

**INTRODUCTION TO FORM 9 – BASELINE LOCAL LAB RESULTS**

It is important to note that there were three form versions, reflecting changing decisions during the course of the study about which laboratory values to record on the form.

**BASELINE LOCAL LAB RESULTS -- FORM 9 QxQ**

Selected results of the complete blood count (CBC), platelet count, and WBC differential, performed at your local laboratory, are to be transcribed onto this form. If these tests were performed within 72 hours prior to enrollment, results may be abstracted as the baseline tests. Otherwise, specimens must be drawn and sent at enrollment and *prior to* the first transfusion, with results transcribed onto this form once received from the lab. Follow your local institution's requirements for requisitions, the type of blood tube or tubes and volumes required for these tests.

**SECTION A -- GENERAL INFORMATION**

- A1.** Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page in the space provided.
- A2.** At the baseline visit, this question will always be completed in advance by the Medical Coordinating Center. Since this form is **only** used at the baseline visit, this number will always be "00".
- A3.** Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.
- A5.** Record the date that this form is completed.
- A6.** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.

**SECTION B -- CBC, Platelets and WBC Differential**

- B1.** Record the date the specimen was drawn for this test, i.e., the date of the blood draw. If the results are being abstracted from tests performed within 72 hours of enrollment, and all that is available is the date the CBC/diff were performed, record that date in the space provided.
- B2.** Record the total white blood cell count reported in  $10^3/\mu\text{L}$  or its equivalent (see page 2).
- B3.** Record the total red cell count reported in  $10^6/\mu\text{L}$  or its equivalent (see page 2).
- B4.** Record the hemoglobin count reported in g/dL or its equivalent (see page 2).
- B5.** Record the reported platelet count in  $10^3/\mu\text{L}$  or its equivalent (see page 2).

**B6 through B11**

*Questions B6 through B11 are not in the 1/15/96 version.*

In the 7/15/95 version Questions B6 through B8 refer to a 3 to 5– part differential as follows:

**B6. through B8.**

Record the percentage and/or absolute counts from a 3 or 5 part automated differential for Lymphocytes, Monocytes and cells synonymously reported as either Neutrophils, Segments (or Segs) or Bands. If, for some reason, a manual rather than automated differential was performed, **please note "manual count" or "manual" on this form.**

In the 8/01/96 version of Form 09 questions B6 –B11 refers to the WBC Differential as follows:

For Questions B6 through B11 (WBC differential), it is preferred that the absolute count rather than the percentage be recorded. If the absolute count is not available for any of the categories listed, then record the percentage. If neither the absolute count nor the percentage is available for any of the categories listed, then record “no result” in the right-hand margin next to the corresponding category.

- B6.** Record the absolute count in  $10^3/\mu\text{L}$ , or percentage, of Neutrophils/Granulocytes.
- B7.** Record the absolute count in  $10^3/\mu\text{L}$ , or percentage, of Bands.
- B8.** Record the absolute count in  $10^3/\mu\text{L}$ , or percentage, of Lymphocytes.
- B9.** Record the absolute count in  $10^3/\mu\text{L}$ , or percentage, of Monocytes.
- B10.** Record the absolute count in  $10^3/\mu\text{L}$ , or percentage, of Eosinophils.
- B11.** Record the absolute count in  $10^3/\mu\text{L}$ , or percentage, of Basophils.

