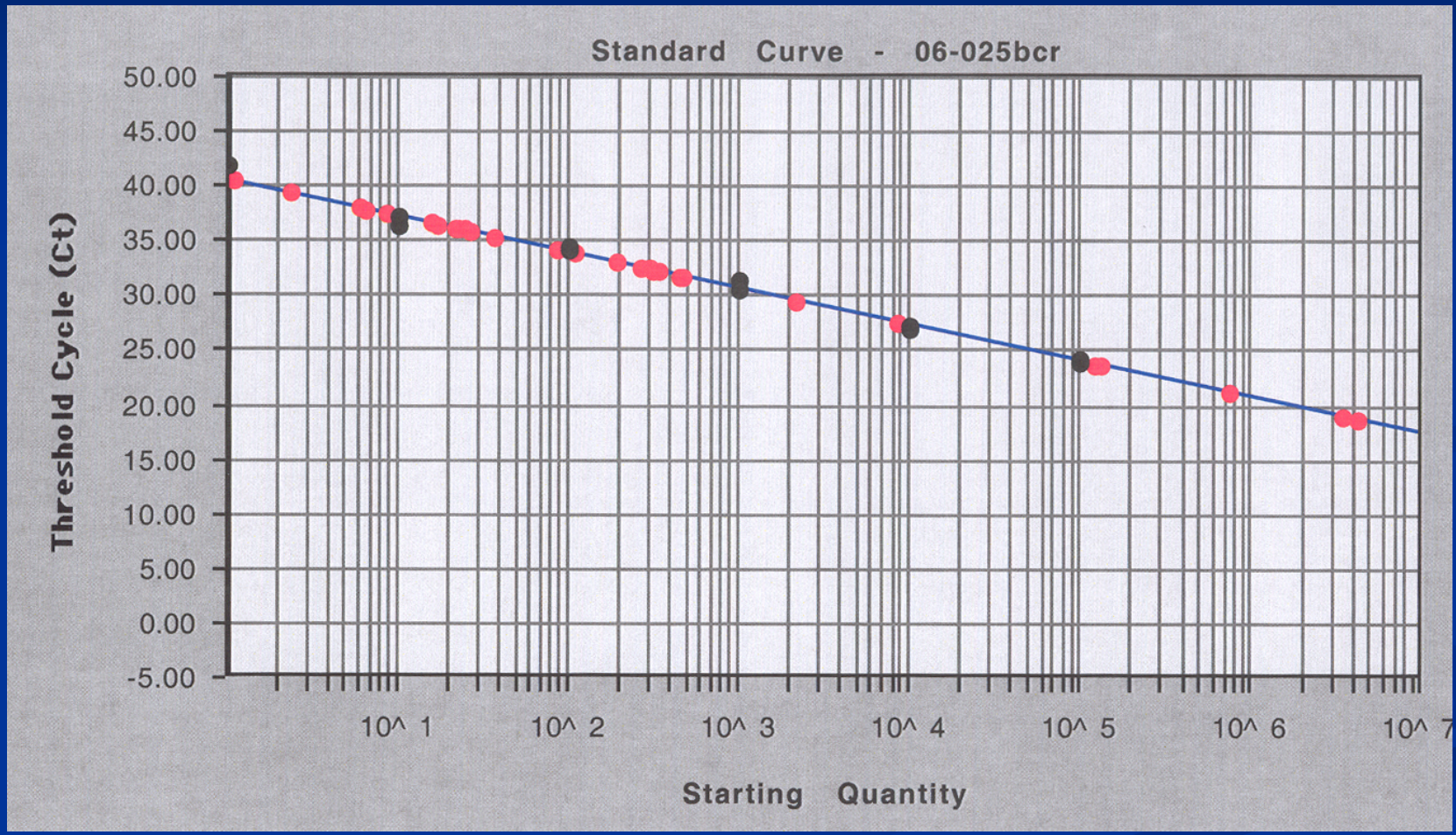
Step 1. Run quantitative PCR with samples and standards on each run



TaqMan chemistry (ABI)
- Primers
- Probe(s) with reporter & quencher fluorochromes
- Hydrolysis of reporter by Taq polymerase

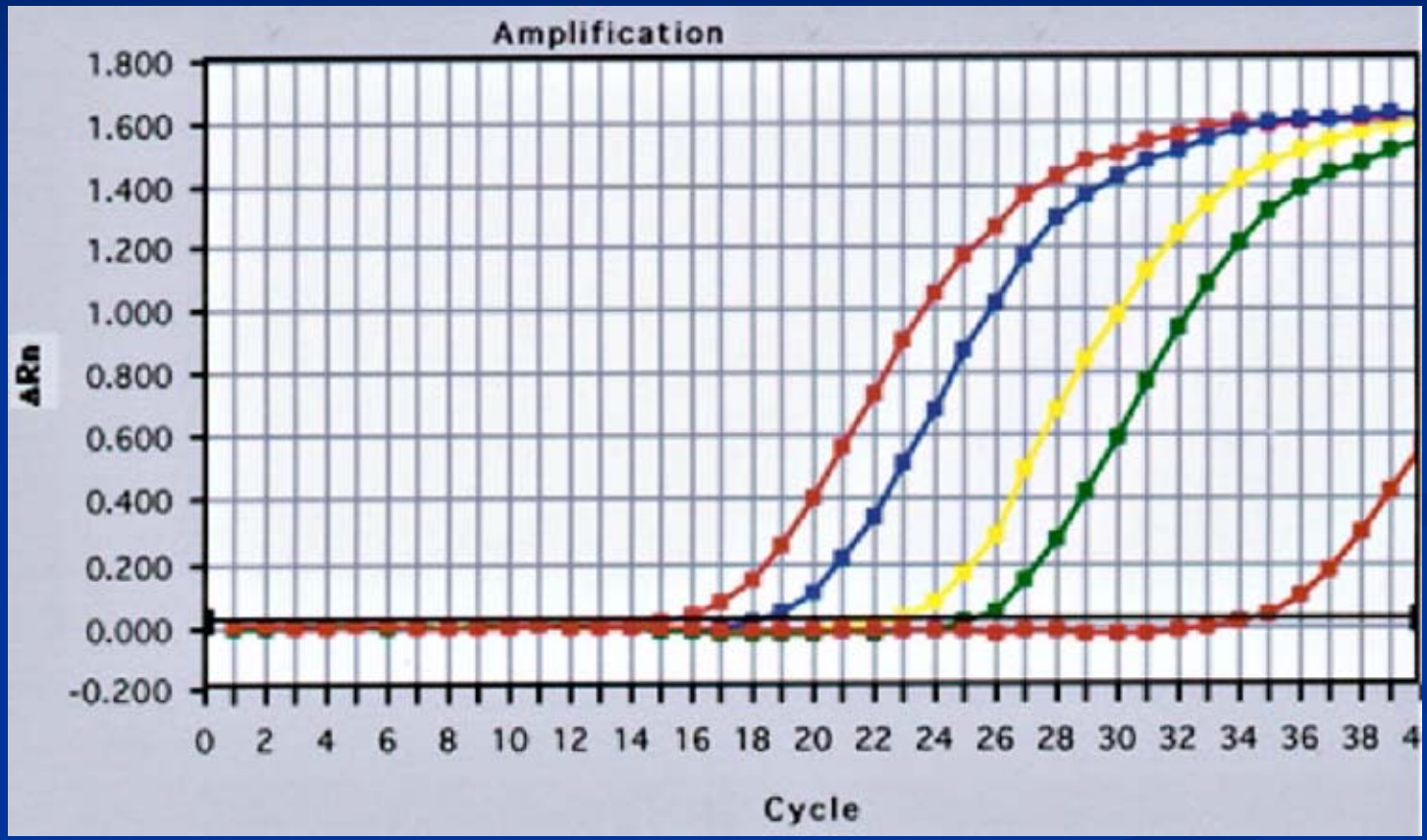


Step 2. Derive absolute copy number by plot of C_t vs. log (control amt)



…reject if variables fall outside the acceptable range

Step 3. Run a normalizing to control for input cell number



Metrics on a range of normalizing genes may be required

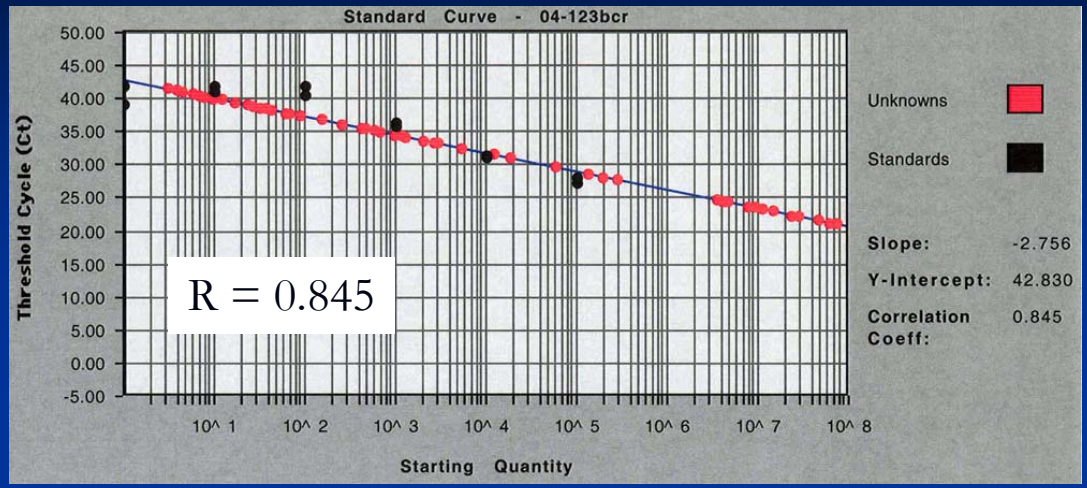
- Transcript stability, cell range, expression level

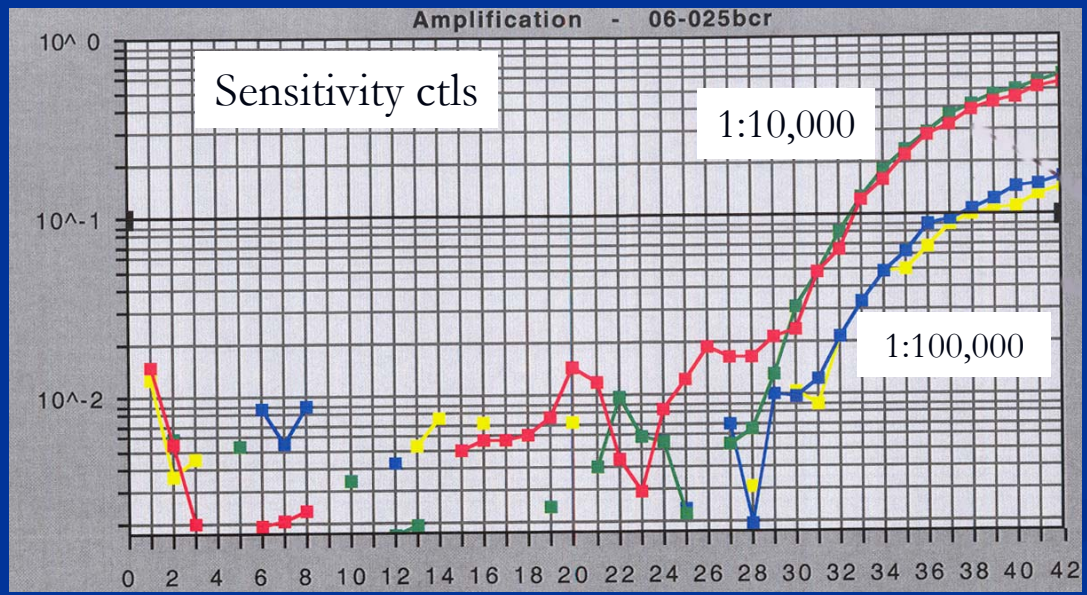
Step 4. Calculate normalized copy # of gene

Well	Reporter	Type	Baseline StdDev	deltaRn	Ct	Quantity	Log 10	Qty Mean	Sample Name	FAM Qty	Ratio
25	VIC	CY	3.38E-03	2.88E-01	24.98	100000	5	100000	5	100000	
26	VIC	CY	2.71E-03	3.17E-01	24.94	100000	5		5	100000	
27	VIC	CY	2.68E-03	2.92E-01	28.51	10000	4	10000	4	10000	
28	VIC	CY	2.25E-03	3.24E-01	28.29	10000	4		4	10000	
29	VIC	CY	2.69E-03	2.61E-01	32.67	1000	3	1000	3	1000	
30	VIC	CY	2.97E-03	3.00E-01	31.8	1000	3		3	1000	
31	VIC	CY	2.51E-03	2.37E-01	35.66	100	2	100	2	100	
32	VIC	CY	1.87E-03	2.05E-01	37.85	100	2		2	100	
1	VIC	CY	3.88E-03	2.22E-01	19.98	1601825	6.20	1616056	69910	3	0.0002
2	VIC	CY	3.88E-03	2.29E-01	19.95	1630287	6.21		69910		
3	VIC	CY	2.85E-03	2.36E-01	19.91	1669026	6.22	1502155	69912	223	0.0124
4	VIC	CY	2.91E-03	2.29E-01	20.29	1335284	6.13		69912	149	
5	VIC	CY	2.23E-03	2.57E-01	21.32	729378	5.86	672285	69917		
6	VIC	CY	3.41E-03	2.60E-01	21.61	615192	5.79		69917		
7	VIC	CY	3.07E-03	2.43E-01	19.99	1592448	6.20	1376120	69986		0.0000
8	VIC	CY	3.38E-03	2.13E-01	20.53	1159793	6.06		69986	0	
13	VIC	CY	2.44E-03	2.04E-01	21.12	820251	5.91	1126501	69813	75	0.0053
14	VIC	CY	2.27E-03	2.29E-01	20.17	1432750	6.16		69813	44	
17	VIC	CY	1.99E-03	2.31E-01	20.75	1019264	6.01	1069457	posct	5573	0.4942
18	VIC	CY	2.00E-03	2.54E-01	20.59	1119650	6.05		posct	4998	
19	VIC	CY	2.69E-03	2.04E-01	21.18	791860	5.90	395930	nc		
20	VIC	CY	2.03E-03	-1.82E-02	42	0	0.59		rc		

Most labs use excel calculations, or stored procedures in home-grown tools

But how quantitative is it, anyway?



