

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 . ($10^3/\mu\text{L}$)
- B3. RBC . ($10^6/\mu\text{L}$)
- B4. Hemoglobin . (g/dL)
- B5. Platelets ($10^3/\mu\text{L}$)
- B6. Lymphocytes a. . % **and/or** b. . ($10^3/\mu\text{L}$)
- B7. Monocytes a. . % **and/or** b. . ($10^3/\mu\text{L}$)
- B8. Neuts/Segs/Bands a. . % **and/or** b. . ($10^3/\mu\text{L}$)

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 . ($10^3/\mu\text{L}$)
- B3. RBC . ($10^6/\mu\text{L}$)
- B4. Hemoglobin . (g/dL)
- B5. Platelets ($10^3/\mu\text{L}$)

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 _ _ . _ (10³/μL)
- B3. RBC _ _ . _ (10⁶/μL)
- B4. Hemoglobin _ _ . _ (g/dL)
- B5. Platelets _ _ _ (10³/μL)

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. _ _ . _ (10³/μL) **or** b. _ _ . _ %
- B7. Bands a. _ _ . _ (10³/μL) **or** b. _ _ . _ %
- B8. Lymphocytes a. _ _ . _ (10³/μL) **or** b. _ _ . _ %
- B9. Monocytes a. _ _ . _ (10³/μL) **or** b. _ _ . _ %
- B10. Eosinophils a. _ _ . _ (10³/μL) **or** b. _ _ . _ %
- B11. Basophils a. _ _ . _ (10³/μL) **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 (10⁶/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 (10³/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 (10³/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 (10³/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 (10³/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 (10³/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 (10³/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 (10³/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 (10³/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 (10³/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 (10³/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