LABORATORY EVALUATION (LE)

DATA SECTION	COMPLETION INSTRUCTIONS
PURPOSE	To collect clinical laboratory test results performed during the course of the study.
PERSON(S) RESPONSIBLE	Study Coordinator/study physician
SOURCE(S) OF INFORMATION	Clinical laboratory
WHEN TO ADMINISTER FORM:	Screening, Baseline week 0 Treatment Weeks 2, 4, 8, 12, 20 and 24 Follow-up Weeks 4 and 12 At the time of premature discontinuation of study
	SPECIFIC INSTRUCTIONS:
PATIENT ID	Record the Patient ID number in the top left corner.
TIME POINT	Record the evaluation time point. Check rescreen if the labs are being performed as part of the rescreen procedure.
DATE OF SAMPLE	Record the date (month/day/year) that the sample was taken for the laboratory tests.
RESULTS	**GENERAL INSTRUCTIONS:** Baseline and treatment weeks 12 and 24 require fasting blood samples. Fasting is defined as a minimum of 8 hours before the visit. Record the result for each test in the unit specified. If the result is not reported according to the unit specified, convert the laboratory result before recording the value on the form. If the test was not performed, check "Not Done". If the date of samples for a given test is not the same as the date of sample obtained at the protocol visit, record the date of sample for that test. Refer to the protocol to determine when each laboratory test is to be performed. **SPECIFIC INSTRUCTIONS:** White blood cells Record result in cells/mm³. Platelets Record result in cells/mm³. Hemoglobin Record result in g/dl. Hematocrit Record result as percent. ALT Record result in IU/L AST Record result in IU/L Total bilirubin Record result in mg/dl. Alkaline phosphatase Record result in IU/L Albumin Record result in g/dl. BUN Record result in mg/dl. Creatinine Record result in mg/dl. TSH Record result in mcU/ml Prothrombin time Record PT in seconds. If a PT control is not specified,

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	use the upper limit of normal provided by the laboratory. INR Record the INR value Cholesterol Record result in mg/dl Triglycerides Record result in mg/dl. If the sample is a non-fasting sample, check the "Non-fasting" checkbox. Insulin Record result in mcU/ml. If the sample is a non-fasting sample, check the "Non-fasting" checkbox. Glucose Record result in mg/dl. If the sample is a non-fasting sample, check the "Non-fasting" checkbox. Pregnancy test (urine): Check "Positive" or "Negative" to indicate the results. Check "N/A" if a pregnancy test is not applicable, i.e. male patients or female patients not of child bearing potential. Check "Not Done" if the test should have been performed but was not performed. **NOTE:** • A urine pregnancy test (for women of childbearing potential) must be performed within the 24-hour period prior to the first dose of study drug. • If the result is positive at anytime through the course of the study, the Principal Investigator should be notified immediately. If the patient has already been started on study medication, the study medication must be immediately discontinued.

Key to abbreviations

- L = liter
- dl = deciliter = 0.1 liter
- ml = milliliter
- g = gram
- mg = milligram
- UI = International Units
- mcU = micro unit