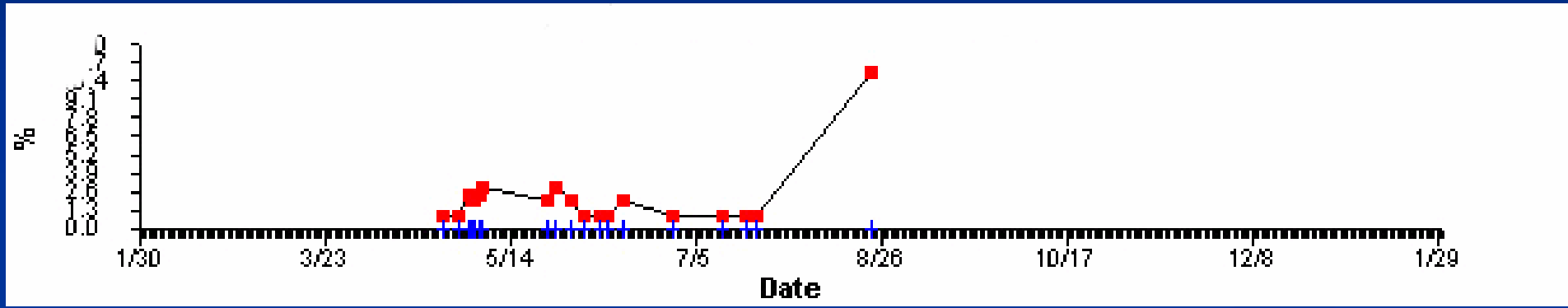


Accuracy: reference samples
Precision: run-to-run variability
Analytical sensitivity: dilution studies and assignment of baselines
Analytical specificity: minimizing false-positives; confimatory technique

In addition to the old standbys of:

Diagnostic Specificity
Diagnostic sensitivity

Monotherapy with imatinib produces resistant disease (2-5%/year)



Related to overcoming imatinib blockade (i.e. bcr-abl dependent):

Point mutations in bcr-abl kinase domain (KD)

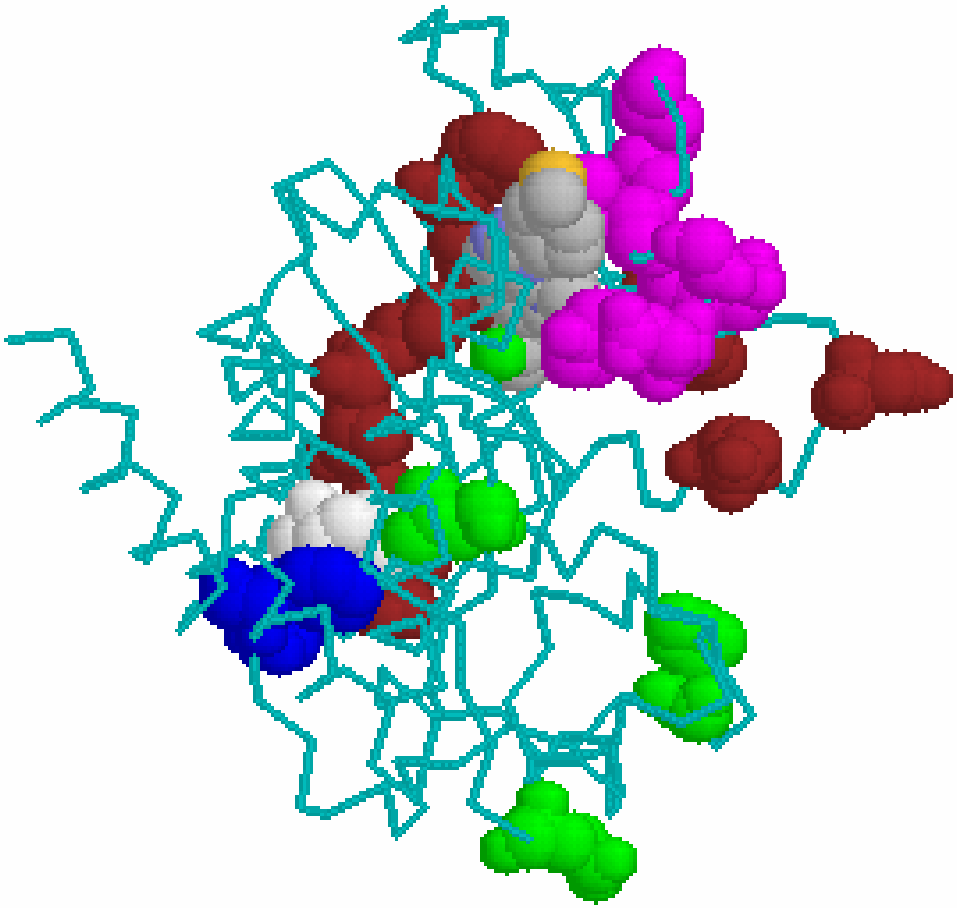
Amplification of the bcr-abl locus (FISH)

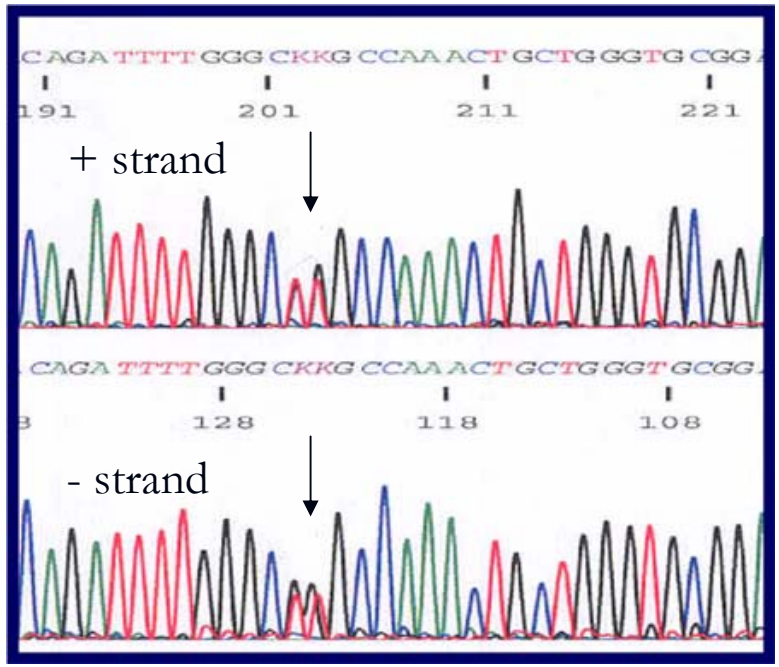
Related to bypassing imatinib (i.e. bcr-abl independent mechanisms):

Activation of others kinases besides bcr-abl (signal bypass)

Clonal evolution (CGH array)

Point mutations in the ABL kinase domain of BCR-ABL mediate ~50% of imatinib resistance

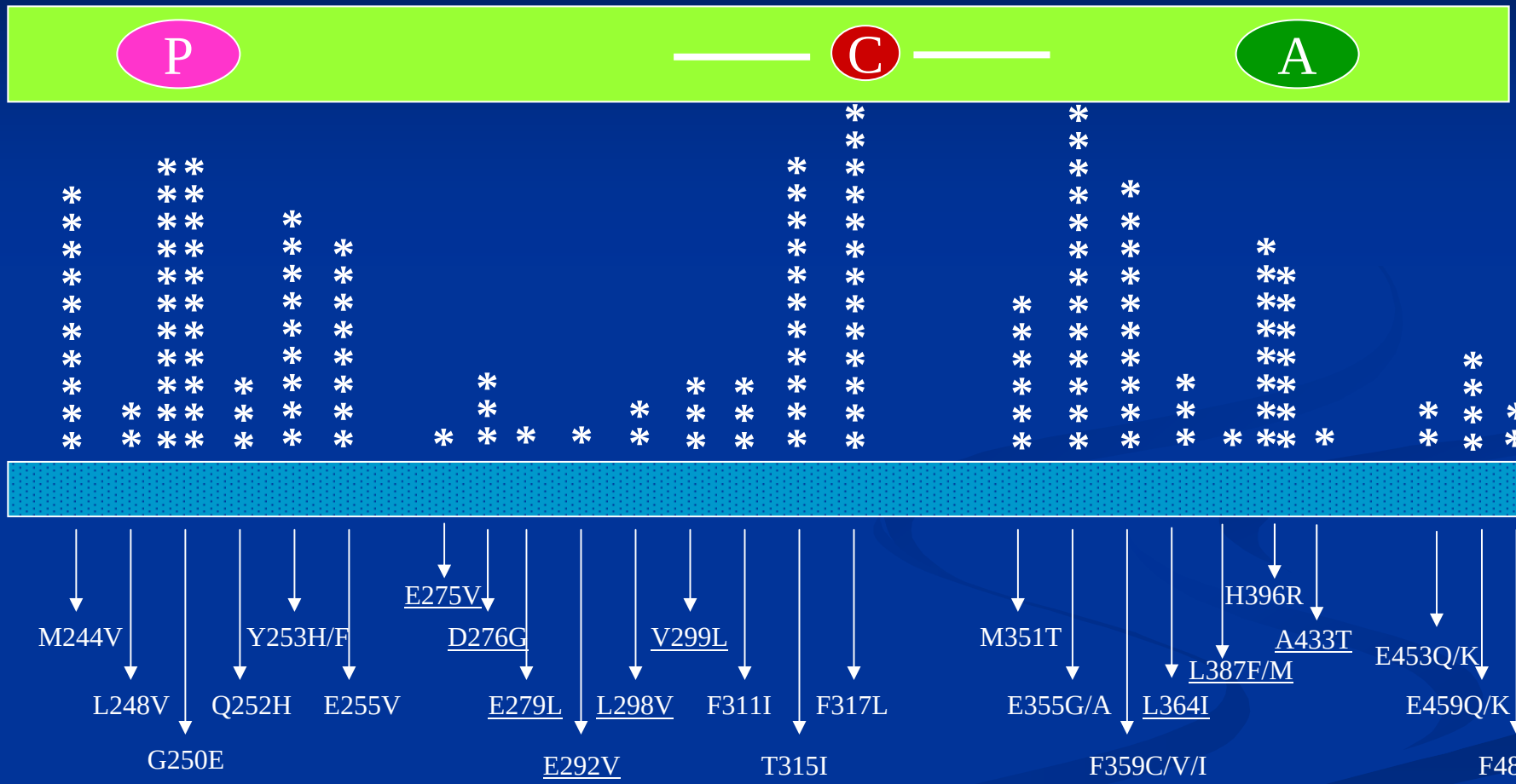




Green: Activation loop, Blue: C-terminal loop, Magenta: P-loop, Brown: Activation/catalytic domain, White: SH2 contact, Gray: imatinib present in binding pocket

Nagar et al, Cancer Res 2002

Localization of ABL kinase domain point mutations in cases of CML with imatinib resistance

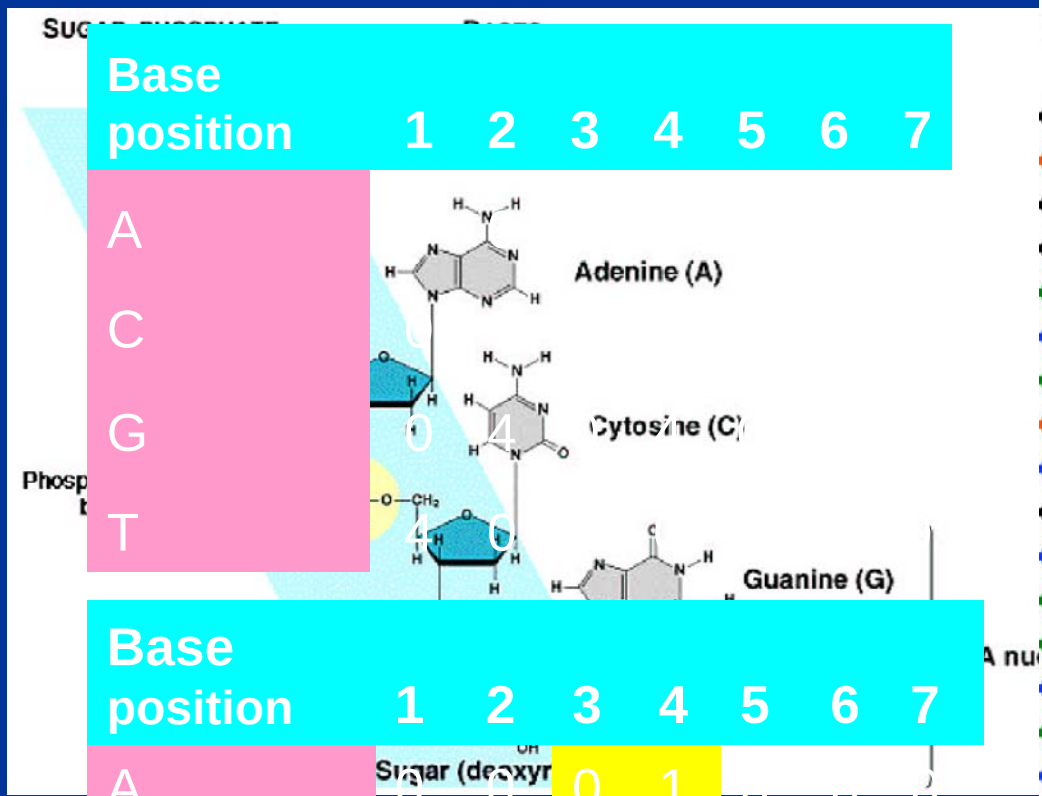


15% of imatinb-resistant CML have 2 mutations, 5% have 3 or more

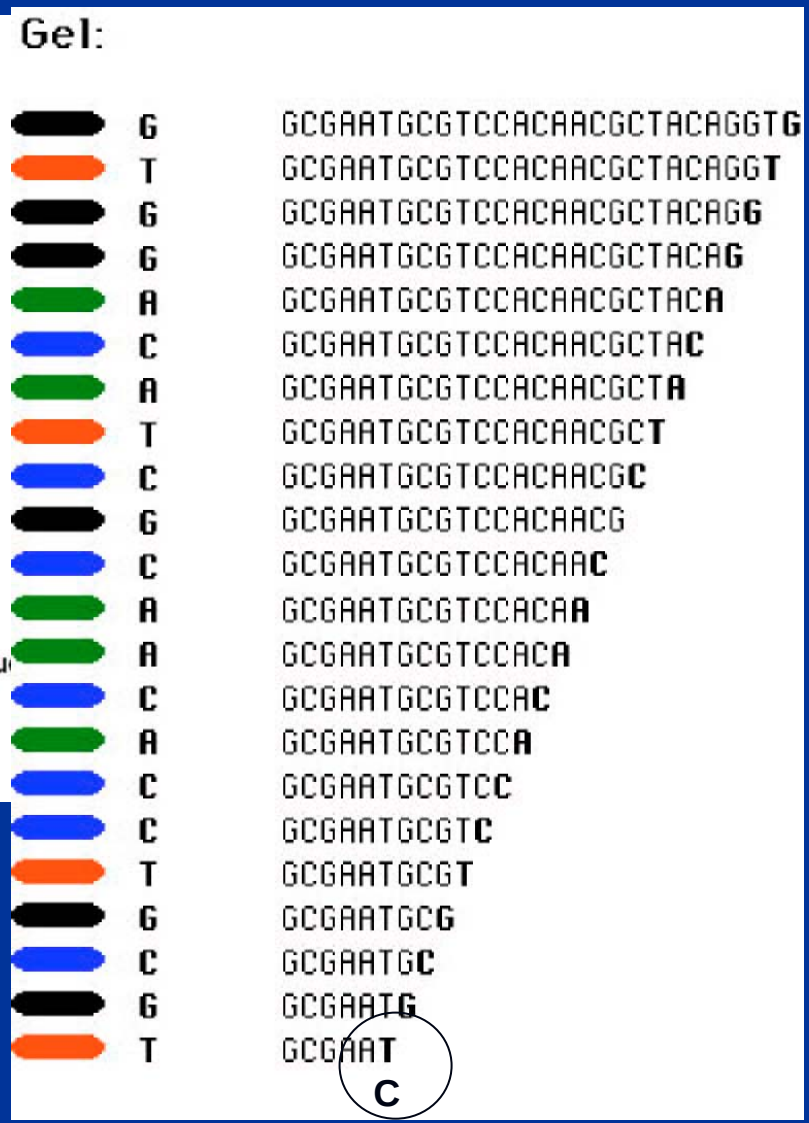
updated 8-05

Representing DNA sequencing data in a format that can be used more effectively for mutation analysis, graphical presentation or outcome prediction

