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Sue Kelly Executive Deputy Commissioner

## Molecular and Cellular Tumor Marker Proficiency Test Event MCTM 10-2012 Summary of results<sup>1</sup>

December 31, 2012

Dear Laboratory Director,

Below is a summary and discussion of the New York State Molecular and Cellular Tumor Markers proficiency test event MCTM 10-2012 from October 23, 2012.

<u>Samples</u>: All laboratories received three (3) different specimens prepared by Wadsworth Center personnel.

Evaluation: Laboratories were asked to perform those molecular assays for which they hold or have applied for a NYS permit. A total of 36 laboratories participated, performing various numbers and combinations of tests. The attached tables summarize the results and methods that were used by participating laboratories. In Table 1, a consensus interpretation is shown of R: rearranged/clonal band detected; G: germline/no clonal band detected; WT: wild-type; MUT: mutated; NEG: negative or not detected; POS: positive or detected; O: oligoclonal; N: no clonal band or fusion product detected. For IGHV only: H: clonal band detected and hypermutated; U: clonal band detected, but not hypermutated; I (Indeterminate) is shown if no consensus was reached because less than three labs performed a test, or if the concordance between labs was less than 80%. Please note that in a change from previous summary tables, only the all method consensus is shown.

Each lab will receive a personalized result sheet by regular mail that shows your lab's results in comparison to the all lab consensus (if any) derived from all methods combined. Two scores were calculated, one for each assay (assay score) across all three samples, and one for each sample (sample score) across all assays performed by your lab for each sample. From the latter we also calculated an overall score. Your assay score is expressed as a fraction, whereby the denominator is the number of samples you analyzed with a given assay and that was evaluable, i.e. produced a consensus, and the numerator is the number of samples for which you agreed with the consensus. For example, 3/3 means you analyzed all 3 samples and agreed with the consensus for all 3 of them. 1/2 would mean you analyzed only two samples, and agreed with the consensus for only one of them. If you reported results from two different methods, each method was

<sup>&</sup>lt;sup>1</sup> The use of brand and/or trade names in this document does not constitute an endorsement of the products on the part of the Wadsworth Center or the New York State Department of Health

scored independently and separate report cards were generated. The assay score is indicated in the 'score' column to the right of each assay you performed. The sample score was calculated as the percentage of 'correct' answers per sample (i.e. that agree with the consensus), based on the number of assays performed per sample that were evaluable. Assays for which no clear consensus was obtained, as indicated by "I", were not included in either the assay or sample score calculation. At the bottom of each sample column on your result sheet you will find the number of assays performed by your lab for the sample, the number of results that were evaluable and used to calculate the score, and the number of 'correct' answers. The actual sample score as % 'correct' answers was calculated by dividing the number of 'correct' answers by the number of evaluable answers times 100. Finally, we also calculated an overall sample score as the average of the three individual sample scores. At this time we did not assign a grade, but may do so in the future. If any of your results are different from the corresponding consensus we ask that you take a careful look at your analysis and investigate why you may have reported a discrepant result. While this may be because of your assay's design and/or sensitivity and thus does not represent an error per se, it could also be a true error, indicating suboptimal performance of your assay, or be due to a contamination in case of apparently false positives.