**SECTION C -- LYMPHOCYTE PHENOTYPING**

Section C appears only in the 7/15/95 and 1/15/96 versions of Form 9

- C1.** Record the date blood was drawn for this test. If the results are being abstracted from tests performed within 72 hours of enrollment, and all that is available is the date the flow cytometry/phenotyping was performed, record that date in the space provided and **note on the form** that this is a test date versus a specimen date.
- C2.a.** Record the percent CD4 reported by your lab, or the CD3+/CD4+ quadrant result, if transcribing from a flow cytometry print-out.
- C2.b.** Record the absolute CD4 count calculated and reported by your local lab. If the count is not reported by your lab, calculate it according to the following formula:

**CD4 % ( C2.a.) x absolute Lymphocyte count (B6. b.) = absolute CD4 count (C2. b.)**  
**If the absolute Lymphocyte count was not reported by your lab, this can be calculated by using the following formula:**

$$\text{Absolute WBC count (B2.)} \times \text{Lymphocyte \% (B6.b.)} = \text{Absolute Lymphocyte count per } \mu\text{L or its equivalent (see below).}$$

- C3.a.** Record the percent CD8 reported by your lab, or the CD3+/CD8+ quadrant result, if transcribing from a flow cytometry print-out.

- C3.b.** Record the absolute CD8 count calculated and reported by your local lab. If the count is not reported by your lab, calculate it according to the formula(s) listed above in C2.b., substituting the CD8 percentage wherever CD4 appears in the formula(s).

**EQUIVALENTS**

$$\begin{aligned} /\mu\text{L} &= /\text{cumm or } /\text{mm}^3 \\ 10^3 &= \text{K} \\ 10^6 /\mu\text{L} &= 10^6 /\text{mm}^3 \\ \text{g/dL} &= \text{Gm/DL} \end{aligned}$$

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)  
FORM 9 -- BASELINE LOCAL LABORATORY RESULTS FORM**

**SECTION A -- GENERAL INFORMATION**

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) \_ \_ \_ - \_ \_ \_ - \_ \_
- A2. Visit number:   0     0
- A3. Subject initials:   \_   .   \_   .   \_
- A4. Form version:   0     7   /   1     5   /   9     5
- A5. Today's date:   \_     \_   /   \_     \_   /   \_     \_
- A6. Initials of person completing form:   \_   .   \_   .   \_

**SECTION B -- CBC/DIFFERENTIAL -- AUTOMATED**

- B1. Specimen date:   \_     \_   /   \_     \_   /   \_     \_
- B2. WBC   \_     \_   .   \_   (10<sup>3</sup>/μL)
- B3. RBC   \_     \_   .   \_   (10<sup>6</sup>/μL)
- B4. Hemoglobin   \_     \_   .   \_   (g/dL)
- B5. Platelets   \_     \_     \_   (10<sup>3</sup>/μL)
- B6. Lymphocytes a.   \_     \_   .   \_   % **and/or** b.   \_     \_   .   \_   (10<sup>3</sup>/μL)
- B7. Monocytes a.   \_     \_   .   \_   % **and/or** b.   \_     \_   .   \_   (10<sup>3</sup>/μL)
- B8. Neuts/Segs/Bands a.   \_     \_   .   \_   % **and/or** b.   \_     \_   .   \_   (10<sup>3</sup>/μL)

**SECTION C -- LYMPHOCYTE PHENOTYPING**

- C1. Specimen date:   \_     \_   /   \_     \_   /   \_     \_
- C2. Lymphocyte marker CD3/CD4 a.   \_     \_   % **and** b.   \_     \_     \_     \_   (per μL)
- C3. Lymphocyte marker CD3/CD8 a.   \_     \_   % **and** b.   \_     \_     \_     \_   (per μL)

**END OF FORM**

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)**  
**FORM 9 -- BASELINE LOCAL LABORATORY RESULTS FORM**

**SECTION A -- GENERAL INFORMATION**

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) \_ \_ \_ - \_ \_ \_ - \_ \_
- A2. Visit number:   0     0
- A3. Subject initials:   .  .  .
- A4. Form version:   0     1   /   1     5   /   9     6
- A5. Today's date:       /       /
- A6. Initials of person completing form:   .  .  .

