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^3?

   ( )$_0$ No ( )$_1$ Yes

7. Is the absolute neutrophil count less than 800/mm_3?

   ( )$_0$ No ( )$_1$ Yes

8. Is the alkaline phosphatase greater than five times the upper limit for your lab?

   ( )$_0$ No ( )$_1$ Yes

9. Is the AST greater than twice the upper limit for your lab?

   ( )$_0$ No ( )$_1$ Yes

10. Is the ALT greater than twice the upper limit for your lab?

    ( )$_0$ No ( )$_1$ Yes

11. Is there any combination of above lab values which the reviewing physician believes may be of concern?

    ( )$_0$ No ( )$_1$ Yes, specify: _____

12. In the opinion of the reviewing physician, is this child on active drug or placebo?

    ( )$_1$ Active ( )$_2$ Placebo ( )$_3$ 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.

Send to:
TLC Data Coordinating Center

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** ( )0 Done ___ ___ ___ ___ K

17. **Absolute neutrophil count** ( )0 Done ___ ___ ___ , ___ ___ ___

18. **Alkaline phosphatase** ( )0 Done ___ ___ ___ ___

19. **AST** ( )0 Done ___ ___ ___

20. **ALT** ( )0 Done ___ ___ ___

OUTCOME

21. Have the abnormal lab results been confirmed?

( )0 No ( )1 Yes

22. Has TLC study drug been interrupted or discontinued?

( )0 No ( )1 Yes

If YES: fill out TLC Form OFF

23. Has this child's treatment assignment been unblinded?

( )0 No ( )1 Yes

If YES: fill out TLC Form UNBLIND

24. Has any other treatment been initiated?

( )0 No ( )1 Yes, specify: _____

25. **Reviewing Physician** _____ ___ - ___ ___ ___ ___
Signature *TLC Code*

26. **Date** ___ ___ / ___ ___ / ___ ___ *mm/dd/yy*

COMMENTS

Send to:
TLC Data Coordinating Center