Base position	1	2	3	4	5	6	7
A							
C							
G							
T							

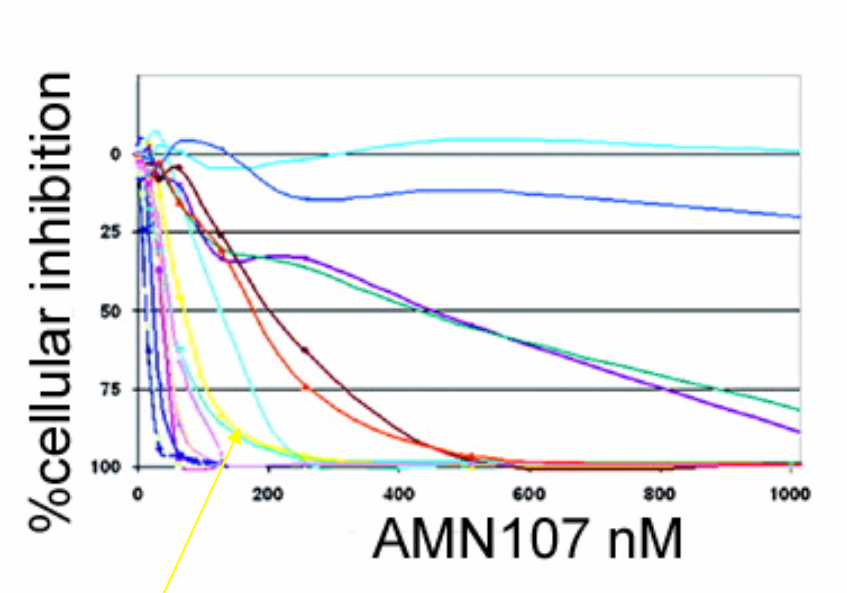


Base position	1	2	3	4	5	6	7
A	0	0	0	1	0	0	0
C	0	0	2	0	0	4	4
G	0	4	2	3	0	0	0
T	4	0	0	0	4	0	0



Tracking mutation site & response following switch to a new kinase inhibitor

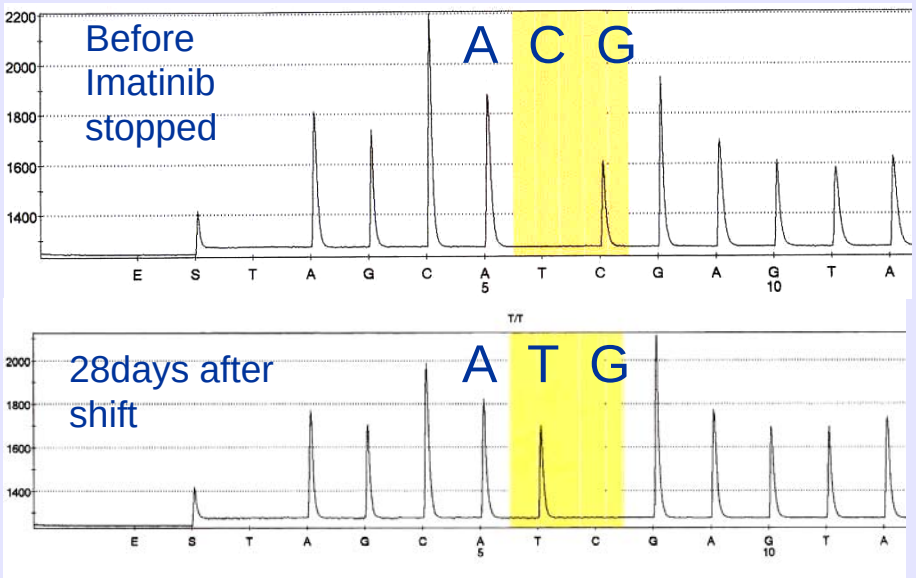
In vitro predicted response



M351T

Actual in vivo response

M351T



Reversion to wild-type at codon 351

Pyrosequencing technique

BCR-ABL mutational analysis:

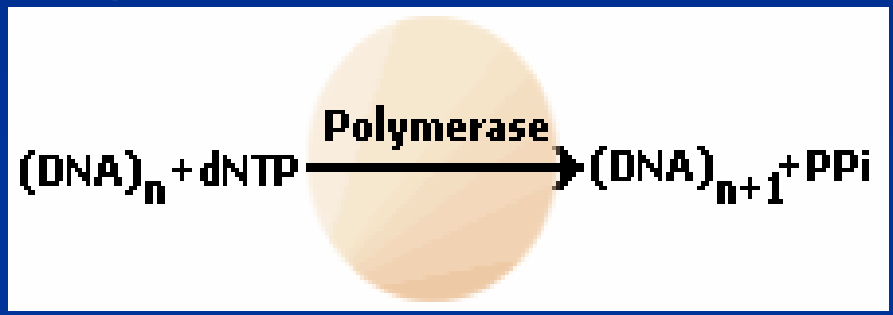
M351T detected in bcr-abl kinase. Seen in 4% of CML with 2nd imatinib resistance

Predicted response to new inhibitors: AMN107: 40%, dasatinib: 53%

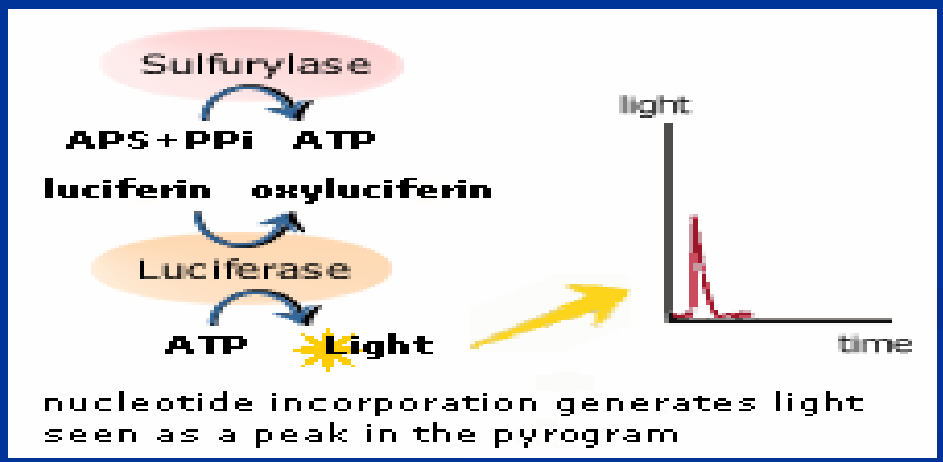
Pyrosequencing as a 96-well high-throughput technique for defined mutations

1. PCR with biotin-primer, purify with avidin beads, annealing of sequencing primer to single stranded template

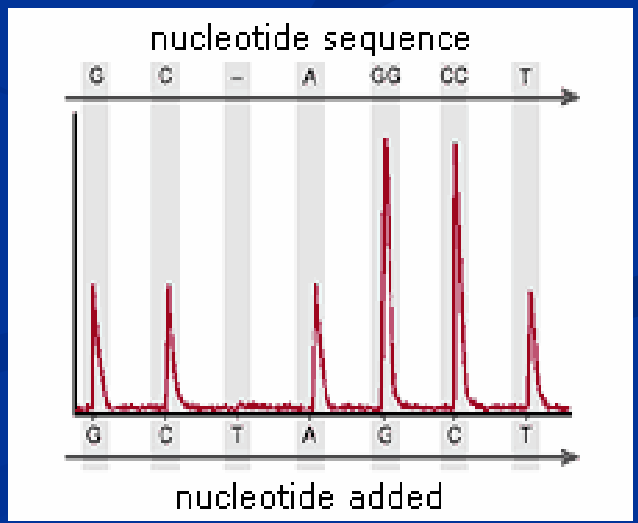
2. Incorporation of each tested nucleotide with release of PPi



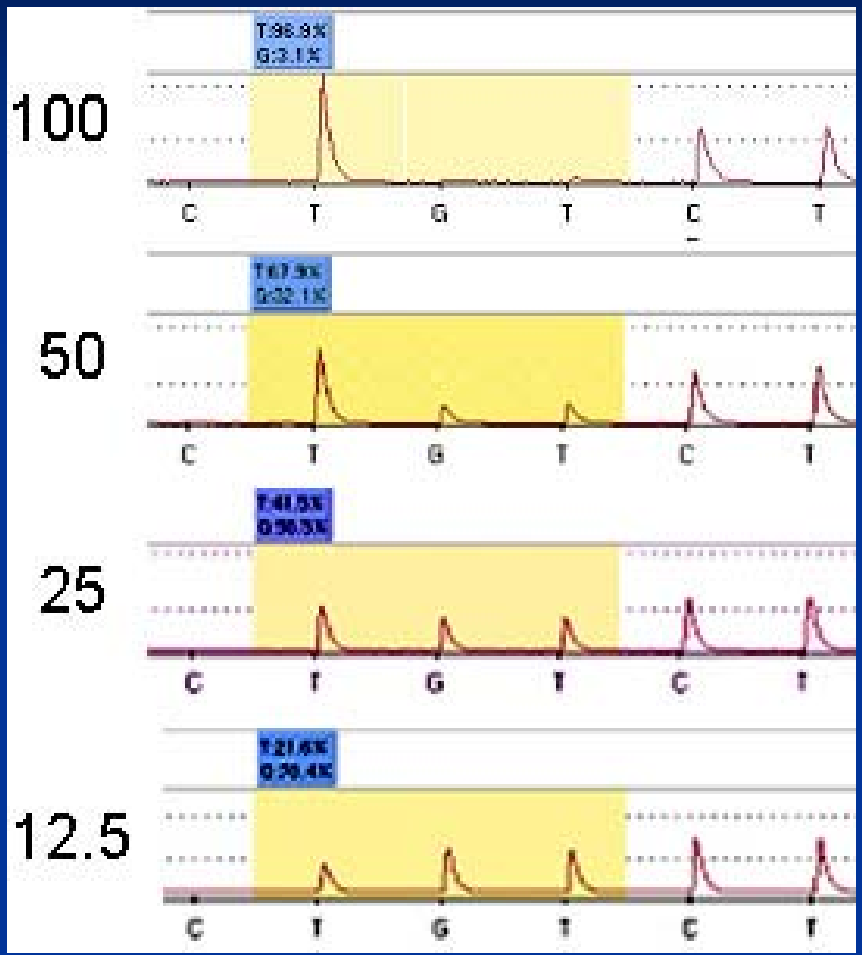
3. Conversion of PPi to ATP to generate visible light



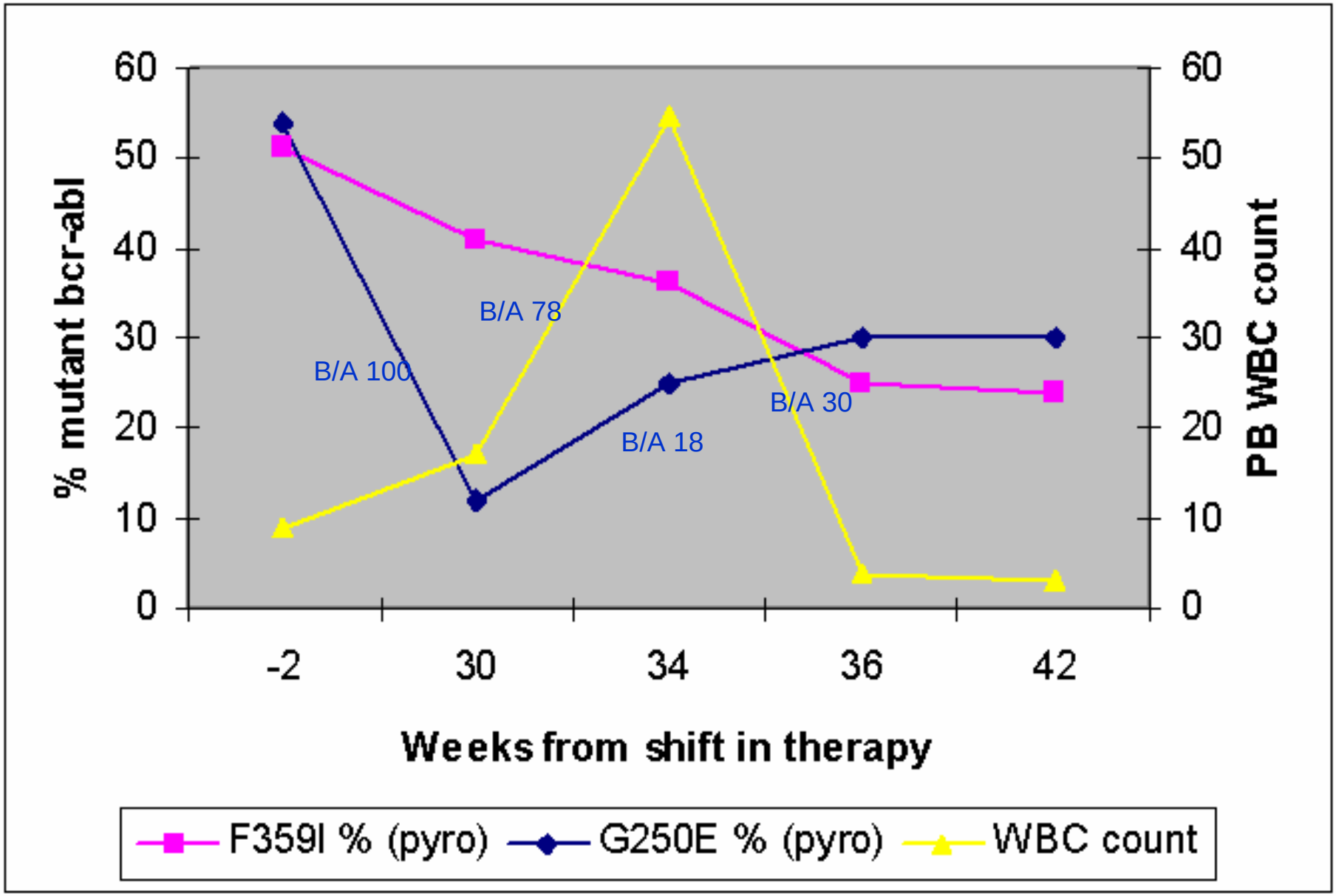
4. Pyrogram (peak height is quantitative)



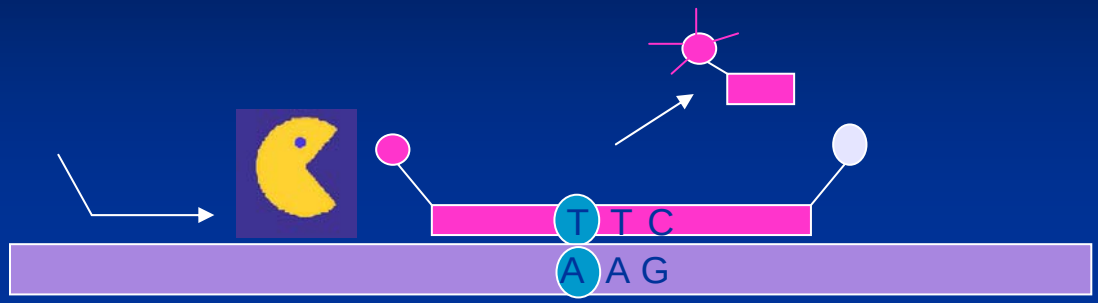
Quantitative detection of mutations by pyrosequencing