### NYS#L/L 2012-04 (Table 1):

B-cell tests: For IgH, 20 out of the 21 laboratories (95%) that used PCR reported a rearrangement. Rearrangements in IGH were detected with the Biomed-2 tubes A-C and D that target the three frameworks and the DH 1-6 region, respectively, but not with the tube E that targets only the DH 7 region. Similarly, labs that used the IVS (not Biomed-2) primers detected a rearrangement in all three framework regions. In comparison for labs that used LDT primers, five out of six (83%) detected a rearrangement in the framework 2 region; but only five out of seven (71%) detected a rearrangement in the framework 3 region; only one lab also used framework 1 primers and detected a rearrangement (Table 2). Six out of seven labs (86%) that tested for IgK reported a rearrangement. Rearrangements in IGK were primarily detected with the Biomed-2 tube A primers, although there was only a majority of five out of seven (71%), which did not reach the 80% required for a consensus (Table 3). No lab reported a translocation involving the IGH/CCND1 or IGH/BCL-2 locus, and no lab tested for the IGH/MYC translocation. Nine labs also tested for IGHV hypermutation, eight out which (89%) reported the sample as hypermutated (family 4-59, 3.2-3.95% mutated), whereas one lab did not detect a clonal band. Two labs also reported IGHV hypermutation with the IVS mix 2 of 3.8 and 5.3%, respectively. Thus, these results suggest that this sample contained a B-cell clone with IGH and IGK gene rearrangements and IGHV hypermutation.

<u>T-cell tests</u>: 18/20 (90%) and 10/11 (91%) laboratories that tested for TRG or TRB, respectively, by PCR found no rearrangement. For TRB one lab reported indeterminate by Southern blot; for TRG one lab reported oligoclonal or rearranged, respectively, by PCR. These results suggest that this sample did not contain cells with TRB and/or TRG gene rearrangements.

<u>EBV</u>: All three labs that tested for EBV by PCR identified the presence of EBV sequences.

<u>Various mutations (Table 6):</u> One lab only detected the NRAS c.35G>T, p.G12V mutation by sequencing; however, three other labs that also tested for NRAS mutation did not detect this mutation. Unfortunately, not enough method details we are given to evaluate whether the

discrepant results are caused by differences in the methods used. No other mutations were detected in any gene.

The results from all other tests performed were negative, although two labs reported very low levels (<1%) of bcr/abl1, p210, positivity.

In aggregate, these results indicate that the sample contained a clonal B-cell population with hypermutation in the IGHV region and the presence of EBV DNA. This conclusion is in agreement with the result from Flow Cytometry, which indicated the presence of a B-cell clone that expressed surface CD19, CD20, CD22, CD23, HLA-DR and CD45 antigens.

#### NYS#L/L 2012-05 (Table 1):

B-cell tests: For IGH and IGK, there was unanimous agreement that these genes were rearranged. Rearrangements in IGH were detected with the Biomed-2 tubes A, B, and C that target all three framework regions, but not with the tubes D and E that target the DH 1-7 regions. In contrast, labs that used the IVS (not Biomed-2) or LDT primers detected a rearrangement in the framework 1 and 2 regions, but not all labs also detected a rearrangement in the framework 3 region (Table 2). Rearrangements in IGK were detected with both Biomed-2 tube A and B primers (Table 3). For IGH/BCL-2 four out of nine labs (45%) reported a translocation, all in the major break point region. In contrast, no lab reported a translocation involving the IGH/CCND1 locus, and no lab tested for the IGH/MYC translocation. Nine labs reported IGHV hypermutation, seven of which assigned it to the IGHV2-70 family (two labs entered VH2-07 and VH3-7, respectively) with a mutation rate ranging from 9.12-11.8%. Two labs also reported IGHV hypermutation with the IVS mix 2, and also assigned it to the IGHV2-70 family with a mutation rate of 12.4 and 13.7%, respectively. Thus, these results suggest that this sample contained a B-cell clone with IGH and IGK gene rearrangements and IGHV hypermutation, and possibly a IGH/BCL-2 translocation in the major breakpoint region.

<u>T-cell tests</u>: 20/20 (100%) and 10/11 (91%) laboratories that tested for TRG or TRB, respectively, by PCR found no rearrangement. For TRB one lab reported indeterminate by Southern blot. These results suggest that this sample did not contain cells with TRB and/or TRG gene rearrangements.

<u>Various mutations (Table 6):</u> Three labs detected a C>T mutation in TP53 at position c.844 corresponding to p.R282W. No other mutations were detected in any gene.

The results from all other tests performed were negative.

