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 report/s 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:	**Reference Range: Lower Limit of Normal**	**Upper Limit of Normal**	**Value**	**For follow-up visits, indicate if result is clinically significant ***
AST (SGOT)	__ __ __	__ __ __	__ __ __	❒ 1 Yes ❒ 0 No
ALT (SGPT)	__ __ __	__ __ __	__ __ __	❒ 1 Yes ❒ 0 No
Gamma GT (Glutamyltransferase)	__ __ __	__ __ __	__ __ __	❒ 1 Yes ❒ 0 No
Alkaline Phosphatase	__ __ __	__ __ __	__ __ __	❒ 1 Yes ❒ 0 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:	**Reference Range: Lower Limit of Normal**	**Upper Limit of Normal**	**Value**	**For follow-up visits, indicate if result is clinically significant ***
PTT (APTT)	__ __ . __	__ __ . __	__ __ . __	❒ 1 Yes ❒ 0 No
PT	__ __ . __	__ __ . __	__ __ . __	❒ 1 Yes ❒ 0 No
Platelets	_ _ _ , _ _ _	_ _ _ , _ _ _	_ _ _ , _ _ _	❒ 1 Yes ❒ 0 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.***

LAB