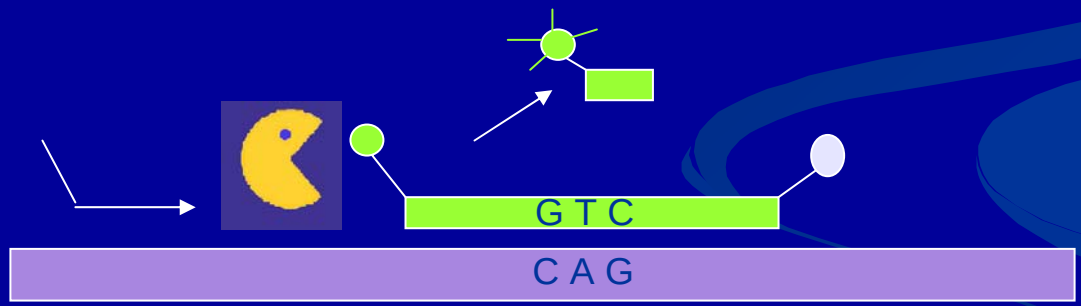
- Dilution studies establish 1:10 maximal quantitative sensitivity of Pyro technique
- Rapid; useful for monitoring treatment response
- Effective therapies will require more sensitive techniques for monitoring


60
50
40
30
20
10
0
% mutant bcr-abl
PB WBC count
B/A 100
B/A 78
B/A 18
B/A 30
-2
30
34
36
42
Weeks from shift in therapy
F359I % (pyro)
G250E % (pyro)
WBC count

Allelic discrimination by quantitative real-time PCR

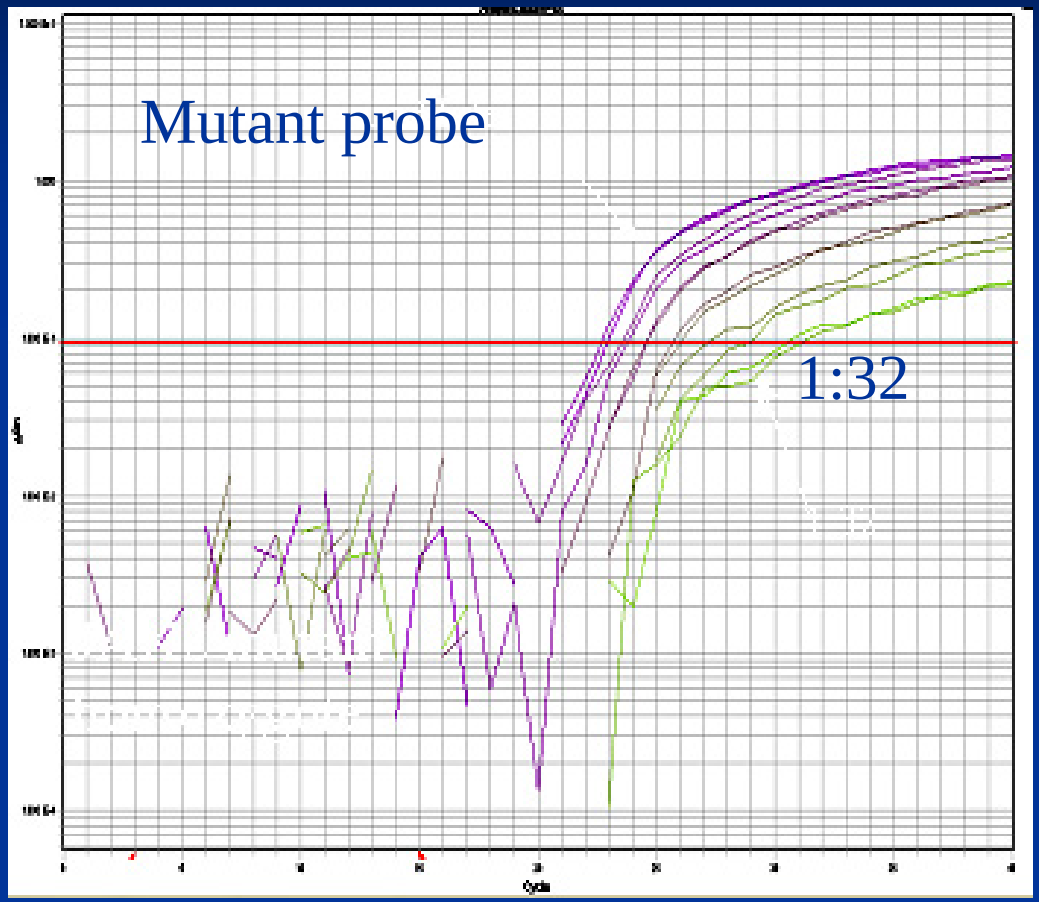


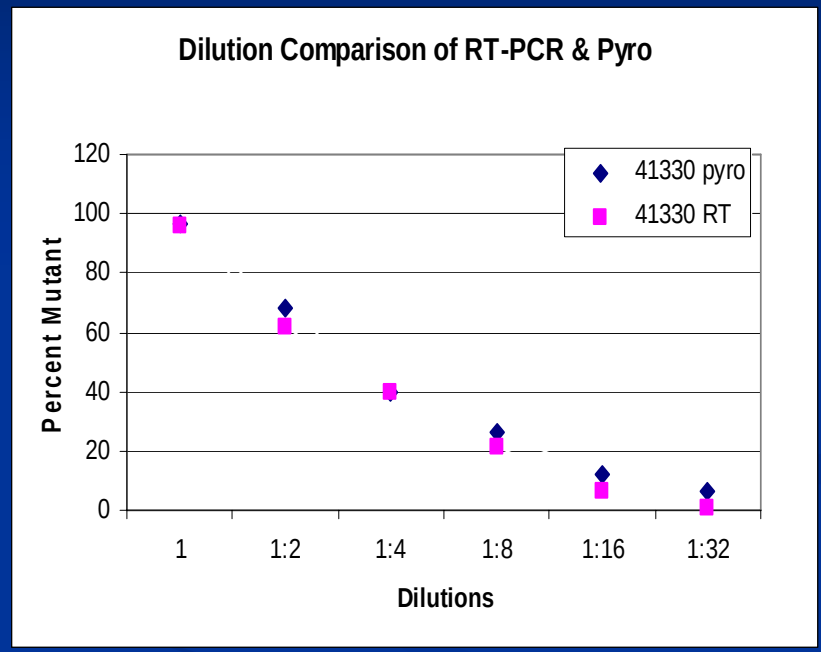
Mutated sequence



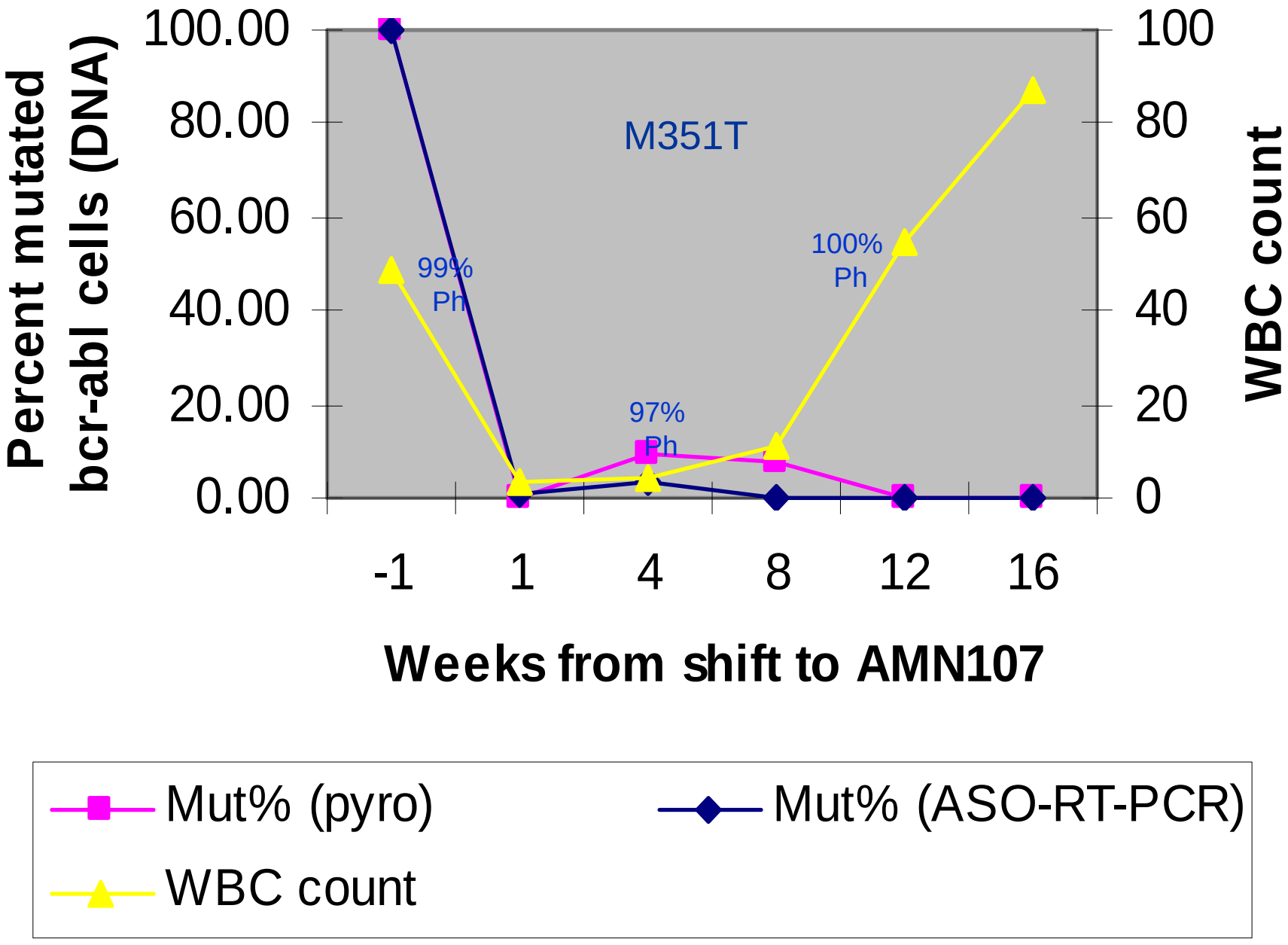
Wild type sequence

ASO-PCR/Pyro are comparable done to 10% with real-time PCR having more sensitivity

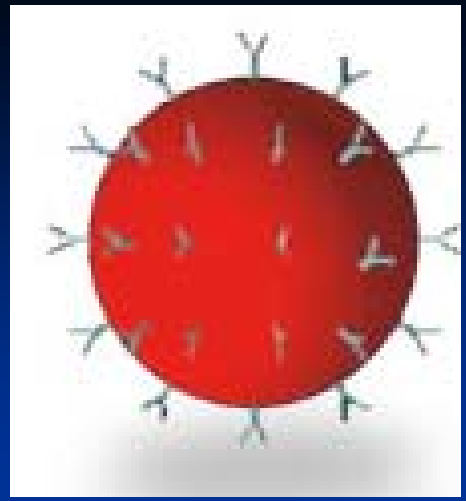


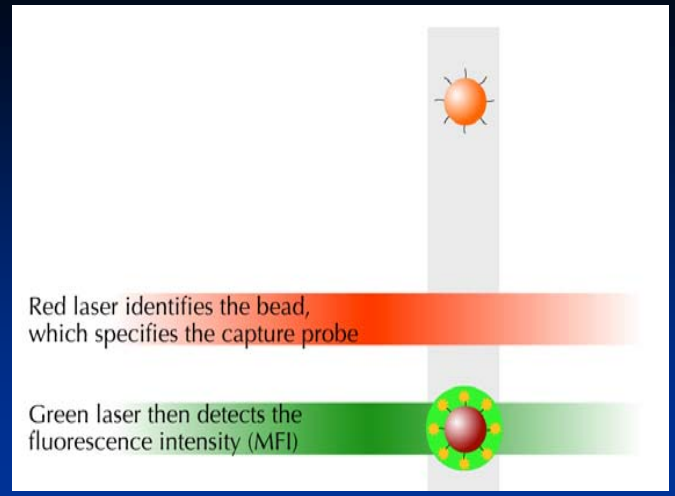


Quantitation based on standard curve


Percent mutated bcr-abl cells (DNA)
100.00
80.00
60.00
40.00
20.00
0.00
100
80
60
40
20
0
WBC count
M351T
99% Ph
97% Ph
100% Ph
-1
1
4
8
12
16
Weeks from shift to AMN107
Mut% (pyro)
Mut% (ASO-RT-PCR)
WBC count

Moving molecular data from single analyte measurements to multiplexing platforms

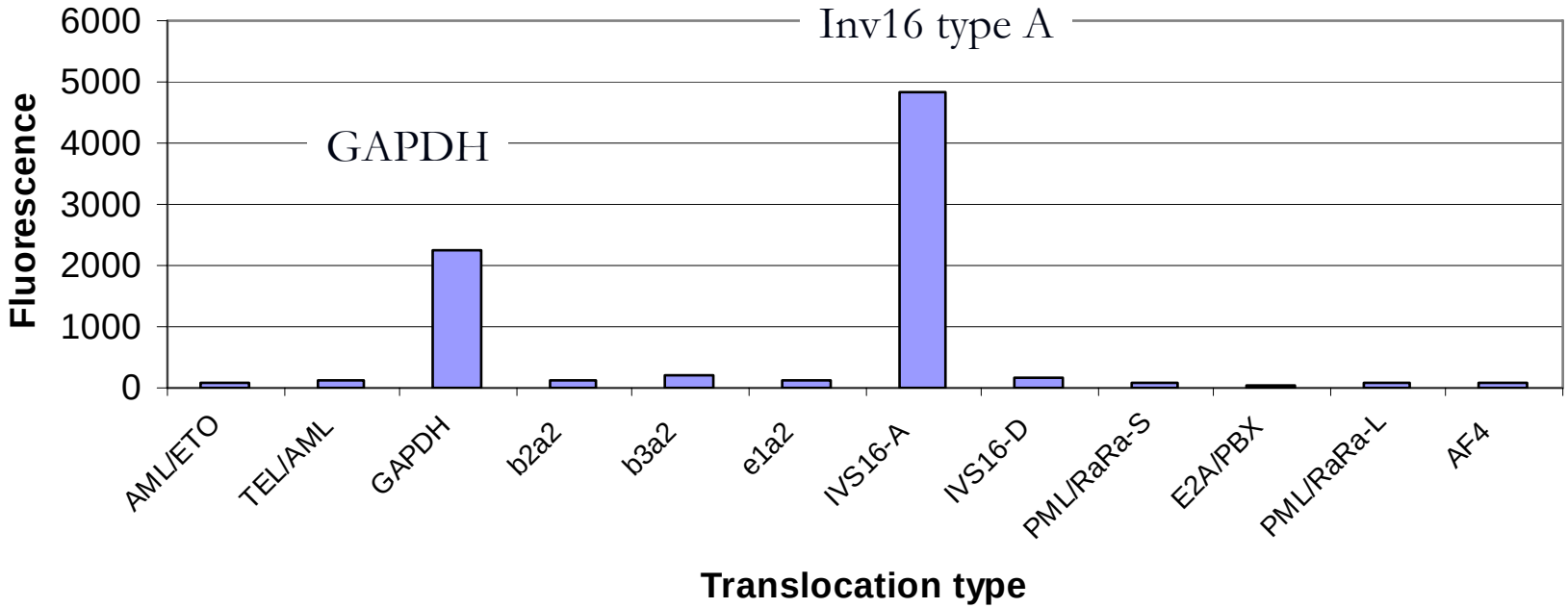


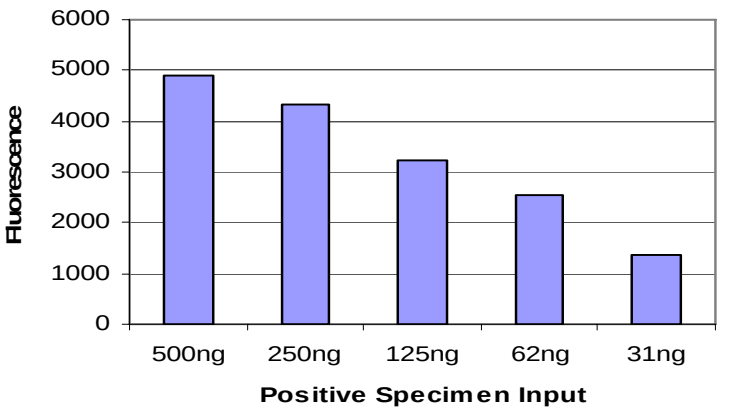


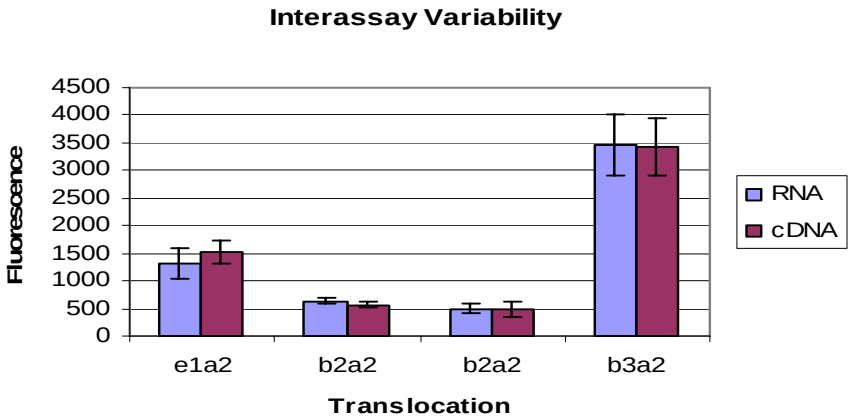
LTx Assay (Asuragen): Panel of acute leukemia translocations