In aggregate, these results indicate that the sample contained a clonal B-cell population with hypermutation in the IGHV region and a TP53 mutation. This conclusion is in agreement with the result from Flow Cytometry which indicated the presence of a B-cell clone positive for CD10, CD19, CD20, CD22, CD23, CD38, and CD45 antigens with kappa expression.

#### NYS#L/L 2012-06 (Table 1):

<u>B-cell tests</u>: For IGH, 18 out of 21 (86%) laboratories reported no rearrangement by PCR. The one lab that did find a rearrangement used the Biomed-2 tube E, but three other labs did not find

a rearrangement with these primers. Furthermore, three labs showed indeterminate results including one by Southern blot. Seven out of eight labs (88%) that tested for IGK by PCR found no rearrangement. No lab reported a translocation involving the IGH/CCND1 or IGH/BCL-2 loci. Thus, there was a consensus that this sample did not contain cells with immunoglobulin gene rearrangements.

<u>T-cell tests</u>: 18 out of 20 laboratories (90%) that tested for TRG by PCR found a rearrangement, possibly involving the  $V\gamma9$  and  $V\gamma10$  regions (Table 5). Seven out of the twelve labs (58%) that tested for TRB reported a rearrangement by PCR whereas three found no rearrangement, and two reported indeterminate, including one of the labs that used Southern blot. There was no clear consensus whether this sample exhibited a TRB rearrangement or not. Interestingly, the majority of the positive results came from the Biomed-2 tube A. Thus, these results suggest that this sample contained a T-cell clone with T-cell receptor gamma gene rearrangement, but uncertain T-cell receptor beta rearrangement.

The results from all other tests performed were negative.

In aggregate, these results indicate that the sample contained a clonal T-cell population. This conclusion is in agreement with the result from Flow Cytometry, which indicated the presence of immature T cells (CD5<sup>dim</sup>, CD7, CD38, CD45, and cytoCD3).

The attached tables show summaries of the results both overall (Table 1) as well as for each individual primer mix for the B- and T-cell tests (Tables 2-5). Furthermore, Table 6 shows a summary of the mutation results, and Tables 7 shows summaries of the methods and reagents used for most of the tests. Figure 1 shows the DNA and RNA yield distributions for the three samples. DNA yields from samples L/L4, 5, and 6 ranged from a minimum of 2.8, 2.6, and 2.6 μg/ml to a maximum of 306.9, 345.4, and 352.9 μg/ml, respectively, corresponding to a 110- to 136-fold difference between lowest and highest yield for each sample. RNA yields for samples L/L4, 5 and 6 also ranged broadly from 2, 4, and 2 µg/ml to 1039.9, 345.5, and 700 µg/ml, respectively, corresponding to a 86- to 520-fold difference between lowest and highest yield for each sample. These results raise the question whether everybody reported their results the same way. Please make sure that you report the DNA and RNA yields microgram (µg) and based on the correct volume of the original blood sample, from which you isolated the DNA and RNA. Do not report the volume as the volume in which you eluded the nucleic acid into. We realize that shipping the samples at room temperature is suboptimal for subsequent RNA analysis. However, because of the combined shipping with the malignant immunophenotyping samples we cannot change that.

Finally, we would like to add some general comments. Please make sure that you select the overall result in the first column, as it is this result that is used in the evaluation. Then fill in or select the part of the additional information as appropriate. Also please make sure that you choose the correct method where there is a choice. If your starting material is DNA you must choose PCR. If your starting material is RNA, you must choose RT-PCR. Please note: RT stands for Reverse Transcription, not real time, and thus should only be used for assays whose starting material is RNA. A few labs did not indicate the methods and/or reagents that they used for their assays or failed to give the overall result in the first column. We cannot properly evaluate your

results without this information. In particular, we ask that if you obtain your primers from InVivoScribe you correctly identify the source as IVS (not Biomed-2) (identified as gene rearrangement assays in their catalog) or IVS (Biomed-2) (identified as gene clonality assays in their catalog); for the purpose of this PT evaluation they are not considered lab developed even if you obtain the individual primer tubes separately as ASR reagents instead of as part of a RUO kit. This will make it easier to compare the performance of individual primer mixes. Finally, we ask that you analyze the samples by all molecular tests performed in your lab for which you hold or have applied for a NYS permit.

