

**STOP II TRIAL
 CORE LABORATORY FORM**

AFFIX PATIENT LABEL HERE

A1. On-site person completing page 1 of form: _____ (Initials):

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A2. Date samples shipped (Month/Day/Year): _____ / _____ / _____

A3. Reason for Collection:

1. Baseline Visit 2. Quarterly Visit
 3. Annual Visit 4. Exit from study

5. Transfusion →

A3.a Date of Transfusion (Month/Day/Year): _____ / _____ / _____
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For Office Use A3.a1

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6. Neurological Event →

A3.b Date of Event (Month/Day/Year): _____ / _____ / _____
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B. SPECIMENS:

Type of Visit	Specimens Required (# in parentheses = # of tubes required)		
	Routine Hematology (Lavender Top)	Serum Chemistries (Red Top)	Serum Repository (Red Top)
Trial Entry	(2) 5 ml	(2) 5 ml*	(1) 5 ml
Quarterly	(1) 5 ml		(1) 5 ml
Annual	(1) 5 ml	(1) 5 ml*	(1) 5 ml
Exit from study	(1) 5 ml	(1) 5 ml*	(1) 5 ml
Transfusion (pre)	(1) 5 ml		
Neurological Event	(1) 5 ml		(1) 5 ml

* Will also be used for infection panel

Amount and type of tube	To be completed by Study Coordinator		For Core Lab use
	Date blood Drawn	# of tubes Enclosed	# of tubes received In good condition
B1. 5 ml lavender-top tube	a. _____ / _____ / _____	b. _____	c. _____
B2. 5 ml red-top tube	a. _____ / _____ / _____	b. _____	c. _____

C. TRANSFUSION STATUS

C1. Has patient been transfused during the last 4 months? 1. NO 2. YES

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C1.a Date of Last Transfusion: _____ / _____ / _____

D. LABORATORY TEST RESULTS (To be completed by MCG Core Lab)

D1. Core Lab person completing form: _____ (Initials):

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D2. Date shipment received (Month/Day/Year): _____/_____/_____

D3. Date Core Lab sections completed (Month/Day/Year): _____/_____/_____

D4. Hemoglobin Analysis:

- a. % S

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- b. % F

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- c. %A₂

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- d. %A

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- e. % other

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D4.e1. SPECIFY: _____

f. Hemoglobin Phenotype

1. SS
 2. Sβ⁰ thal
 3. Other →

D4.f1. SPECIFY: _____

D5. CBC

		Reference Range				
a. White Cell Count (x 10 ⁹ /l) (<u>uncorrected</u> for nRBCs)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table>				3.5 - 22.5	
b. Red Cell Count (x10 ¹² /l)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table>				1.5 - 5	
c. Hemoglobin (g/dl)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table>				5 - 12	
d. Hematocrit (%)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table>				14 - 36	
e. Mean Cell Volume (fl)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table>				60 - 110	
f. Mean Cell Hemoglobin (pg)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table>				22 - 35	
g. Mean Cell Hemoglobin Concentration (g/dl)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table>					
h. RDW (%)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table>					
D6. Reticulocyte Count (%)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td></tr></table>				0 - 30	
D7. Platelet Count (x10 ⁹ /l)	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td><td style="width: 20px; height: 15px;"></td></tr></table>					100 - 750

D8. WBC Differential/Nucleated RBCs

- a. PMN (%)
- b. Bands (%)
- c. Lymphocytes (%)
- d. Monocytes (%)
- e. Eosinophils (%)
- f. Basophils (%)
- g. Other (includes atypical cells, myelocytes, metamyelocytes) (%)
- h. Nucleated Red Blood Cells (/100 WBC)

D9. Serum Ferritin (ng/ml)

D10. Serum chemistries

- | | | Reference Range |
|-----------------------------|---|-----------------|
| a. ALT (SGPT) (U/l) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | 0 - 75 |
| b. GGT (U/l) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | 12 - 89 |
| c. LDH (U/l) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | 50 - 1000 |
| d. Total Bilirubin (mg/dl) | <input type="text"/> <input type="text"/> . <input type="text"/> | .5 - 1.0 |
| e. Direct Bilirubin (mg/dl) | <input type="text"/> <input type="text"/> . <input type="text"/> | 0 - 1.0 |

D11. β^S Haplotype: _____

D12. Number α Genes:

D13. Infection Panel:

- a. Hepatitis B Surface Antibody 1. **NEGATIVE** 2. **POSITIVE**
- b. Hepatitis C Antibody 1. **NEGATIVE** 2. **POSITIVE**

D14. Serum repository sample received

 1. **NO** 2. **YES**