

INTRODUCTION TO FORM 27 – QUARTERLY 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.

QUARTERLY LOCAL LAB RESULTS – FORM 27 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. 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.** Enter the visit number.
- 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.** A CBC with platelets and WBC differential are required at each VATS quarterly visit. If results of these tests are not available, or the blood for these tests was not drawn for some reason, check the "No" box and specify the reason these results are missing. Information for example, such as "the patient refused the blood draw" or the "specimen was drawn but clotted" or "lost in transit to the lab," should be recorded here.
- B2.** Record the date the specimen was drawn for this test, i.e., the date of the blood draw.
- B3.** Record the total white blood cell count reported in $10^3/\mu\text{L}$ or its equivalent (see page 2).
- B4.** Record the total red cell count reported in $10^6/\mu\text{L}$ or its equivalent (see page 2).
- B5.** Record the hemoglobin count reported in g/dL or its equivalent (see page 2).
- B6.** Record the reported platelet count in $10^3/\mu\text{L}$ or its equivalent (see page 2).

B7 through B12

Questions B7 through B12 are not in the 1/15/96 version.

In the 7/15/95 version Questions B7 through B9 refer to a 3 to 5– part differential as follows:

B7. through B9.

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 B7 –B12 refers to the WBC Differential as follows:

For Questions B7 through B12 (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.

- B7.** Record the absolute count in $10^3/\mu\text{L}$, or percentage, of Neutrophils/Granulocytes.
- B8.** Record the absolute count in $10^3/\mu\text{L}$, or percentage, of Bands.
- B9.** Record the absolute count in $10^3/\mu\text{L}$, or percentage, of Lymphocytes.
- B10.** Record the absolute count in $10^3/\mu\text{L}$, or percentage, of Monocytes.
- B11.** Record the absolute count in $10^3/\mu\text{L}$, or percentage, of Eosinophils.
- B12.** Record the absolute count in $10^3/\mu\text{L}$, or percentage, of Basophils.

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 27 -- QUARTERLY LOCAL LABORATORY RESULTS FORM

SECTION A -- GENERAL INFORMATION

A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) _ _ _ - _ _ _ - _ _

A2. Visit number: _ _

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. Are CBC/Differential results available? 1. Yes
 2. No → a. Specify reason: → STOP. FORM COMPLETE.

B2. Specimen date: _ _ / _ _ / _ _

B3. WBC _ _ _ . _ _ (10³/μL)

B4. RBC _ _ _ . _ _ (10⁶/μL)

B5. Hemoglobin _ _ _ . _ _ (g/dL)

B6. Platelets _ _ _ _ _ (10³/μL)

B7. Lymphocytes a. _ . _ _ % **and/or** b. _ . _ _ (10³/μL)

B8. Monocytes a. _ . _ _ % **and/or** b. _ . _ _ (10³/μL)

B9. Neuts/Segs/Bands a. _ . _ _ % **and/or** b. _ . _ _ (10³/μL)

END OF FORM

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 27 -- QUARTERLY LOCAL LABORATORY RESULTS FORM

SECTION A -- GENERAL INFORMATION

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) _ _ _ - _ _ _ - _ _
- A2. Visit number: _ _
- 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. Are CBC/Differential results available? 1. Yes
 2. No → a. Specify reason: → STOP. FORM COMPLETE.
- B2. Specimen date: _ _ / _ _ / _ _
- B3. WBC _ _ _ . _ _ (10³/μL)
- B4. RBC _ _ _ . _ _ (10⁶/μL)
- B5. Hemoglobin _ _ _ . _ _ (g/dL)
- B6. Platelets _ _ _ _ _ (10³/μL)

END OF FORM

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 27 -- QUARTERLY LOCAL LABORATORY RESULTS FORM

SECTION A -- GENERAL INFORMATION

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) _____ - _____ - _____
- A2. Visit number: _ _ _
- 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. Are CBC/Platelets results available? 1. Yes 2. No → a. Specify reason: → STOP. FORM COMPLETE.

- B2. Specimen date: _ _ / _ _ / _ _
- B3. WBC _ _ _ . _ _ (10³/μL)
- B4. RBC _ _ _ . _ _ (10⁶/μL)
- B5. Hemoglobin _ _ . _ (g/dL)
- B6. Platelets _ _ _ _ (10³/μL)

For Questions B7 through B12 the absolute differential is preferable to the percentage.
 Record the percentage only if the absolute value is not available.