If you have any questions, comments or suggestions, you may contact me by phone or email at 518-474-2088 or <a href="mailto:schneid@wadsworth.org">schneid@wadsworth.org</a>. For specific questions about your lab's report or the evaluation please contact Dr. Rong Yao at (518) 474-1744 or <a href="mailto:yaor@wadsworth.org">yaor@wadsworth.org</a> or Ms. Susanne McHale at (518) 486-5775 or <a href="mailto:smchale@wadsworth.org">smchale@wadsworth.org</a>.

Please note there was a change to TWO Molecular and Cellular Tumor Marker PT mail-outs in 2012, with the next one being:

Mail-out date

March 19, 2013 October 22, 2013 **Due Date** 

April 17, 2013 November 20, 2013

Sincerely,

Erasmus Schneider, Ph.D. Director, Oncology Section

Clinical Laboratory Evaluation Program

Wadsworth Center, Room E604

Pelenerdes

Empire State Plaza

Albany, NY 12201-0509

# New York State Molecular and Cellular Tumor Marker Proficiency Test Event MCTM 10-2012 Table 1: Summary of results

A / O I -		1.0.6	2042.04					// 2042 /	<b>N</b> E				// 2042 /	20	
Assay / Sample	R/H	G/U	2012-04 I	O/N	Cons#	R/H	G/U	./L 2012-0	O/N	Cons#	R/H	G/U	./L 2012-0	O/N	Cons#
IGH	22	1			R	23				R	1	19	3		G
IGK	6	1			R	7				R	1	7			G
TRB	1	10	1		G		10	2		G	7	3	2		ı
TRG	1	18		1	G		20			G	18	2			R
IGHV	8			1	н	9				н				9	N
	POS	NEG	ı			POS	NEG	ı			POS	NEG	ı		
IGH/BCL2		9			NEG	4	5			ı		9			NEG
IGH/CCND1		3			NEG		3			NEG		3			NEG
IGH/MYC															
	MUT*	WT*	ı			MUT*	WT*	ı			MUT*	WT*	ı		
JAK2 V617F		28			WT		28			WT		28			WT
JAK2 Exon 12		8			WT		8			WT		8			WT
MPL		11			WT		11			WT		11			WT
FLT3 ITD		6			WT		6			WT		6			WT
FLT3 TKD		5			WT		5			WT		5			WT
NPM1		11			WT		11			WT		10			WT
СЕВРА		6			WT		6			WT		6			WT
IDH1		4			WT		3			WT		4			WT
IDH2		2			- 1		2			1		2			1
KIT		7			WT		7			WT		7			WT
	POS	NEG	ı			POS	NEG	ı			POS	NEG	ı		
BCR/ABL1 p210	2	20			NEG	1	21			NEG	1	21			NEG
BCR/ABL1 p190		19			NEG		19			NEG		19			NEG
BCR/ABL1 p210/p190		6			NEG		6			NEG		6			NEG
	MUT*	WT*	ı	N		MUT*	WT*	ı	N		MUT*	WT*	ı	N	
ABL Kinase domain		1		3	1		1		3	ı		1		3	ı
	POS	NEG	1			POS	NEG	ı			POS	NEG	ı		
PML/RARA Long		6			NEG		6			NEG		6			NEG
PML/RARA short		6			NEG		6			NEG		6			NEG
PML/RARA variable		3			NEG		3			NEG		3			NEG
PML/RARA L/S/V		1			ı		1			ı		1			ı
AML1/ETO		4			NEG		4			NEG		4			NEG
NPM1/ALK															
ETV6/RUNX1		2			1		2			ı		2			1
CBFB/MYH11		3			NEG		3			NEG		3			NEG
TCF3/PBX1		1			1		1			ı		1			ı
MLL/AF4		2			1		2			ı		2			ı
	MUT*	WT*	1			MUT*	WT*	ı			MUT*	WT*	1		
TP53		3			WT	3				MUT		3			WT
KRAS		9			WT		9			WT		9			WT
NRAS	1	3			1		4			WT		4			WT
HRAS		2			ı		2			ı		2			ı
BRAF		9			WT		9			WT		9			WT
	POS	NEG	1			POS	NEG	ı			POS	NEG	1		
EBV	3				POS		3			NEG		3			NEG
Interpretation:	Clonal B-cell	population with	IGH and I	GK rearran		Clonal B-	cell popula	tion with I	GH and IGI	<	Clonal T-cell populatioin with TRG rearrangement				
Comments	IGHV hypermi	utation and EB	v			rearrange	ments and	і і вну һур	ermutation	I					-
						<u> </u>					<u> </u>				