- Luminex cytometer
- BCR/ABL – b3/a2, b2/a2,
- BCR/ABL – e1/a2
- E2A/PBX1 – t(1;19)
- TEL/AML1 – t(12;21)
- MLL/AF4 – t(4;11)
- PML/RARA (LF, SF)
- CBFB/MYH11 (A, D)
- AML1/ETO – t(8;21)
- GAPDH

LTx Complete Panel





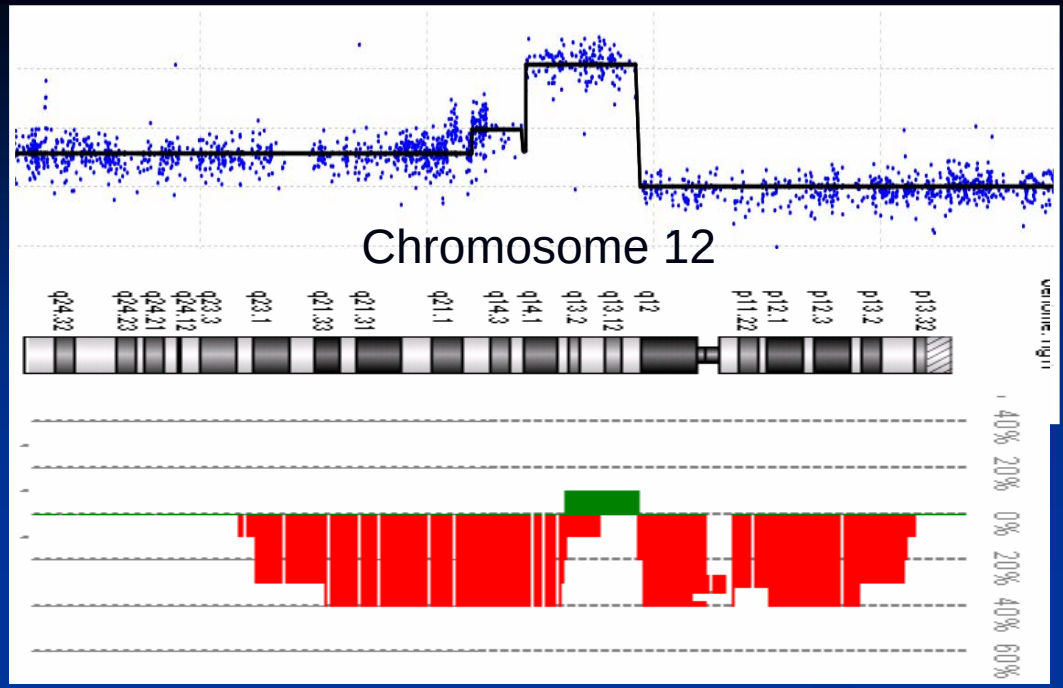


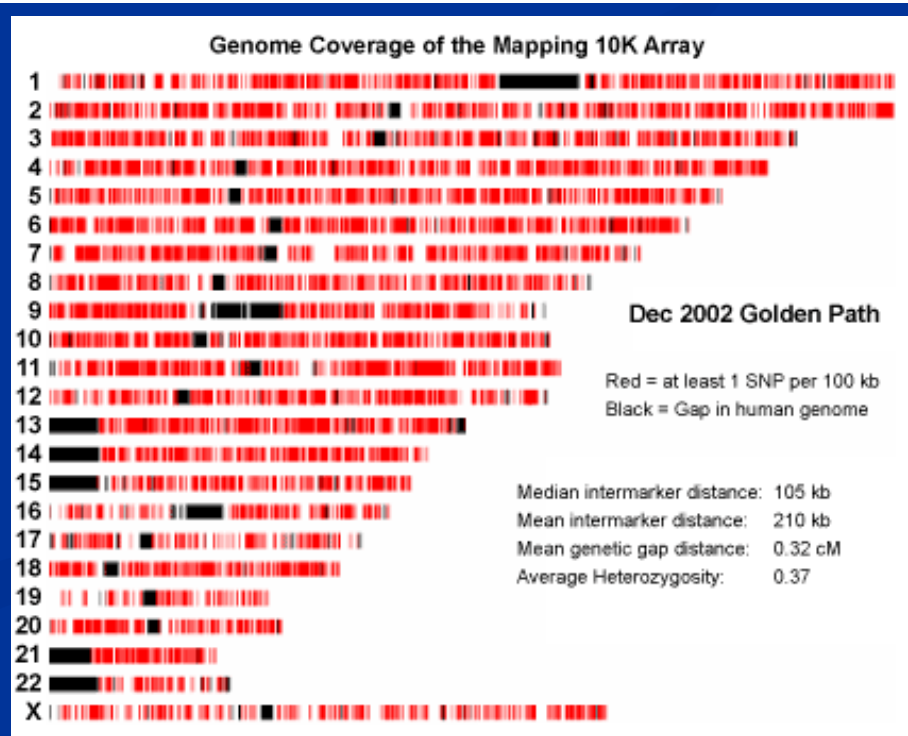
Scaling up to genomics

- Array CGH
- SNP profiling
- Expression microarrays
- Mass spectrometric

The rules for large-scale multiplexing are in evolution

1. Metrics to evaluate runs
   - Range of statistical tests
2. Fixed analysis methods
   - Data masking
3. Graphical representation





The time has arrived for a fully functional molecular module in the LIS

Our partnership with SCC on SoftGene

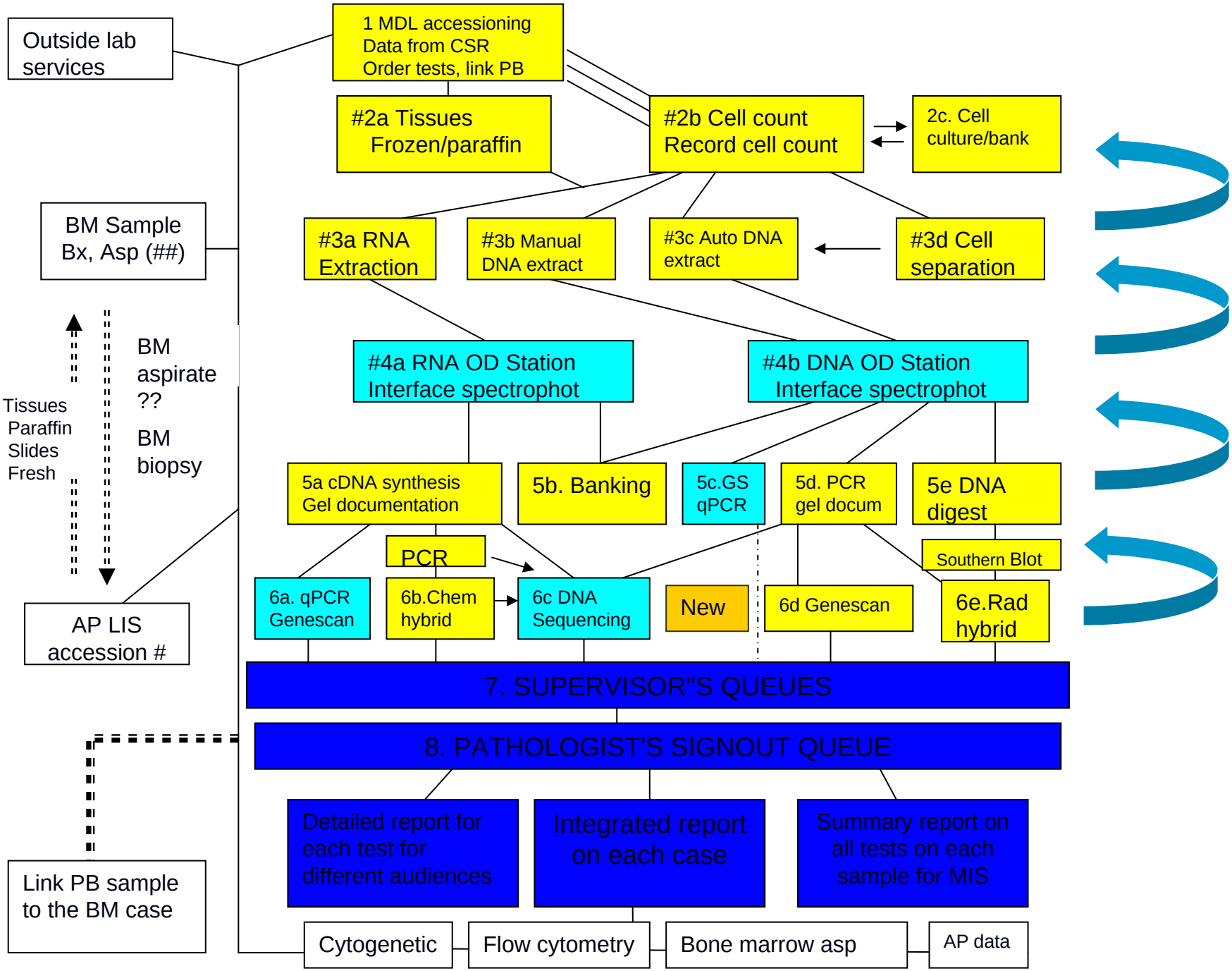
…and our own attempts

to improve processes in the molecular lab

Why?