- B7. Neutrophils/Granulocytes a. _ _ . _ (10³/μL) **or** b. _ . _ %
- B8. Bands a. _ _ . _ (10³/μL) **or** b. _ . _ %
- B9. Lymphocytes a. _ _ . _ (10³/μL) **or** b. _ . _ %
- B10. Monocytes a. _ _ . _ (10³/μL) **or** b. _ . _ %
- B11. Eosinophils a. _ _ . _ (10³/μL) **or** b. _ . _ %
- B12. Basophils a. _ _ . _ (10³/μL) **or** b. _ . _ %

END OF FORM

QUARTERLY LOCAL LAB RESULTS – FM27DATA CODEBOOK

PUB_ID ----- SUBJECT ID
 type: numeric (float)
 range: [1,530] units: 1
 unique values: 365 coded missing: 0 / 2032
 mean: 263.822
 std. dev: 155.79
 percentiles: 10% 25% 50% 75% 90%
 43 132 266 399 482

VISNUM ----- A2.VISIT NUMBER
 type: string (str2)
 unique values: 15 coded missing: 0 / 2032
 tabulation: Freq. Value
 326 "03"
 283 "06"
 239 "09"
 208 "12"
 183 "15"
 166 "18"
 144 "21"
 123 "24"
 98 "27"
 81 "30"
 76 "33"
 58 "36"
 27 "39"
 14 "42"
 6 "45"

VISNUM:

1. This form is only used at quarterly visits (QU 03, QU 06, QU 09, etc.). Therefore, this variable is always coded as 03, 06, 09, etc.

FORM_V ----- A4.FORM VERSION
 type: numeric (float)
 label: FORM_V
 range: [12979,13362] units: 1
 unique values: 3 coded missing: 0 / 2032
 tabulation: Freq. Numeric Label
 56 12979 07/15/95
 59 13163 01/15/96
 1917 13362 08/01/96

CBC_DONE ----- B1.CBC/DIFFERENTIAL RESULTS AVAILABLE?

type: numeric (float)
 label: CBC_DONE
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 2032
 tabulation: Freq. Numeric Label
 1934 1 1:Yes
 98 2 2:No

CBC_DATE ----- B2.CBC/PLATELET SPECIMEN DATE

type: numeric (float)
 range: [49,1377] units: 1
 unique values: 774 coded missing: 98 / 2032
 mean: 459.355
 std. dev: 310.801
 percentiles: 10% 25% 50% 75% 90%
 97 189 386.5 662 925

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 ----- B3.WBC (10³/uL)

type: numeric (float)
 range: [.4,46.4] units: .1
 unique values: 152 coded missing: 99 / 2032
 mean: 4.95572
 std. dev: 3.09458
 percentiles: 10% 25% 50% 75% 90%
 2.1 3.1 4.4 6 8.2

RBC ----- B4.RBC (10⁶/uL)

type: numeric (float)
 range: [1.2,5.8] units: .1
 unique values: 43 coded missing: 101 / 2032
 mean: 3.58006
 std. dev: .682757
 percentiles: 10% 25% 50% 75% 90%
 2.7 3.1 3.6 4 4.5

LYMPH_UL ----- B7b.LYMPHOCYTE (10³/uL) [7/15/95]

type: numeric (float)

range: [.1,2.2] units: .1
 unique values: 12 coded missing: 2014 / 2032

tabulation:	Freq.	Value
	4	.1
	1	.2
	2	.3
	2	.4
	1	.6
	2	.7
	1	.8
	1	1.1
	1	1.2
	1	1.5
	1	1.6
	1	2.2

LYMPH_UL:

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

MONOPER ----- B8a.MONOCYTES (%) [7/15/95]

type: numeric (float)

range: [0,20] units: .1
 unique values: 25 coded missing: 1990 / 2032

tabulation:	Freq.	Value
	1	0
	1	2
	1	3
	3	4
	1	4.8
	3	5
	1	5.1
	1	5.3
	2	6
	2	6.3
	2	7
	1	7.2
	2	8
	3	9
	1	10.4
	1	10.7
	1	11
	4	12
	2	13
	2	14
	1	15.6
	3	16
	1	16.5
	1	18
	1	20

MONOPER:

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

MONO_UL ----- B8b.MONOCYTES (10³/uL) [7/15/95]

type: numeric (float)
 range: [0,.7] units: .1
 unique values: 6 coded missing: 2014 / 2032

tabulation:	Freq.	Value
	1	0
	7	.1
	4	.2
	4	.3
	1	.5
	1	.7

MONO_UL:

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

NEUTSPER ----- B9a.NEUTS/SEGS/BANDS (%) [7/15/95]

type: numeric (float)
 range: [13.9,90.1] units: .1
 unique values: 37 coded missing: 1990 / 2032

mean:	64.2119				
std. dev:	18.7737				
percentiles:	10%	25%	50%	75%	90%
	38	51	68.85	79	88

NEUTSPER:

- Question B9.a. on form version 07/15/95

GRANULPR:

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

BANDSAB ----- B8a.BANDS (10³/uL) [8/1/96]

type: numeric (float)
 range: [0,11.9] units: .1
 unique values: 18 coded missing: 1790 / 2032

tabulation:	Freq.	Value
	184	0
	24	.1
	6	.2
	6	.3
	3	.4
	2	.5
	1	.6
	1	.7
	2	.8
	1	.9
	3	1
	2	1.1
	1	1.2
	1	1.5
	2	2
	1	4.3
	1	5.2
	1	11.9

BANDSAB:

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

BANDSPR ----- B8b.BANDS (%) [8/1/96]

type: numeric (float)
 range: [0,73] units: .1
 unique values: 39 coded missing: 1314 / 2032

mean: 3.60808
 std. dev: 7.48235

percentiles:	10%	25%	50%	75%	90%
	0	0	0	4	12

BANDSPR:

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

LYMPHABS ----- B9a.LYMPHOCYTES (10³/uL) [8/1/96]

type: numeric (float)

range: [0,6.2]

units: .1

unique values: 50

coded missing: 970 / 2032

mean: 1.42458

std. dev: .916345

percentiles:	10%	25%	50%	75%	90%
	.4	.8	1.3	1.9	2.5

LYMPHABS:

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

LYMPHPRC ----- B9b.LYMPHOCYTES (%) [8/1/96]

type: numeric (float)

range: [0,76]

units: .1

unique values: 275

coded missing: 1138 / 2032

mean: 27.2937

std. dev: 14.024

percentiles:	10%	25%	50%	75%	90%
	10	16	27	37.5	45.1

LYMPHPRC:

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

MONOCABS ----- B10a.MONOCYTES (10³/uL)

type: numeric (float)

range: [0,1.6]

units: .1

unique values: 16

coded missing: 967 / 2032

tabulation:	Freq.	Value
	5	0
	50	.1
	178	.2
	235	.3
	213	.4
	156	.5
	85	.6
	64	.7
	46	.8
	11	.9
	8	1
	7	1.1
	3	1.2
	2	1.3
	1	1.5
	1	1.6

MONOCABS:

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

MONOCPRC ----- B10b.MONOCYTES (%)

type: numeric (float)

range: [0,44.8] units: .1
 unique values: 136 coded missing: 1142 / 2032

mean: 8.70472
 std. dev: 4.74441

percentiles:	10%	25%	50%	75%	90%
	4	6	8	11	14

MONOCPRC:

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

EOSINABS ----- B11a.EOSINOPHILS 10[^]/uL

type: numeric (float)

range: [0,2.5] units: .1
 unique values: 17 coded missing: 981 / 2032

tabulation:	Freq.	Value
	173	0
	437	.1
	217	.2
	97	.3
	47	.4
	26	.5
	18	.6
	5	.7
	10	.8
	9	.9
	4	1
	3	1.1
	1	1.2
	1	1.4
	1	1.6
	1	2.4
	1	2.5

EOSINABS:

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

EOSINPRC ----- B11b.EOSINOPHILS (%)

type: numeric (float)
 range: [0,39] units: .1
 unique values: 130 coded missing: 1140 / 2032
 mean: 3.65135
 std. dev: 4.71634
 percentiles: 10% 25% 50% 75% 90%
 0 1 2 4.5 9

EOSINPRC:

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

BASOPHAB ----- B12a.BASOPHILS (10^3/uL)

type: numeric (float)
 range: [0,.5] units: .1
 unique values: 5 coded missing: 990 / 2032
 tabulation: Freq. Value
 691 0
 339 .1
 7 .2
 4 .3
 1 .5

BASOPHAB:

1. Question B12.a on form version 08/01/96

BASOPHPR ----- B12b.BASOPHILS (%)

type: numeric (float)
 range: [0,6] units: .1
 unique values: 28 coded missing: 1146 / 2032
 mean: .549549
 std. dev: .657864
 percentiles: 10% 25% 50% 75% 90%
 0 0 .4 1 1

BASOPHPR:

1. Question B12.b on form version 08/01/96