R: rearranged/clonal band detected; G: germline/no clonal band detected; O: oligoclonal; For IGHV only: H: clonal band detected and hypermutated; U: clonal band detected, but not hypermutated; N: no clonal band detected. MUT: mutated; WT: wild-type; N: no fusion product detected; NEG: neagtive or not detected; POS: positive or detected; I: indeterminate, a clear interpretation is not possible.

<sup>&</sup>lt;sup>a</sup>Consensus based on ≥80% concordance: I if no consensus or <3 results \*For details of which exons/codons were analyzed see table 6.

Table 2. Summary for IGH primer mixes

	l	/L 2012-04			L/L 2012-05	)	L/L 2012-06			
	R	G	cons	R	G	cons	R	G	cons	
LDT FR 1	1	0	I	1	0	I	0	1	I	
LDT FR 2	5	1	R	6		R	0	7	G	
LDT FR 3	5	2	ı	4	3	l I	0	6	G	
Biomed-2 Tube A	10		R	10		R	0	10	G	
Biomed-2 Tube B	11		R	11		R	0	11	G	
Biomed-2 Tube C	10		R	10		R	0	10	G	
Biomed-2 Tube D	3		R	0	3	G	0	3	G	
Biomed-2 Tube E	0	4	G	0	4	G	1	3	1	
IVS FR 1	6		R	6		R	0	6	G	
IVS FR 2	7		R	7		R	0	5	G	
IVS FR 3	8	0	R	2	6	I	0	7	G	

Table 3. Summary for IGK primer mixes

		L/L 2012-04			L/L 2012-05	5	L/L 2012-06			
	R	G	cons	R	G	cons	R	G	cons	
LDT Tube A	1	0	I	1	0	I	0	1		
LDT Tube B	0	1	1	1		I	0	1	I	
Biomed-2 Tube A	5	2	l I	6	1	R	0	7	G	
Biomed-2 Tube B	2	4	l I	7		R	1	6	G	

Table 4. Summary for TRB primer mixes

	l	/L 2012-04			L/L 2012-05		L/L 2012-06			
	R	G	cons	R	G	cons	R	G	cons	
LDT Tube A	0	2	I	0	1	I	1	0	I	
LDT Tube B	0	1	I	0	1	I	0	1	I	
Biomed-2 Tube A	0	8	G	0	9	G	6	3	I	
Biomed-2 Tube B	0	10	G	0	9	G	2	8	G	
Biomed-2 Tube C	1	9	G	1	8	G	2	8	G	

Table 5. Summary for TRG primer mixes

	L/L 2012-04				L/L 2012-05	5	L/L 2012-06			
	R	G	cons	R	G	cons	R	G	cons	
LDT Vy1-8	0	6	G	0	6	G	1	5	G	
LDT Vy9	0	4	G	0	4	G	4	0	R	
LDT Vy10	0	5	G	0	5	G	4	1	R	
LDT Vy11	0	4	G	0	4	G	1	3	I	
Biomed-2 Tube A	0	12	G	0	12	G	12	0	R	
Biomed-2 Tube B	1	9	G	0	11	G	10	1	R	
IVS Mix 1	0	2	ı	0	2	ı	2	0	ı	
IVS Mix 2	0	2	ı	0	2	ı	2	0	ı	
IVS v2.0	0			0			0	0		