**SECTION B -- CBC/PLATELETS**

- B1. Specimen date:       /       /
- B2. WBC                   (10<sup>3</sup>/μL)
- B3. RBC                   (10<sup>6</sup>/μL)
- B4. Hemoglobin             (g/dL)
- B5. Platelets                   (10<sup>3</sup>/μL)

**SECTION C -- LYMPHOCYTE PHENOTYPING**

- C1. Specimen date:       /       /
- C2. Lymphocyte marker CD3/CD4 a.          % **and** b.                   (per μL)
- C3. Lymphocyte marker CD3/CD8 a.          % **and** b.                   (per μL)

**END OF FORM**

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)**  
**FORM 9 -- BASELINE LOCAL LABORATORY RESULTS FORM**

**SECTION A -- GENERAL INFORMATION**

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) \_ \_ \_ - \_ \_ \_ - \_ \_
- A2. Visit number:   0     0
- A3. Subject initials:   \_   .   \_   .   \_   .
- A4. Form version:   0     8   /   0     1   /   9     6
- A5. Today's date:   \_     \_   /   \_     \_   /   \_     \_
- A6. Initials of person completing form:   \_   .   \_   .   \_   .

**SECTION B -- PLATELETS AND CBC WITH DIFFERENTIAL**

- B1. Specimen date:   \_     \_   /   \_     \_   /   \_     \_
- B2. WBC        .        ( $10^3/\mu\text{L}$ )
- B3. RBC        .        ( $10^6/\mu\text{L}$ )
- B4. Hemoglobin        .        (g/dL)
- B5. Platelets        .        ( $10^3/\mu\text{L}$ )

For Questions B6 through B11 the absolute differential is preferable to the percentage.  
 Record the percentage only if the absolute value is not available.

- B6. Neutrophils/Granulocytes a.        .        ( $10^3/\mu\text{L}$ ) **or** b.        .        %
- B7. Bands a.        .        ( $10^3/\mu\text{L}$ ) **or** b.        .        %
- B8. Lymphocytes a.        .        ( $10^3/\mu\text{L}$ ) **or** b.        .        %
- B9. Monocytes a.        .        ( $10^3/\mu\text{L}$ ) **or** b.        .        %
- B10. Eosinophils a.        .        ( $10^3/\mu\text{L}$ ) **or** b.        .        %
- B11. Basophils a.        .        ( $10^3/\mu\text{L}$ ) **or** b.        .        %

**END OF FORM**

## BASELINE LOCAL LAB RESULTS – FM09DATA CODEBOOK

PUB\_ID ----- SUBJECT ID

type: numeric (float)

range:	[1,531]	units:	1
unique values:	523	coded missing:	0 / 523

mean:	265.262
std. dev:	153.341

percentiles:	10%	25%	50%	75%	90%
	54	132	266	398	477

VISNUM ----- A2.VISIT NUMBER

type: string (str2)

unique values:	1	coded missing:	0 / 523
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tabulation:	Freq.	Value
	523	"00"

VISNUM:

1. Since this form is only used at baseline visit (QU 00), this variable is always coded as 00.

FORM\_V ----- A4.FORM VERSION

type:	numeric (float)
label:	FORM_V

range:	[12979,13362]	units:	1
unique values:	3	coded missing:	0 / 523

tabulation:	Freq.	Numeric	Label
	129	12979	07/15/95
	75	13163	01/15/96
	319	13362	08/01/96

CBC\_DATE ----- B1.CBC/PLATELET SPECIMEN DATE

type: numeric (float)  
 range: [-20,304] units: 1  
 unique values: 18 coded missing: 0 / 523

tabulation:

Freq.	Value
1	-20
1	-15
2	-8
3	-7
1	-6
1	-4
5	-3
22	-2
106	-1
336	0
30	1
4	2
4	3
3	4
1	9
1	24
1	48
1	304

CBC\_DATE:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization; positive values indicate dates subsequent to Randomization)

