

TLC Trial Form V1 REVIEW.04

Review of Eligibility Lab Results

Pre-Randomization Visit 1

Center ID: _____ - _____
Screening ID: S _____ - _____
Visit Code: V 1
Date labs done _____ / _____ / _____ mm/dd/yy

INSTRUCTIONS: This form is to be completed as lab results from Pre-Randomization Visit 1 become available.

LOCAL LABORATORY RESULTS

1. **Hemoglobin** _____ . _____
2. **Red cell distribution width** _____ . _____
3. **MCV** _____ . _____
4. **Platelet count** _____ K
5. **Absolute neutrophil count** _____ , _____
6. **Alkaline phosphatase** _____
7. **AST** _____
8. **ALT** _____
9. **Serum creatinine** _____ . _____

EVALUATION OF ELIGIBILITY BASED ON LOCAL LAB RESULTS

10. Is the hemoglobin less than 9.0?
 No Yes
11. Is the serum creatinine greater than 1.0?
 No Yes

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

12. Is the hemoglobin greater than or equal to 9.0 but less than 10.0 **AND** is the RDW increased?
 No Yes
13. Is the platelet count less than 150,000/mm³?
 No Yes
14. Is the absolute neutrophil count less than 800/mm³?
 No Yes
15. Is the alkaline phosphatase greater than twice the upper limit of normal for your lab?
 No Yes
16. Is the AST greater than twice the upper limit of normal for your lab?
 No Yes

Send to:
TLC Data Coordinating Center

Center ID: _____ - _____
 Screening ID: S _____ - _____
 Visit Code: _____ V 1
 Date labs done _____ / _____ / _____ mm/dd/yy

17. Is the ALT greater than twice the upper limit of normal for your lab?

()₀ No ()₁ Yes

If you have answered Yes to any of the above questions, this child's enrollment must be DEFERRED pending resolution of abnormalities.

CDC LAB RESULTS

18. CDC PbB _____

19. Is the CDC PbB less than 20 µg/dL or greater than 44 µg/dL?

()₀ No ()₁ Yes

20. CDC Ferritin _____ ()₁ not available

*If the CDC PbB is less than 20 or greater than 44 µg/dL, this child is **NOT ELIGIBLE** for the TLC Trial.*

ADMINISTRATIVE MATTERS

21. Date form completed _____ / _____ / _____ mm/dd/yy

22. TLC Staff _____ - _____
Signature TLC Code

23. Eligibility status ()₁ Eligible ()₂ Not eligible, specify _____
 ()₃ Defer, specify _____

If deferred:

24. Date of V1A _____ / _____ / _____ mm/dd/yy Time _____ : _____

COMMENTS