Table 6: Summary of mutation assay results (All results are WT except where indicated)

L/L 2012-04		12-04		L/L 20	12-05		L/L 20	2012-06		
Gene	exons/codons tested	Result (WT if not indicated)	# of results entered	exons/codons tested	Result (WT if not indicated)	# of results entered	exons/codons tested	Result (WT if not indicated)	# of results entered	
JAK2 Exon 12										
MPL	codon 515		3	codon 515		3	codon 515		3	
	codon 505/515 (exon 10, 11)		2	codon 505/515 (exon 10, 11)		2	codon 505/515 (exon 10, 11)		2	
	exon 10		1	exon 10		1	exon 10		1	
FLT3 TKD	D835		1	D835		1	D835		1	
	D835/836		2	D835/836		2	D835/836		2	
СЕВРА	only one exon		1	only one exon		1	only one exon		1	
	exon 1		1	exon 1		1	exon 1		1	
	chromosome 19, single exon		1	chromosome 19, single exon		1	chromosome 19, single exon		1	
IDH1										
IDH2										
кіт	exon 17		1	exon 17		1	exon 17		1	
	exon 7		1	exon 7		1	exon 7		1	
	exon 8/17		1	exon 8/17		1	exon 8/17		1	
	D816		1	D816		1	D816		1	
TP53	exon 5-9		1	exons 4-9	p.R282W	1	exon 5-9		1	
				exon 8	g.14513C>T, p.R282W	1				
				exons 5-9	g.18775C>T, p.R282W	1				
KRAS	codon 12/13/61		3	codon 12/13/61	·	3	codon 12/13/61		3	
	codon 12/13		6	codon 12/13		6	codon 12/13		6	
NRAS	exon 1,2 (incl. codons 12/13/61)		2	codon 12/13/61		2	codon 12/13/61		2	
	exons 2-3	c.35G>T, p.G12V	1	exons 2-3 (not indicated)		1	exonsn 2-3 (not indicated)		1	
HRAS	codons 12/13/61		1	codon 12/13/61		1	codon 12/13/61		1	
			1			1			1	
BRAF	codon 599-602, exon 15		1	codon 599-602, exon 15		1	codon 599-602, exon 15		1	
	codon 600		3	codon 600		3	codon 600		3	
	exon 15		1	exon 15		1	exon 15		1	
	exon 11, 12, 15		1	exon 11, 12, 15		1	exon 11, 12, 15		1	
	exon 15, c1799T>A		1	exon 15, c1799T>A		1	exon 15, c1799T>A		1	
EGFR	exon 19/858		1	exon 19/858		1	exon 19/858		1	
PIK3CA										
PDGFRA										
WT1										
RUNX1	exon 1-8		1	exon 1-8		1	exon 1-8		1	

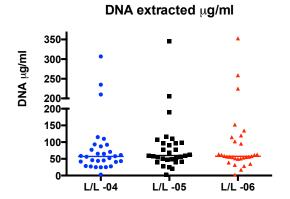
NOTE: each gene listed was analyzed by at least one laboratory for the presence of mutations; no entry means no specific mutation data were reported.

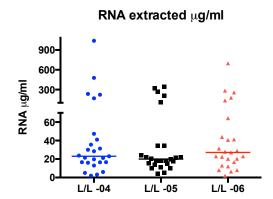
Table 7: Summary of methods and reagents used