WBC ----- B2.WBC (10^3/uL)

type: numeric (float)  
 range: [.1,20.3] units: .1  
 unique values: 106 coded missing: 0 / 523

mean: 3.75583  
 std. dev: 2.8221

percentiles: 10% 25% 50% 75% 90%  
 1.4 1.9 3 4.6 7.1



RBC ----- B3.RBC (10<sup>6</sup>/uL)

type: numeric (float)  
 range: [.5,4] units: .1  
 unique values: 33 coded missing: 2 / 523  
 mean: 2.35777  
 std. dev: .578445  
 percentiles: 10% 25% 50% 75% 90%  
 1.6 2 2.4 2.8 3.1

HEMOGLOB ----- B4.HEMOGLOBIN (g/dL)

type: numeric (float)  
 range: [2.2,13.3] units: .1  
 unique values: 76 coded missing: 0 / 523  
 mean: 7.27878  
 std. dev: 1.37883  
 percentiles: 10% 25% 50% 75% 90%  
 5.7 6.6 7.3 8 8.8

PLATELET ----- B5.PLATELETS (10<sup>3</sup>/uL)

type: numeric (float)  
 range: [4,810] units: 1  
 unique values: 290 coded missing: 9 / 523  
 mean: 213.603  
 std. dev: 125.683  
 percentiles: 10% 25% 50% 75% 90%  
 71 118 186 290 385

LYMPHPER ----- B6a.LYMPHOCYTE (%) [7/15/95]

type: numeric (float)  
 range: [1,62] units: .1  
 unique values: 65 coded missing: 423 / 523  
 mean: 16.758  
 std. dev: 12.6709  
 percentiles: 10% 25% 50% 75% 90%  
 4.3 8 13 25.25 33.8

LYMPHPER:

1. Question B6.a. on form version 07/15/95

LYMPH\_UL ----- B6b.LYMPHOCYTE (10<sup>3</sup>/uL) [7/15/95]

type: numeric (float)  
 range: [.1,1.3] units: .1  
 unique values: 11 coded missing: 474 / 523

tabulation:	Freq.	Value
	6	.1
	12	.2
	9	.3
	2	.4
	5	.5
	3	.7
	2	.8
	4	1
	3	1.1
	1	1.2
	2	1.3

LYMPH\_UL:

1. Question B6.b. on form version 07/15/95

MONOPER ----- B7a.MONOCYTES (%) [7/15/95]

type: numeric (float)  
 range: [0,40] units: .1  
 unique values: 52 coded missing: 423 / 523

mean:	9.014				
std. dev:	6.88912				
percentiles:	10%	25%	50%	75%	90%
	2	5	7.95	11.75	18

MONOPER:

1. Question B7.a. on form version 07/15/95

MONO\_UL ----- B7b.MONOCYTES (10<sup>3</sup>/uL) [7/15/95]

type: numeric (float)  
 range: [0,.7] units: .1  
 unique values: 8 coded missing: 474 / 523

tabulation:	Freq.	Value
	2	0
	15	.1
	16	.2
	9	.3
	3	.4
	2	.5
	1	.6
	1	.7

## MONO\_UL:

1. Question B7.b. on form version 07/15/95

NEUTSPER ----- B8a.NEUTS/SEGS/BANDS (%) [7/15/95]  
 type: numeric (float)  
 range: [22.7,97] units: .1  
 unique values: 73 coded missing: 424 / 523  
 mean: 67.5879  
 std. dev: 17.8339  
 percentiles: 10% 25% 50% 75% 90%  
 41.1 55 70.4 81.6 88

## NEUTSPER:

1. Question B8.a. on form version 07/15/95

NEUTS\_UL ----- B8b.NEUTS/SEGS/BANDS (10<sup>3</sup>/uL) [7/15/95]  
 type: numeric (float)  
 range: [.2,12.1] units: .1  
 unique values: 30 coded missing: 475 / 523  
 mean: 2.02292  
 std. dev: 1.83758  
 percentiles: 10% 25% 50% 75% 90%  
 .5 .9 1.75 2.75 3.4

