

# ICCTG PROTOCOL #1

## Lab Results

Patient ID: \_\_\_\_\_  
 Patient Initials: \_\_\_\_\_  
 Clinical Center: \_\_\_\_\_  
 Contact Week: \_\_\_\_\_  
 Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 month day year  
 RC ID: \_\_\_\_\_

(Research Coordinator completed prior to Baseline 2, week 24, and when clinically indicated.)  
 (Please attach a copy of the lab reports with all personal identifiers concealed)

1. Date blood sample taken:

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 month day year

(The Baseline 2 visit must occur within 4 weeks of the date sample taken.)

2. Liver Function Tests:

	<u>Reference Range:</u>		<u>Value</u>	For follow-up visits, indicate if result is clinically significant *
	<u>Lower Limit of Normal</u>	<u>Upper Limit of Normal</u>		
AST (SGOT)	____	____	____	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No
ALT (SGPT)	____	____	____	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No
Gamma GT (Glutamyltransferase)	____	____	____	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No
Alkaline Phosphatase	____	____	____	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No

(AST, ALT, Gamma GT, and Alkaline Phosphatase must be within **1.5 times your institution's upper limits of normal** for entry into the study at the Baseline 2 visit. See MOP for further instructions.)

3. Blood Coagulation:

	<u>Reference Range:</u>		<u>Value</u>	For follow-up visits, indicate if result is clinically significant *
	<u>Lower Limit of Normal</u>	<u>Upper Limit of Normal</u>		
PTT (APTT)	____.____	____.____	____.____	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No
PT	____.____	____.____	____.____	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No
Platelets	____,____	____,____	____,____	<input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No

(PTT and PT should be below your institution's **upper limits of normal** and **Platelets** must be within your institution's **upper and lower limits of normal** for entry into the study at the Baseline 2 visit.)

\* If clinically significant, an Adverse Event form must be completed.