

# TLC Trial Form VISIT1A.04

## Repeat Eligibility Lab Work

### Pre-Randomization Visit 1A

Center ID: \_\_\_\_\_ - \_\_\_\_\_  
Screening ID: S \_\_\_\_\_ - \_\_\_\_\_  
Visit Code: V1 \_\_\_\_\_  
Date of Visit V1A \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**INSTRUCTIONS:** This form is to be filled out at Pre-Randomization Visit V1A, for local lab tests repeated because of abnormality at Pre-Randomization Visit 1. Do not repeat any lab tests which were normal at Pre-Randomization Visit 1.

#### LOCAL LABORATORY TESTS

1. **Hemoglobin** ( )<sub>0</sub> Done \_\_\_\_\_ . \_\_\_\_\_
2. **Platelet count** ( )<sub>0</sub> Done \_\_\_\_\_ K
3. **Absolute neutrophil count** ( )<sub>0</sub> Done \_\_\_\_\_ , \_\_\_\_\_
4. **Alkaline phosphatase** ( )<sub>0</sub> Done \_\_\_\_\_
5. **AST** ( )<sub>0</sub> Done \_\_\_\_\_
6. **ALT** ( )<sub>0</sub> Done \_\_\_\_\_

#### REVIEW OF LABORATORY RESULTS

7. Is the hemoglobin less than 10.0?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes ( )<sub>2</sub> Not applicable
8. Is the platelet count less than 150,000/mm<sup>3</sup>?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes ( )<sub>2</sub> Not applicable
9. Is the absolute neutrophil count less than 800/mm<sup>3</sup>?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes ( )<sub>2</sub> Not applicable
10. Is the alkaline phosphatase greater than twice the upper limit of normal for your lab?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes ( )<sub>2</sub> Not applicable
11. Is the AST greater than twice the upper limit of normal for your lab?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes ( )<sub>2</sub> Not applicable
12. Is the ALT greater than twice the upper limit of normal for your lab?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes ( )<sub>2</sub> Not applicable

*If you have answered "Yes" to any of the above questions, this child is **NOT ELIGIBLE** for the TLC Trial.*

*Date of Visit V1A*      \_\_\_\_ / \_\_\_\_ / \_\_\_\_