

A1. Site/Study ID #: _____ / _____ / _____ A2. Date of Exam: _____ / _____ / _____
 Month Day Year A3. Staff Initials: _____

A4. Follow-up visits: 2 Week 1 Month 2 Month 3 Mon 6 Mon 12Mon 18 Month 24 Mon Transplant

DCC

To

SECTION B: Bilirubin

Test		Lab Value (use earliest value if repeated on same day)	
B01	Total bilirubin	B01MG _____ . _____ mg/dl	B01ND 8. <input type="checkbox"/> ND
B47.	Indirect bilirubin	B02MG _____ . _____ mg/dl	B02ND 8. <input type="checkbox"/> ND
B48.	Direct bilirubin	B03MG _____ . _____ mg/dl	B03ND 8. <input type="checkbox"/> ND
B49.	Unconjugated bilirubin	B03MG _____ . _____ mg/dl	B04ND 8. <input type="checkbox"/> ND
B50.	Conjugated bilirubin	B05MG _____ . _____ mg/dl	B05ND 8. <input type="checkbox"/> ND

CMMNT Comment

Total Bilirubin = MUST be reported for all START Subjects within 72 hours of a actual laboratory results and then Form 23a and the laboratory results MUST be scanned and sent to CHILDREN-PM@umich.edu . Please ensure that you password protect the documents.

Please record total bilirubin as reported by the laboratory

Admin Tasks:

Create new CRF

Header Verification

Programming:

Reporting for this form should be similar to the SAE email reporting/notification system

Forms Tracking for this form

Query site within visit window of calculated visit date must have *actual and scheduled* visit date documented

If no laboratory result entered on form within 72 hours of scheduled visit or actual visit (whichever is earliest) must query site for result and notify PM

PM Report - date entered, time of entry, visit and value

So for the Form 23 2 week labs, 23 F/U Labs if they are in START then are they required to complete the bilirubin on those forms AND on this form for all START visits where labs are required

Edit Checks:

B46 complete, no option of ND as response

B47+B48=B46

Lab Value Range Checks for B46, B47. B48, B49, B50

