

TLC Trial Form VISIT1A.04 Repeat Eligibility Lab Work Pre-Randomization Visit 1A

Center ID:	_____ - _____
Screening ID:	S _____ - _____
Visit Code:	V1 _____
Date of Visit VIA	____ / ____ / ____

INSTRUCTIONS: This form is to be filled out at Pre-Randomization Visit VIA, 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** ()₀ Done _____ . _____
2. **Platelet count** ()₀ Done _____ K
3. **Absolute neutrophil count** ()₀ Done _____ , _____
4. **Alkaline phosphatase** ()₀ Done _____
5. **AST** ()₀ Done _____
6. **ALT** ()₀ Done _____

REVIEW OF LABORATORY RESULTS

7. Is the hemoglobin less than 10.0?
()₀ No ()₁ Yes ()₂ Not applicable
8. Is the platelet count less than 150,000/mm³?
()₀ No ()₁ Yes ()₂ Not applicable
9. Is the absolute neutrophil count less than 800/mm³?
()₀ No ()₁ Yes ()₂ Not applicable
10. Is the alkaline phosphatase greater than twice the upper limit of normal for your lab?
()₀ No ()₁ Yes ()₂ Not applicable
11. Is the AST greater than twice the upper limit of normal for your lab?
()₀ No ()₁ Yes ()₂ Not applicable
12. Is the ALT greater than twice the upper limit of normal for your lab?
()₀ No ()₁ Yes ()₂ Not applicable

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

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ADMINISTRATIVE MATTERS

13. **Date form completed** _____ / _____ / _____ mm/dd/yy
14. **TLC staff** _____
Signature _____ *TLC Code* _____
15. **Eligibility status** ()₁ Eligible ()₂ Not eligible, specify _____

COMMENTS