## NEUTS\_UL:

1. Question B8.b. on form version 07/15/95

LYMPH\_DT ----- C1.SPEC DATE - LYMPHOCYTE PHENOTYPING  
 type: numeric (float)  
 range: [-2165,14] units: 1  
 unique values: 51 coded missing: 347 / 523  
 mean: -35.3011  
 std. dev: 183.06  
 percentiles: 10% 25% 50% 75% 90%  
 -53 -6.5 0 0 1

## LYMPH\_DT:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization; positive values indicate dates subsequent to Randomization)

LYMPH\_DZ ----- DATE IMPUTATION INDICATOR -- LYMPH\_DT  
 type: numeric (float)  
 label: LYMPH\_DZ  
 range: [1,3] units: 1  
 unique values: 2 coded missing: 0 / 523  
 tabulation: Freq. Numeric Label  
                   522 1 Date not imputed  
                   1 3 July 1 imputed

## LYMPH\_DZ:

- Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing.

CD3\_CD4P ----- C2a.CD3/CD4 (%) [7/15/95 & 1/15/96]  
 type: numeric (float)  
 range: [0,67] units: 1  
 unique values: 27 coded missing: 351 / 523  
 mean: 5.63372  
 std. dev: 7.97215  
 percentiles: 10% 25% 50% 75% 90%  
                   1 1 3 6 14

## CD3\_CD4P:

- Question C2.a. on form versions 07/15/95 and 01/15/96

CD3\_CD4M ----- C2b.CD3/CD4 (/uL) [7/15/95 & 1/15/96]  
 type: numeric (float)  
 range: [0,1425] units: 1  
 unique values: 65 coded missing: 353 / 523  
 mean: 45.8765  
 std. dev: 127.161  
 percentiles: 10% 25% 50% 75% 90%  
                   1 5 11.5 40 99.5

## CD3\_CD4M:

- Question C2.b. on form versions 07/15/95 and 01/15/96

CD3\_CD8P ----- C3a.CD3/CD8 (%) [7/15/95 & 1/15/96]

type: numeric (float)

range: [0,91] units: 1

unique values: 65 coded missing: 357 / 523

mean: 54.253  
std. dev: 17.7841

percentiles:	10%	25%	50%	75%	90%
	32	42	57	66	76

CD3\_CD8P:

1. Question C3.a. on form versions 07/15/95 and 01/15/96

CD3\_CD8M ----- C3b.CD3/CD8 (/uL) [7/15/95 & 1/15/96]

type: numeric (float)

range: [0,1673] units: 1

unique values: 139 coded missing: 359 / 523

mean: 322.317  
std. dev: 264.193

percentiles:	10%	25%	50%	75%	90%
	66	128	248.5	439	690

CD3\_CD8M:

1. Question C3.b. on form versions 07/15/95 and 01/15/96

GRANULAB ----- B6a.NEUTRO/GRANUL (10<sup>3</sup>/uL) [8/1/96]

type: numeric (float)

range: [.3,15.8] units: .1

unique values: 57 coded missing: 361 / 523

mean: 2.72346  
std. dev: 2.45831

percentiles:	10%	25%	50%	75%	90%
	.8	1.3	1.9	3.2	5.8

GRANULAB:

1. Question B6.a on form version 08/01/96

GRANULPR ----- B6b.NEUTRO/GRANUL (%) [8/1/96]

type: numeric (float)  
 range: [9,90] units: .1  
 unique values: 102 coded missing: 350 / 523  
 mean: 59.4746  
 std. dev: 18.1961  
 percentiles: 10% 25% 50% 75% 90%  
                   33 47 61.3 72 82.5

GRANULPR:

1. Question B6.b on form version 08/01/96

BANDSAB ----- B7a.BANDS (10<sup>3</sup>/uL) [8/1/96]

type: numeric (float)  
 range: [0,1] units: .1  
 unique values: 7 coded missing: 481 / 523  
 tabulation: Freq. Value  
                   23 0  
                   7 .1  
                   5 .2  
                   1 .3  
                   3 .4  
                   2 .8  
                   1 1

