

# TLC Trial Form LABRVW.04 Local Lab Review

Center ID:	_____ - _____
Study ID:	T _____ - _____
Visit Code:	T _____
Date labs done	____ / ____ / ____

**INSTRUCTIONS:** This form is to be filled out by a physician not involved in patient care when local lab results return during treatment phase.

## LOCAL LABORATORY RESULTS

1. **Platelet count** \_\_\_\_\_ **K**
2. **Absolute neutrophil count** \_\_\_\_\_, \_\_\_\_\_
3. **Alkaline phosphatase** \_\_\_\_\_
4. **AST** \_\_\_\_\_
5. **ALT** \_\_\_\_\_

## LOCAL LABORATORY REVIEW

6. Is the platelet count less than 150,000/mm<sup>3</sup>?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes
7. Is the absolute neutrophil count less than 800/mm<sup>3</sup>?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes
8. Is the alkaline phosphatase greater than five times the upper limit for your lab?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes
9. Is the AST greater than twice the upper limit for your lab?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes
10. Is the ALT greater than twice the upper limit for your lab?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes
11. Is there any combination of above lab values which the reviewing physician believes may be of concern?  
( )<sub>0</sub> No ( )<sub>1</sub> Yes, specify: \_\_\_\_\_
12. In the opinion of the reviewing physician, is this child on active drug or placebo?  
( )<sub>1</sub> Active ( )<sub>2</sub> Placebo ( )<sub>3</sub> No opinion

13. **Reviewing Physician** \_\_\_\_\_  
*Signature* \_\_\_\_\_ *TLC Code* \_\_\_\_\_
14. **Date** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy

*If you have answered "Yes" to any of the above questions, please repeat the lab tests in question and fill out the remainder of this form.*

Center ID:	_____ - _____
Study ID:	T _____ - _____
Visit Code:	T _____
Date labs done	____ / ____ / ____

The remainder of this form is to be filled out only if local lab abnormalities are found during the treatment phase.

**REPEAT LOCAL LAB WORK**

- 15. **Date of repeat** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy
- 16. **Platelet count** ( )<sub>o</sub> Done \_\_\_\_\_ K
- 17. **Absolute neutrophil count** ( )<sub>o</sub> Done \_\_\_\_\_ , \_\_\_\_\_
- 18. **Alkaline phosphatase** ( )<sub>o</sub> Done \_\_\_\_\_
- 19. **AST** ( )<sub>o</sub> Done \_\_\_\_\_
- 20. **ALT** ( )<sub>o</sub> Done \_\_\_\_\_

**OUTCOME**

- 21. Have the abnormal lab results been confirmed?  
( )<sub>o</sub> No ( )<sub>i</sub> Yes
- 22. Has TLC study drug been interrupted or discontinued?  
( )<sub>o</sub> No ( )<sub>i</sub> Yes  
*If YES: fill out TLC Form OFF*
- 23. Has this child's treatment assignment been unblinded?  
( )<sub>o</sub> No ( )<sub>i</sub> Yes  
*If YES: fill out TLC Form UNBLIND*
- 24. Has any other treatment been initiated?  
( )<sub>o</sub> No ( )<sub>i</sub> Yes, specify: \_\_\_\_\_

25. **Reviewing Physician** \_\_\_\_\_  
*Signature* \_\_\_\_\_  
*TLC Code*

26. **Date** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy

**COMMENTS**