15,000 samples

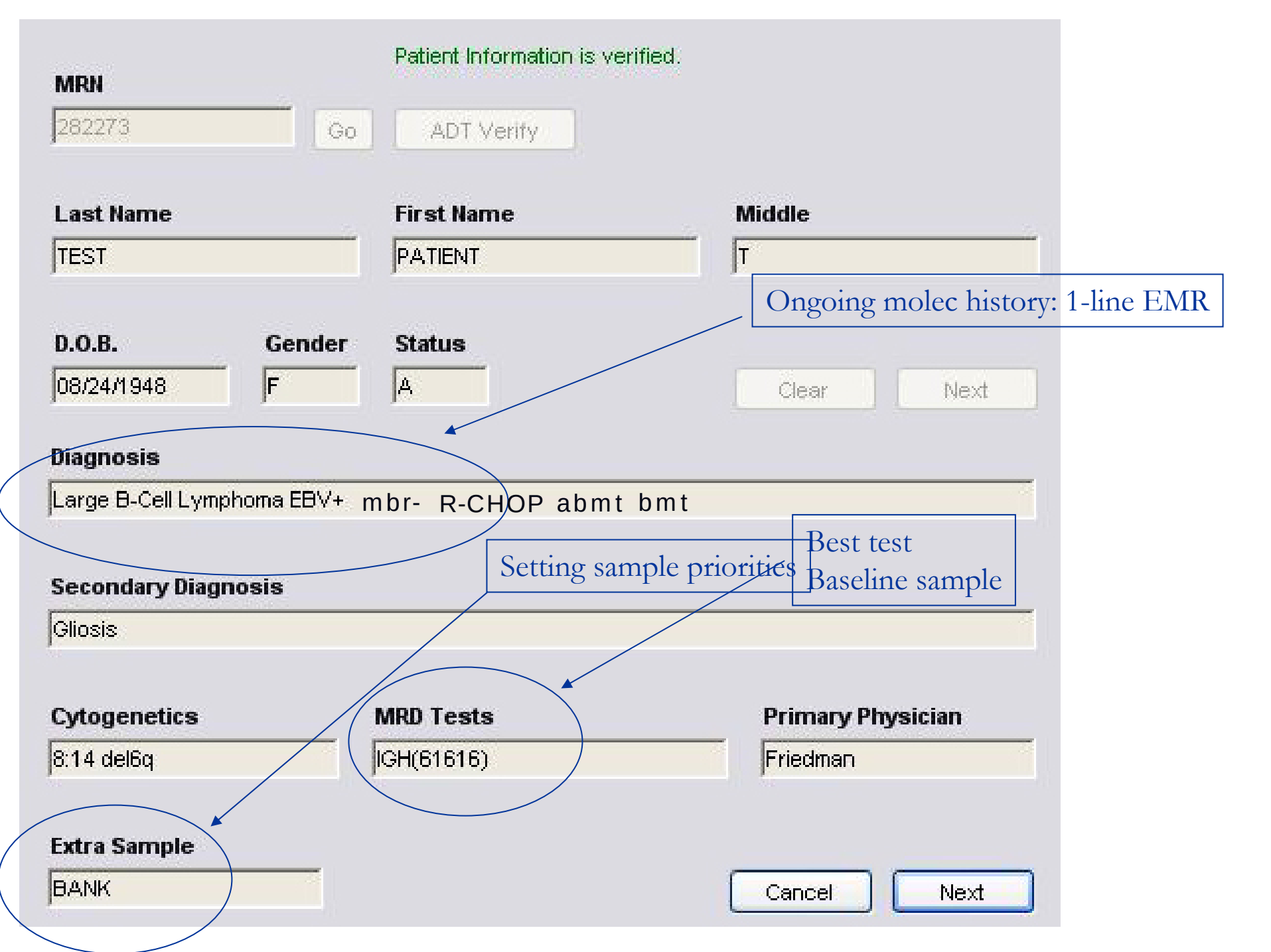
35,000 oncology tests

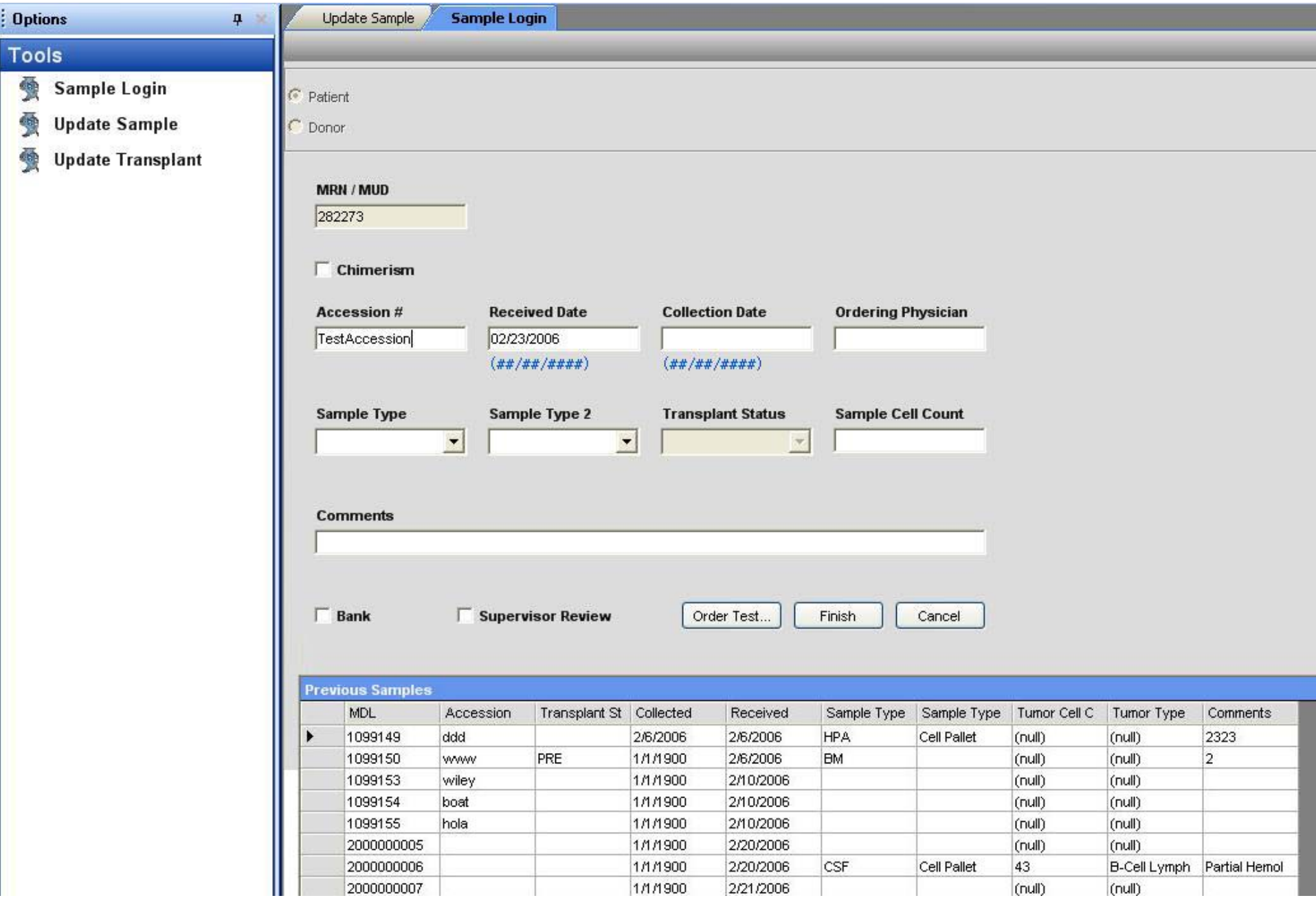

Outside lab services
1 MDL accessioning
Data from CSR
Order tests, link PB
#2a Tissues
Frozen/paraffin
#2b Cell count
Record cell count
2c. Cell culture/bank
BM Sample
Bx, Asp (##)
#3a RNA Extraction
#3b Manual DNA extract
#3c Auto DNA extract
#3d Cell separation
BM aspirate ??
BM biopsy
Tissues
Paraffin
Slides
Fresh
#4a RNA OD Station
Interface spectrophot
#4b DNA OD Station
Interface spectrophot
5a cDNA synthesis
Gel documentation
5b. Banking
5c.GS qPCR
5d. PCR gel docum
5e DNA digest
PCR
Southern Blot
6a. qPCR Genescan
6b.Chem hybrid
6c DNA Sequencing
New
6d Genescan
6e.Rad hybrid
AP LIS accession #
7. SUPERVISOR"S QUEUES
8. PATHOLOGIST'S SIGNOUT QUEUE
Detailed report for each test for different audiences
Integrated report on each case
Summary report on all tests on each sample for MIS
Link PB sample to the BM case
Cytogenetic
Flow cytometry
Bone marrow asp
AP data

The sample processing station: Where the molecular lab succeeds...or fails

Sample processing station: Where the molecular lab succeeds...or fails

- The problems
  - Correcting mistaken orders
    - Confusion about which test to do when
    - Tests that was previously informative: t(14;18) PCR if –ve before
  - Avoiding redundant orders
    - One-time tests (somatic hypermutation in CLL)
    - PB/BM duplicates
    - MRD samples outside of time-frame for clinical protocols
  - Limited sample quantities
    - Competing requirements for DNA, RNA, protein assays
    - Paraffin-embedded fixed material
- The solutions
  - Internal tracking of prior laboratory results
  - Smart “banking” solutions
  - Optimization of extraction techniques


Patient Information is verified.
MRN
282273
Go
ADT Verify
Last Name
TEST
First Name
PATIENT
Middle
T
Ongoing molec history: 1-line EMR
D.O.B.
08/24/1948
Gender
F
Status
A
Clear
Next
Diagnosis
Large B-Cell Lymphoma EBV+ mbr- R-CHOP abmt bmt
Best test
Baseline sample
Setting sample priorities
Secondary Diagnosis
Gliosis
Cytogenetics
8;14 del6q
MRD Tests
IGH(61616)
Primary Physician
Friedman
Extra Sample
BANK
Cancel
Next


Options
Tools
Sample Login
Update Sample
Update Transplant
Update Sample
Sample Login
Patient
Donor
MRN / MUD
282273
Chimerism
Accession #
TestAccession
Received Date
02/23/2006
(##/##/####)
Collection Date
(##/##/####)
Ordering Physician
Sample Type
Sample Type 2
Transplant Status
Sample Cell Count
Comments
Bank
Supervisor Review
Order Test...
Finish
Cancel
Previous Samples
MDL
Accession
Transplant St
Collected
Received
Sample Type
Sample Type
Tumor Cell C
Tumor Type
Comments
1099149 ddd 2/6/2006 2/6/2006 HPA Cell Pallet (null) (null) 2323
1099150 www PRE 1/1/1900 2/6/2006 BM (null) (null) 2
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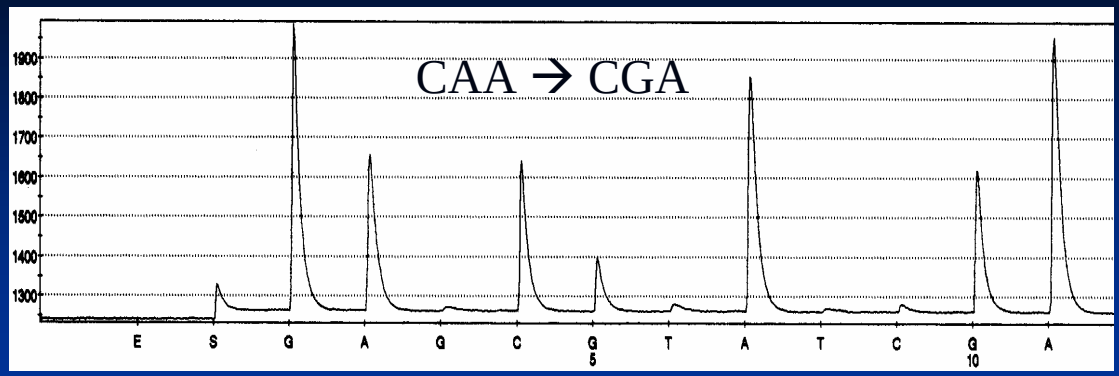
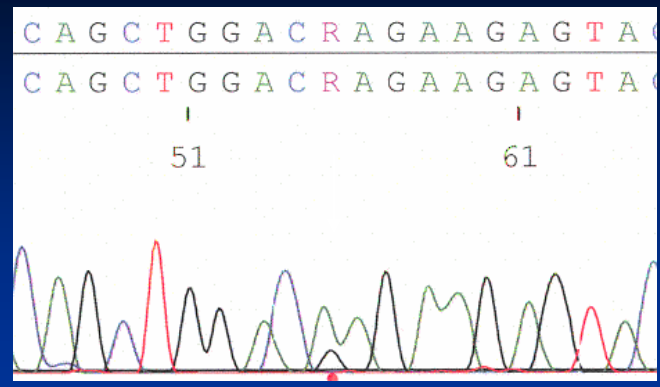
2000000007 1/1/1900 2/21/2006 (null) (null)

RAS mutational analysis of melanoma by DNA sequencing





The Basic Case Process

1. Tissue slides ⇒ microdissected
2. DNA extracted (WS)
3. OD taken ⇒ amount/purity (WS)
4. PCR (WS)
5. Pyrosequencing (WS)
6. Repeat PCR
7. Sample cleanup
8. Cycle sequencing (WS)
9. CE run
10. Analysis
11. Integration with other data
12. Report generation

The Wish List

1. Slide archiving/image of area chosen
2. Instrument interface,
3. Amount of sample remaining
4. QC on reagents (enzyme, primers)
5. Instrument interface, scheduling
6. Rules for repeats
7. Product tracking/barcoding
8. Cycle sequencing (WS)
9. Project management
10. Integrated viewers
11. Tracking of other results in lab
12. Viewing data in other labs

Agile programming in molecular labs is…test/worksheet building

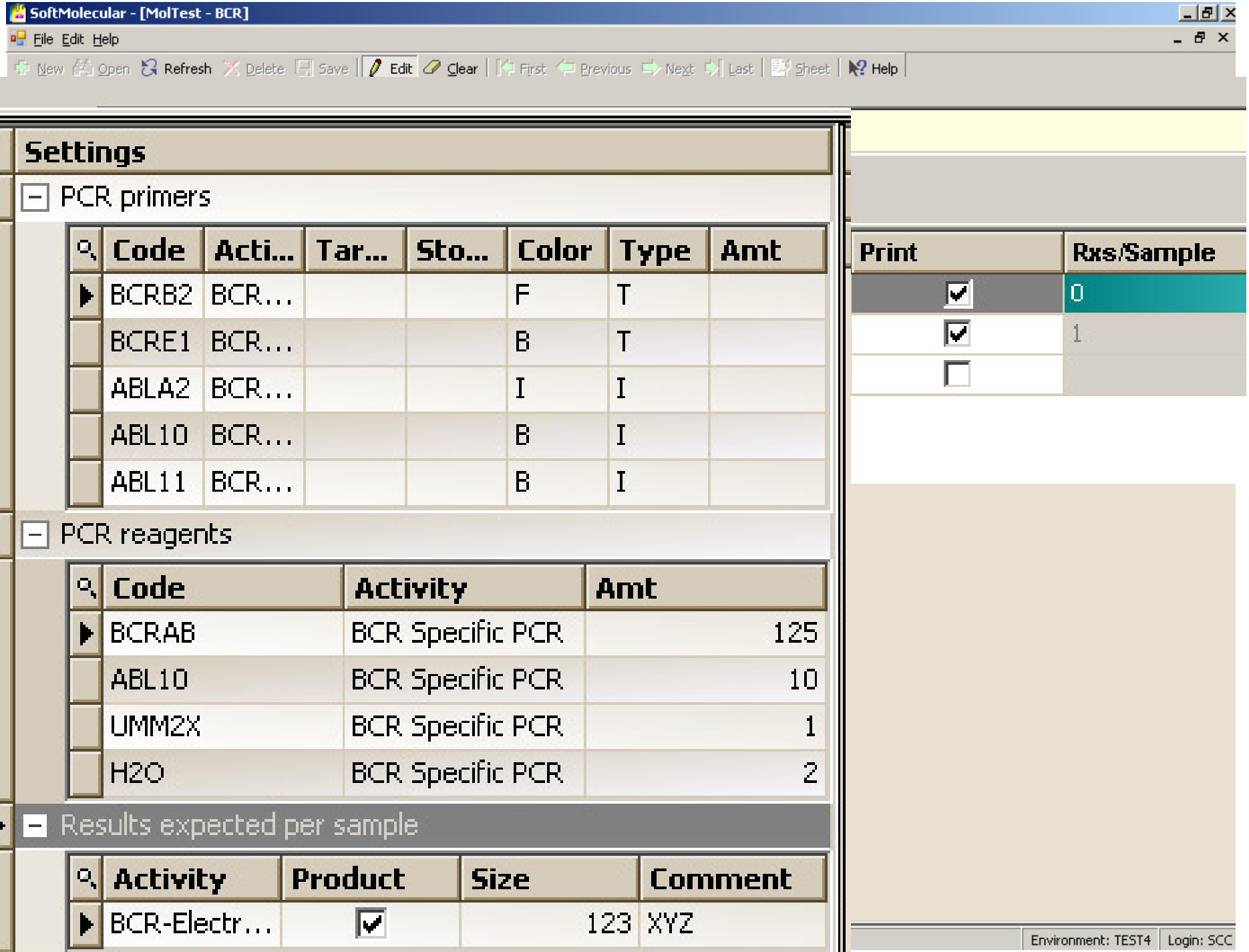
Flexible as to format, scale, data entry, baseline, controls, drag-n-drop

Date:	1/0/1900			**TI:**	0						**Reviewed by:**		
		1	2	3	4	5	6	7	8	9	10	11	12
	PATIENT NAME	**Patient G**	**Patient I**	**Patient H**	**Patient G**	**Patient F**	**Patient E**	**Patient D**	**Patient C**	**Patient B**	**Patient A**	**Positive Control**	**Negative Control**
ID		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
A	**K-12,13**	61584	61583	61582	61580	61579	61577	61575	61573	61572	61571	29884	36539
		13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
B	**K-61**	61584	61583	61582	61580	61579	61577	61575	61573	61572	61571	33475	36539
		25	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**
C	**N-12,13**	61584	61583	61582	61580	61579	61577	61575	61573	61572	61571	28912	36539
		37	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**
D	**N-61**	61584	61583	61582	61580	61579	61577	61575	61573	61572	61571	23879	36539
H		**RC K-12 A**	**RC K-12 A**	**RC K-61 B**	**RC K-61 B**	**RC N-12 C**	**RC N-12 C**	**RC N-61 D**	**RC N-61 D**				