	Total	SB	PCR	Seq	PCR + Seg	Lab developed	IVS (Biomed-	IVS (not Biomed-2)	Lab developed and IVS (Biomed-2)	Qualitative	Quantitative				
IGH	10tai 27	3B 2	26	Seq 0		aevelopea 7	2) 11	Biomea-2)	(Blomed-2)	Qualitative	Quantitative				
IGH	9		26 9		0		8	0	0						
TRB		0	9 11	0	0	1	8 10	0	0						
TRG	14 23	<b>2</b> 0	23	0	0	3 10	10 12	0	0						
IGHV	9	0	2	0	7	5	4	0	0						
IGH/BCL2	10	0	10	0	0	5	5	0	0						
IGH/CCND1	3	0	3	0	0	3	0	0	0						
IGH/MYC	0	0	0	0	0	0	0	0	0						
							Lab					Qual and			
	Total	PCR	RT-PCR	Com	PCR + Seq	RT-PCR Seq		(Oissen)	C	Qualitative	Quantitative	Quant			
141/21/0475				Seq	•		developed	(Qiagen)	Seegene		•				
JAK2 V617F	29	22	2	0	3	0	21	8	0	13	12	4			
JAK2 Exon 12 MPL	8	3	0	0	3	0	8	0	0						
	11	4	1	0	6	0	11		0						
FLT3 ITD	6	6	0	0	0	0	5	1	0						
FLT3 TKD	5	5	0	0	0	0	4	1	0						
NPM1	11	11	0	0	0	0	10	1	0						
CEBPA	6	2	0	0	4	0	6	0	0						
IDH1	5	2	0	0	3	0	5	0	0						
IDH2	2	0	0	0	2	0	2	0	0						
KIT	7	2	0	0	5	0	7	0	0						
							Lab	Ipsogen						Qual and	
	Total	PCR	RT-PCR	Seq	PCR + Seq	RT-PCR Seq	developed	(Qiagen)	Roche	Cepheid	Asuragen	Qualitative	Quantitative	Quant	IS Normalized
BCR/ABL1 p190	23	0	23	0	0	0	16	5	0	0	1			_	
BCR/ABL1 p210	25	0	25	0	0	0	16	6	0	0	1	1	18	6	11
BCR/ABL1 p210/p190	14	0	12	0	0	0	9	0	3	0	0	3	7	2	4
Abl Kinase domain	5	0	1	2	0	0	0	0	0	0	0				
PML/RARA	11	0	11	0	0	0	10	1	0	0	0	2	9	0	0
AML1/ETO	4	0	4	0	0	0	4	0	0	0	0	2	2	0	0
NPM1/ALK	0	1	0	0	0	0	1	0	0	0	0	1	0	0	0
ETV6/RUNX1	2	0	2	0	0	0	2	0	0	0	0	1	1	0	0
CBFB/MYH11	3	0	3	0	0	0	3	0	0	0	0	2	1	0	0
TCF3/PBX1	1	0	1	0	0	0	1	0	0	0	0	1	0	0	0
MLL/AF4	2	0	2	0	0	0	2	0	0	0	0	2	0	0	0
				202	Lab	0.1		0.11							
	Total	PCR	Seq	PCR + Seq	developed	Other	Roche Cobas	Other							
TP53	3	0	0	0	3	0									
KRAS	10	5	0	0	5	0									
NRAS	4	0	0	0	3	0									
HRAS	2	1	0	0	2	0									
							1								
EBV	3	3	0	0	3	0									
BRAF EBV	9	6 3	0	0	6 3	0	1								

NOTE: any discrepancies between the numbers in this table and the number of results in Table 1 are caused by incomplete and/or inconsistent data submission by some labs

Figure 1. NYS MCTM PT 10-12 DNA and RNA yields. The yields were converted to ug DNA and RNA per 1 ml blood.





	L/L 2012-04	L/L 2012-05	L/L 2012-06		L/L 2012-04	L/L 2012-05	L/L 2012-06
	DNA	DNA	DNA		RNA	RNA	RNA
Mean	74.6	80.8	85.5	Mean	102.5	64.4	81.5
Median	57.2	60.0	57.5	Median	23.00	20.00	27.14
Min	2.8	2.6	2.6	Min	2.0	4.0	2.0
Max	306.9	345.4	352.9	Max	1039.9	345.5	699.9