BANDSAB:

1. Question B7.a on form version 08/01/96

BANDSPR ----- B7b.BANDS (%) [8/1/96]

type: numeric (float)  
 range: [0,40] units: .1  
 unique values: 30 coded missing: 385 / 523  
 mean: 6.10507  
 std. dev: 8.62382  
 percentiles: 10% 25% 50% 75% 90%  
                   0 0 3 8 18

BANDSPR:

1. Question B7.b on form version 08/01/96

LYMPHABS ----- B8a.LYMPHOCYTES (10<sup>3</sup>/uL) [8/1/96]

type: numeric (float)

range: [0,8] units: .1  
 unique values: 29 coded missing: 361 / 523

mean: .828395  
 std. dev: .859616

percentiles:	10%	25%	50%	75%	90%
	.2	.3	.65	.9	1.7

LYMPHABS:

1. Question B8.a on form version 08/01/96

LYMPHPRC ----- B8b.LYMPHOCYTES (%) [8/1/96]

type: numeric (float)

range: [1,73] units: .1  
 unique values: 99 coded missing: 349 / 523

mean: 22.9506  
 std. dev: 15.3595

percentiles:	10%	25%	50%	75%	90%
	6	10	18.9	33	46

LYMPHPRC:

1. Question B8.b on form version 08/01/96

MONOCABS ----- B9a.MONOCYTES (10<sup>3</sup>/uL)

type: numeric (float)

range: [0,5] units: .1  
 unique values: 14 coded missing: 363 / 523

tabulation:	Freq.	Value
	4	0
	38	.1
	39	.2
	31	.3
	18	.4
	7	.5
	9	.6
	5	.7
	1	.8
	3	.9
	2	1
	1	1.1
	1	1.4
	1	5

## MONOCABS:

- Question B9.a on form version 08/01/96

MONOCPRC ----- B9b.MONOCYTES (%)

type: numeric (float)

range: [0,29] units: .1  
 unique values: 66 coded missing: 348 / 523

mean: 8.348  
 std. dev: 5.28265

percentiles:	10%	25%	50%	75%	90%
	3	4.9	7	11.6	16

## MONOCPRC:

- Question B9.b on form version 08/01/96

EOSINABS ----- B10a.EOSINOPHILS (10<sup>3</sup>/uL)

type: numeric (float)

range: [0,1] units: .1  
 unique values: 9 coded missing: 375 / 523

tabulation:	Freq.	Value
	81	0
	38	.1
	11	.2
	5	.3
	5	.4
	3	.5
	2	.7
	1	.8
	2	1

## EOSINABS:

- Question B10.a on form version 08/01/96

EOSINPRC ----- B10b.EOSINOPHILS (%)

type: numeric (float)

range: [0,39] units: .1  
 unique values: 41 coded missing: 351 / 523

mean: 2.03605  
 std. dev: 4.24732

percentiles:	10%	25%	50%	75%	90%
	0	0	1	2	5



## EOSINPRC:

1. Question B10.b on form version 08/01/96

BASOPHAB ----- B11a.BASOPHILS (10<sup>3</sup>/uL)

type: numeric (float)

range: [0,.3] units: .1

unique values: 3 coded missing: 384 / 523

tabulation: Freq. Value

117	0
21	.1
1	.3

## BASOPHAB:

1. Question B11.a on form version 08/01/96

BASOPHPR ----- B11b.BASOPHILS (%)

type: numeric (float)

range: [0,7] units: .1

unique values: 20 coded missing: 354 / 523

tabulation: Freq. Value

84	0
4	.1
7	.2
5	.3
8	.4
4	.5
3	.6
4	.7
2	.8
3	.9
29	1
2	1.1
1	1.2
2	1.5
1	1.6
1	1.8
6	2
1	3
1	4
1	7

## BASOPHPR:

1. Question B11.b on form version 08/01/96