MASTER MIX	**LOT #**	**RUN #**
K-12,13		
K-61		0
N-12,13		
N-61		

AMPLITAQ GOLD		
LOT #		
Exp. Date		
CYCLER #		

GEL QC	
DATE:	
TI:	
PASSED	
REPEAT	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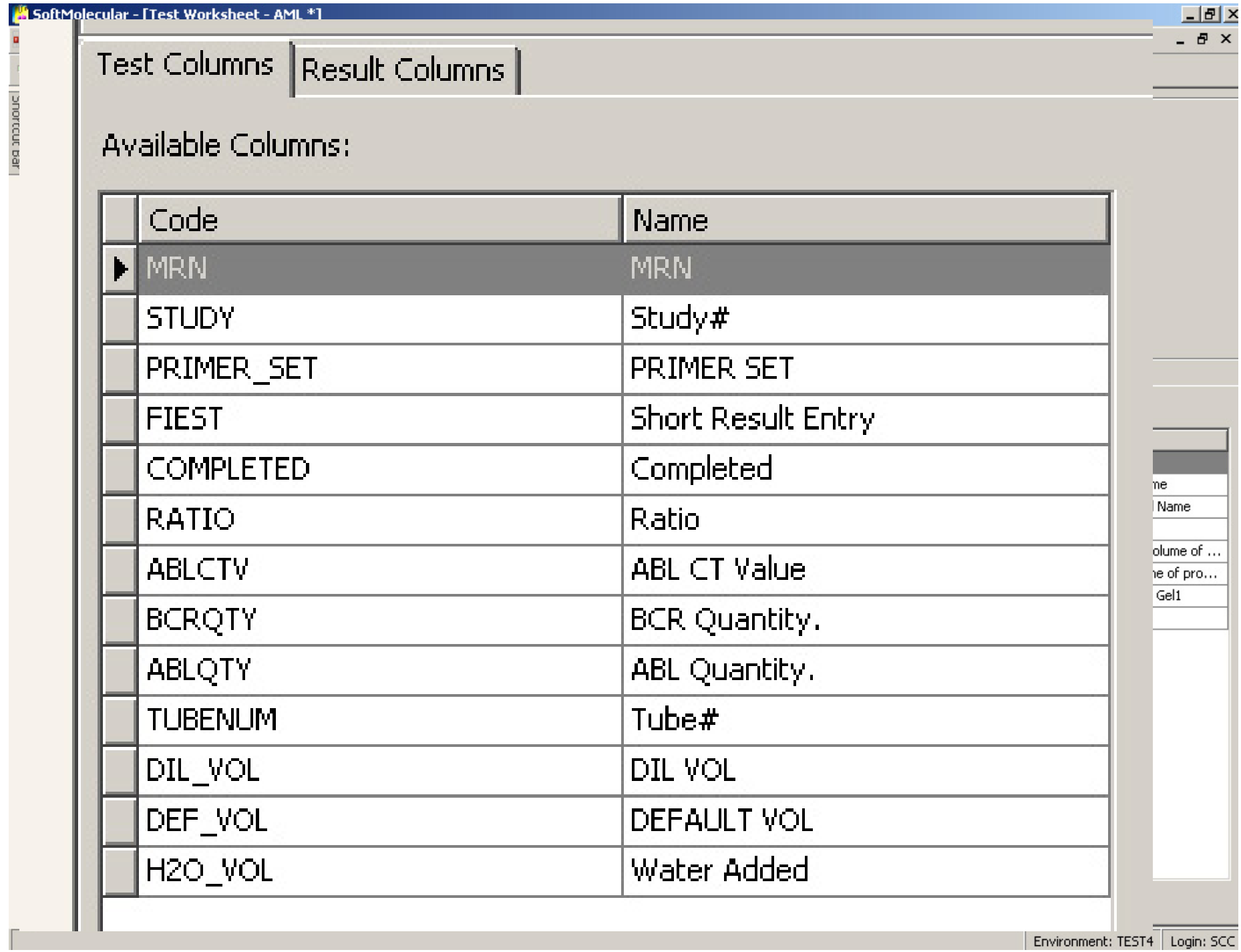
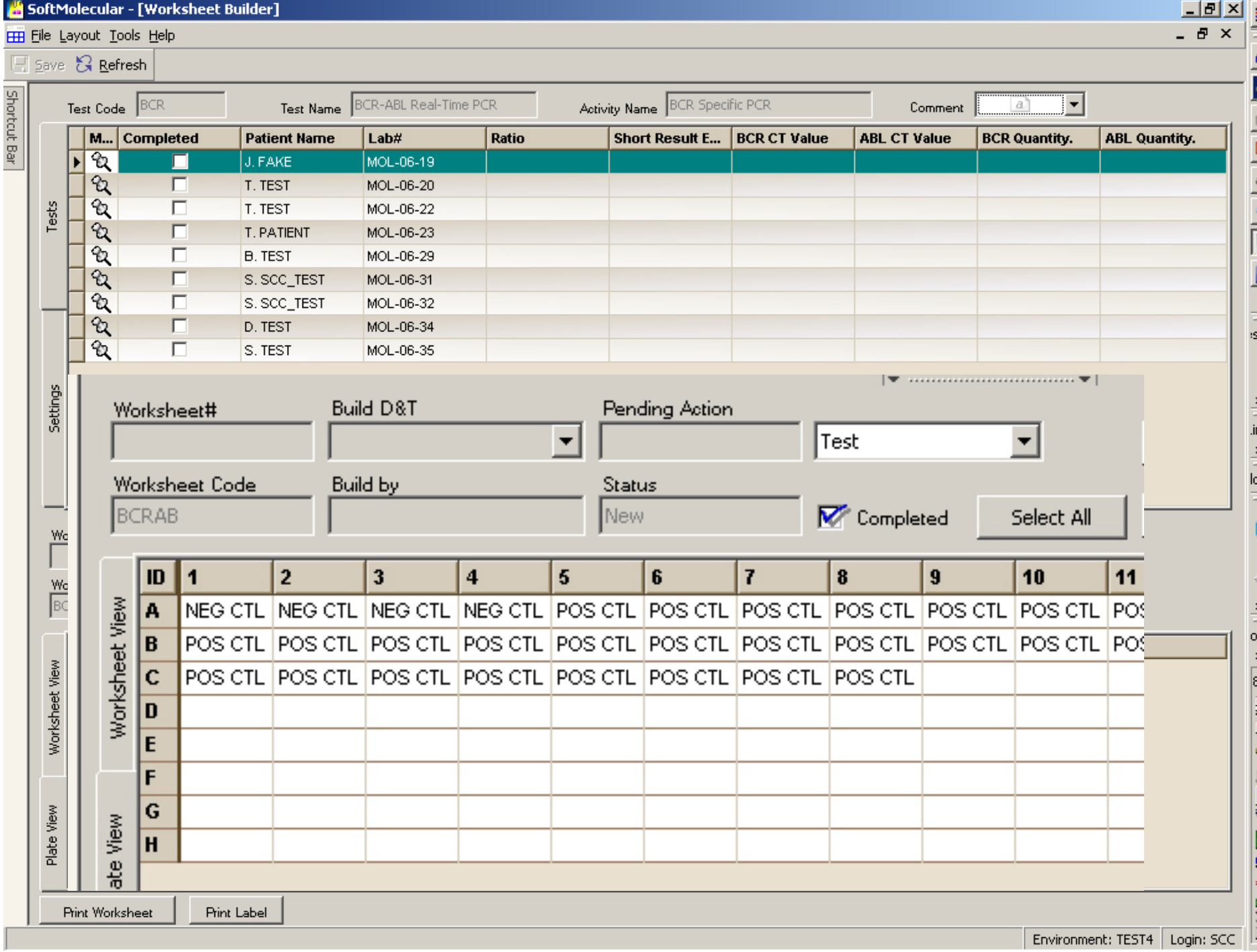
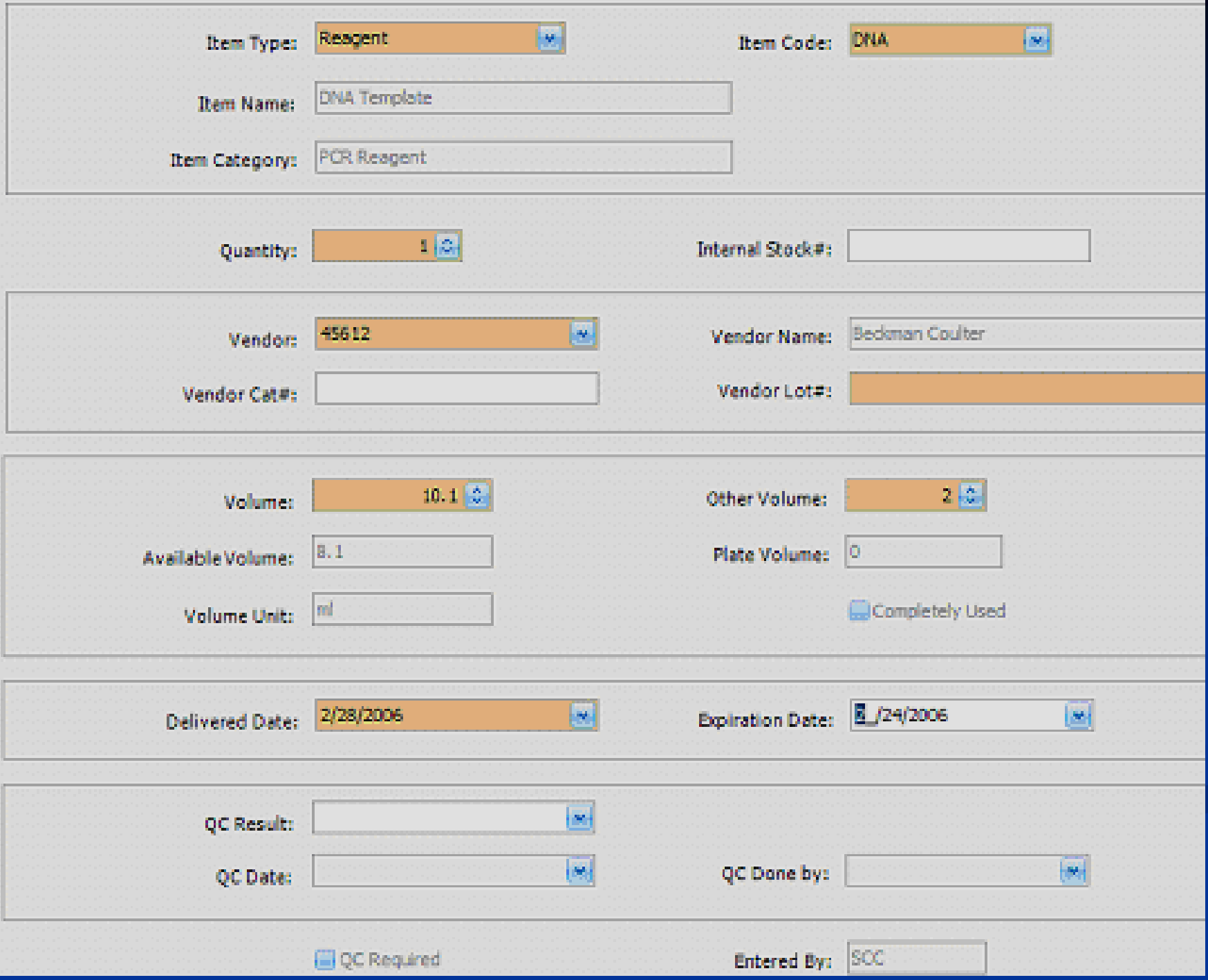
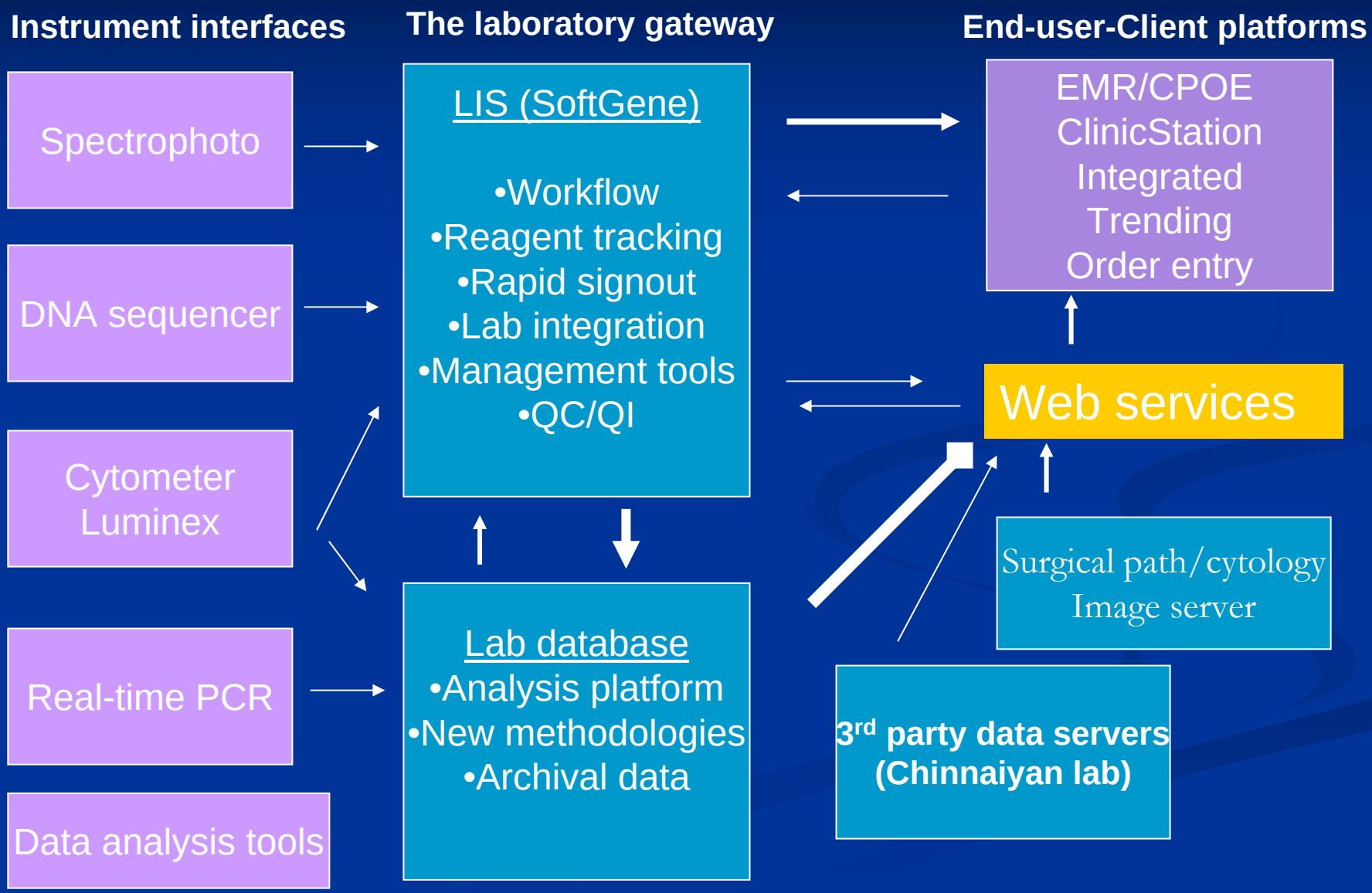
File Edit Help
New Open Refresh Delete Save Edit Clear First Previous Next Last Sheet Help
Settings
PCR primers
Code Acti... Tar... Sto... Color Type Amt
BCRB2 BCR... F T
BCRE1 BCR... B T
ABLA2 BCR... I I
ABL10 BCR... B I
ABL11 BCR... B I
PCR reagents
Code Activity Amt
BCRAB BCR Specific PCR 125
ABL10 BCR Specific PCR 10
UMM2X BCR Specific PCR 1
H2O BCR Specific PCR 2
Results expected per sample
Activity Product Size Comment
BCR-Electr... 123 XYZ
Print Rxs/Sample
0
1
Environment: TEST4
Login: SCC

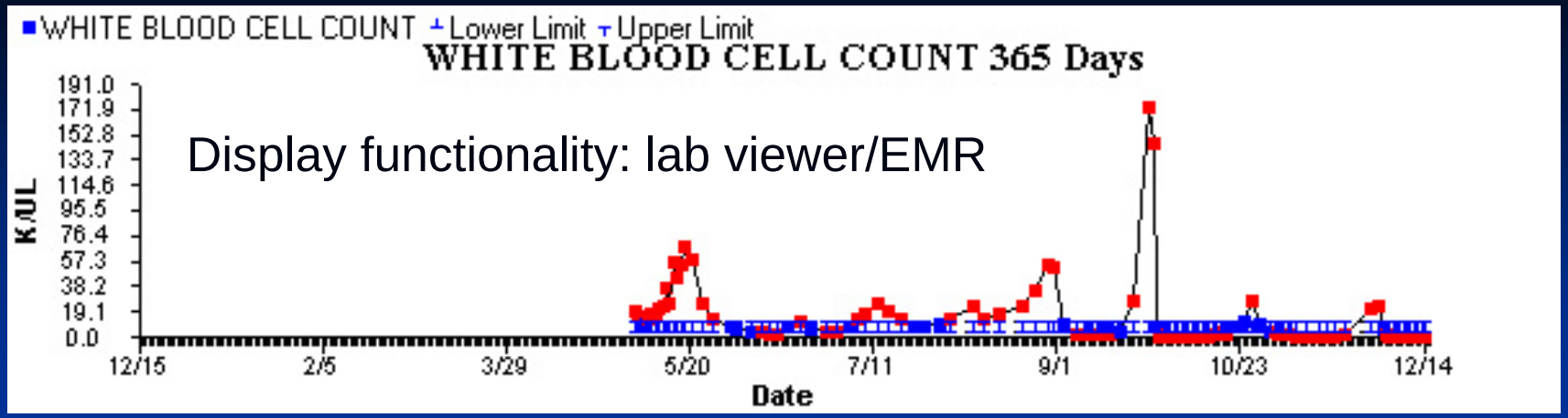

SoftMolecular - [Test Worksheet - AML *]
Test Columns
Result Columns
Available Columns:
Code
Name
MRN
MRN
STUDY
Study#
PRIMER_SET
PRIMER SET
FIEST
Short Result Entry
COMPLETED
Completed
RATIO
Ratio
ABLCTV
ABL CT Value
BCRQTY
BCR Quantity.
ABLQTY
ABL Quantity.
TUBENUM
Tube#
DIL_VOL
DIL VOL
DEF_VOL
DEFAULT VOL
H2O_VOL
Water Added
Environment: TEST4
Login: SCC


SoftMolecular - [Worksheet Builder]
File Layout Tools Help
Save Refresh
Test Code BCR
Test Name BCR-ABL Real-Time PCR
Activity Name BCR Specific PCR
Comment
Tests
Settings
Worksheet View
Plate View
M... Completed Patient Name Lab# Ratio Short Result E... BCR CT Value ABL CT Value BCR Quantity. ABL Quantity.
J. FAKE MOL-06-19
T. TEST MOL-06-20
T. TEST MOL-06-22
T. PATIENT MOL-06-23
B. TEST MOL-06-29
S. SCC_TEST MOL-06-31
S. SCC_TEST MOL-06-32
D. TEST MOL-06-34
S. TEST MOL-06-35
Worksheet#
Build D&T
Pending Action
Test
Worksheet Code
BCRAB
Build by
Status
New
Completed
Select All
ID 1 2 3 4 5 6 7 8 9 10 11
A NEG CTL NEG CTL NEG CTL NEG CTL POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL
B POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL
C POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL POS CTL
D
E
F
G
H
Print Worksheet
Print Label
Environment: TEST4
Login: SCC

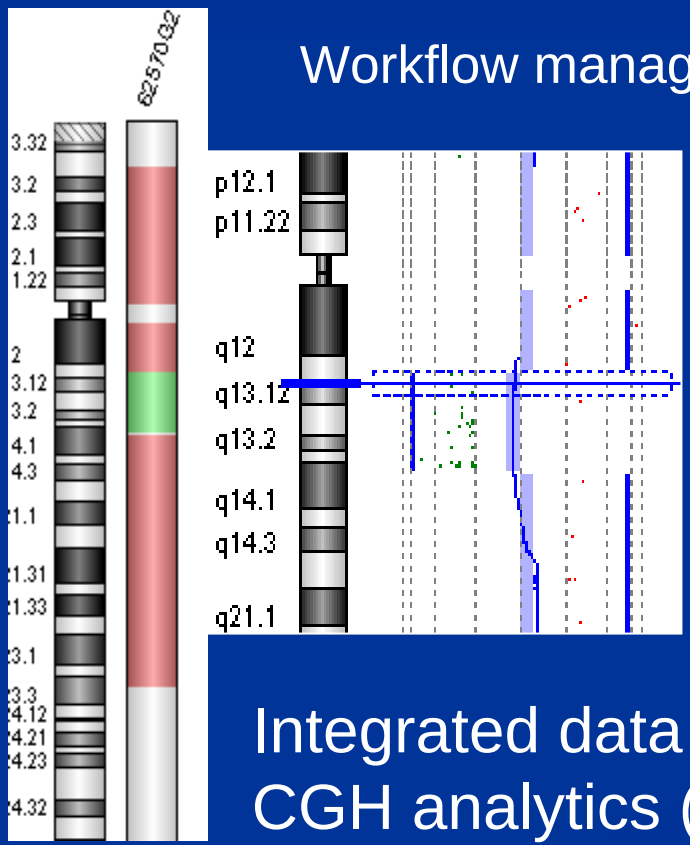

Item Type:
Reagent
Item Code:
DNA
Item Name:
DNA Template
Item Category:
PCR Reagent
Quantity:
1
Internal Stock#:
Vendor:
45612
Vendor Name:
Beckman Coulter
Vendor Cat#:
Vendor Lot#:
Volume:
10.1
Other Volume:
2
Available Volume:
8.1
Plate Volume:
0
Volume Unit:
ml
Completely Used
Delivered Date:
2/28/2006
Expiration Date:
/24/2006
QC Result:
QC Date:
QC Done by:
QC Required
Entered By:
SCC

A complex & flexible model to data integration

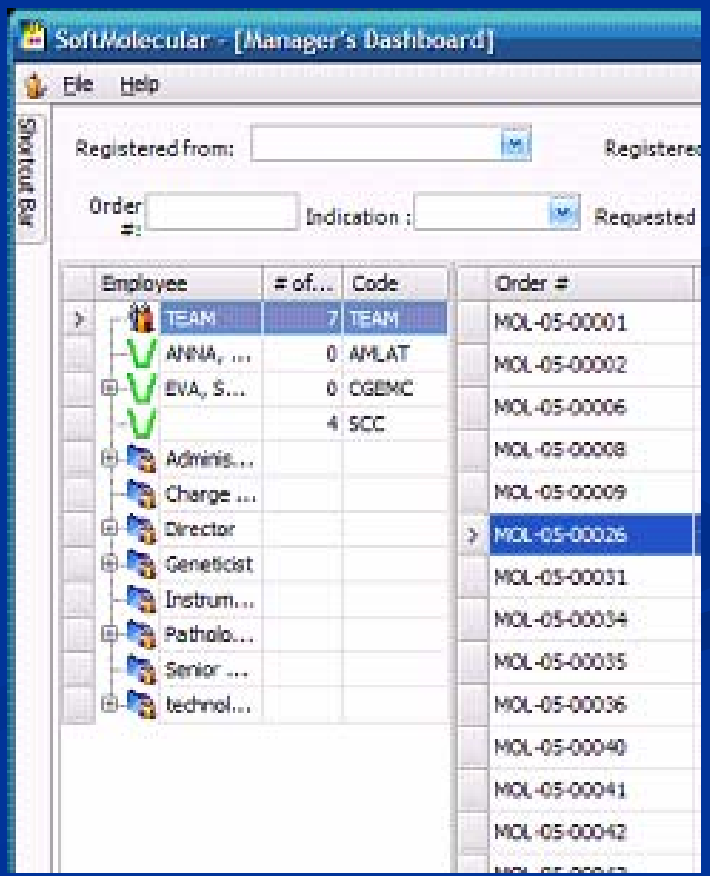




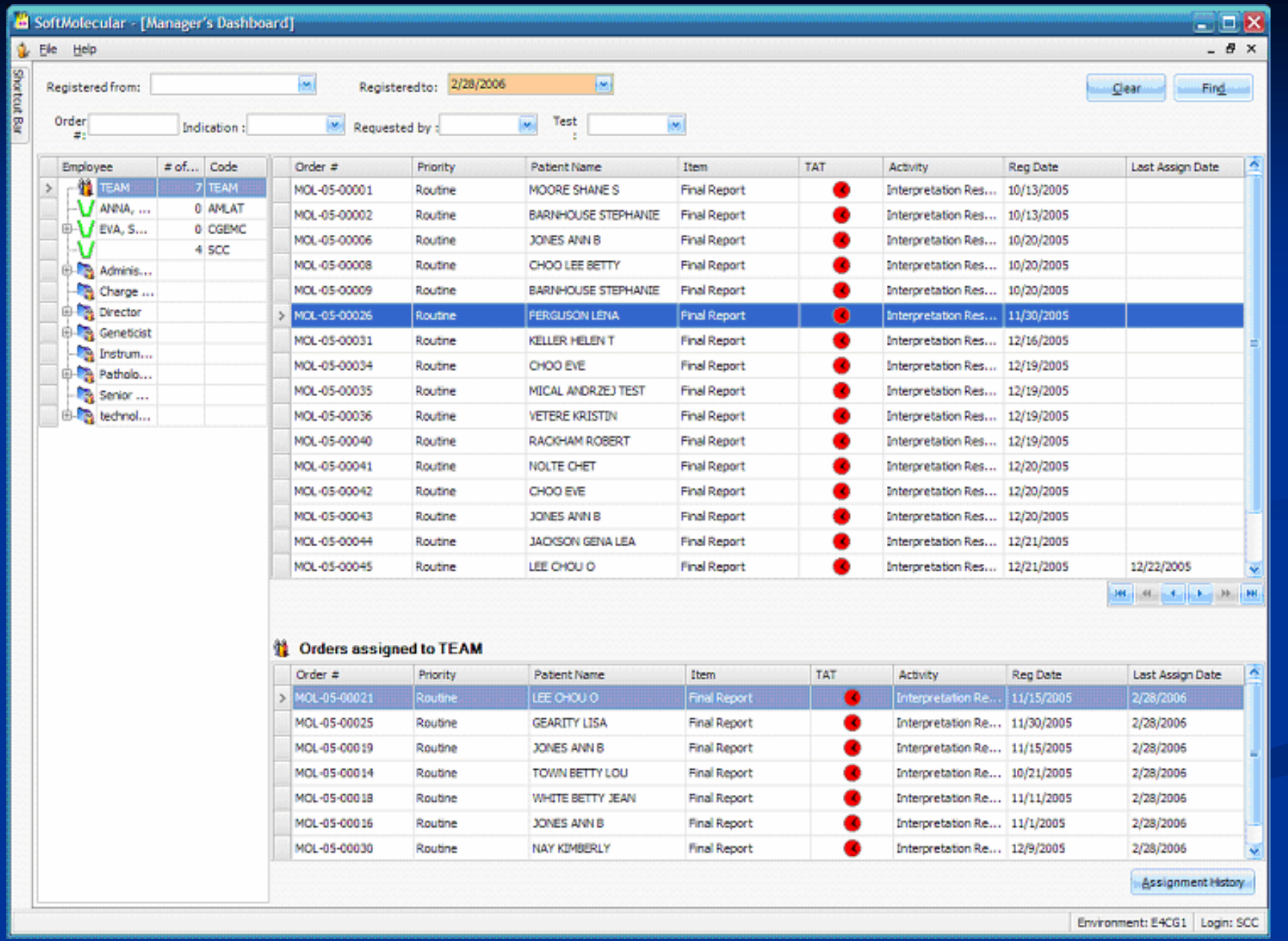
Display functionality: lab viewer/EMR



Workflow management: LIS



Integrated data analysis: CGH analytics (Agilent)


SoftMolecular - [Manager's Dashboard]
File
Help
Shortcut Bar
Registered from:
Registered to:
2/28/2006
Clear
Find
Order #:
Indication :
Requested by :
Test :
Employee
of...
Code
TEAM
ANNA, ...
EVA, S...
Adminis...
Charge ...
Director
Geneticist
Instrum...
Patholo...
Senior ...
technol...
Order #
Priority
Patient Name
Item
TAT
Activity
Reg Date
Last Assign Date
MOL-05-00001 Routine MOORE SHANE S Final Report Interpretation Res... 10/13/2005
MOL-05-00002 Routine BARNHOUSE STEPHANIE Final Report Interpretation Res... 10/13/2005
MOL-05-00006 Routine JONES ANN B Final Report Interpretation Res... 10/20/2005
MOL-05-00008 Routine CHOO LEE BETTY Final Report Interpretation Res... 10/20/2005
MOL-05-00009 Routine BARNHOUSE STEPHANIE Final Report Interpretation Res... 10/20/2005
MOL-05-00026 Routine FERGUSON LENA Final Report Interpretation Res... 11/30/2005
MOL-05-00031 Routine KELLER HELEN T Final Report Interpretation Res... 12/16/2005
MOL-05-00034 Routine CHOO EVE Final Report Interpretation Res... 12/19/2005
MOL-05-00035 Routine MICAL ANDRZEJ TEST Final Report Interpretation Res... 12/19/2005
MOL-05-00036 Routine VETERE KRISTIN Final Report Interpretation Res... 12/19/2005
MOL-05-00040 Routine RACKHAM ROBERT Final Report Interpretation Res... 12/19/2005
MOL-05-00041 Routine NOLTE CHET Final Report Interpretation Res... 12/20/2005
MOL-05-00042 Routine CHOO EVE Final Report Interpretation Res... 12/20/2005
MOL-05-00043 Routine JONES ANN B Final Report Interpretation Res... 12/20/2005
MOL-05-00044 Routine JACKSON GENA LEA Final Report Interpretation Res... 12/21/2005
MOL-05-00045 Routine LEE CHOU O Final Report Interpretation Res... 12/21/2005 12/22/2005
Orders assigned to TEAM
Order #
Priority
Patient Name
Item
TAT
Activity
Reg Date
Last Assign Date
MOL-05-00021 Routine LEE CHOU O Final Report Interpretation Re... 11/15/2005 2/28/2006
MOL-05-00025 Routine GEARITY LISA Final Report Interpretation Re... 11/30/2005 2/28/2006
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MOL-05-00014 Routine TOWN BETTY LOU Final Report Interpretation Re... 10/21/2005 2/28/2006
MOL-05-00018 Routine WHITE BETTY JEAN Final Report Interpretation Re... 11/11/2005 2/28/2006
MOL-05-00016 Routine JONES ANN B Final Report Interpretation Re... 11/1/2005 2/28/2006
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Assignment History
Environment: E4CG1
Login: SCC

General design principles for complex (molecular) technologies

- Workflow and test-building functionalities belong in the LIS (not the EMR, middleware)
- Data analysis belongs in 3rd party applications
- Internal lab reports & data stored in each laboratory will never match the EMR
  - Essential elements for process improvements, new technology development must be hidden since many of these values hold “less truth” than the reported values
- In-house informatics is essential

Thanks to:

Molec Dx

- Raja Luthra, PhD
- Stan Hamilton, MD
- Mohamed Gomah
- Vu Pham
- Danielle Cooper

The Soft Project

- SCC
  - Gilbert Hakim
  - Leszek Rumak
- Betty Madrid
- Don Brath
- Mark Routbort, MD