Laboratory Evaluation (Pediatric)

General Instructions

The Laboratory Evaluation form captures results from laboratory tests performed throughout the trial.

In the treated group, the Laboratory Evaluation form is completed at the Screening visit (up to 6 weeks prior to randomization), the Baseline visit, and every treatment and follow-up visit.

In the control group, the Laboratory Evaluation form is completed at the Screening visit (up to 6 weeks prior to randomization), the Baseline visit, and at weeks 8, 12, 20, 36, 48, 72, and 96.

Specific Instructions

Patient ID**:** Record the Patient ID in the top right hand corner.

Date of Evaluation: Record the date (month/day/year) the sample for the laboratory tests was collected.

Protocol Timepoint: Record the protocol timepoint that corresponds to the visit.

Laboratory Results

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. If the test was not performed, check "Not Done".

Results that are reported below the lower level of detection record "BLD" [-6].
Results that are reported above the upper level of detection record "AUD" [-7].

If the date of samples for a given test is not the same as the "Date of Evaluation" recorded at the top of the form, record the date of sample for that test.

Creatinine clearance in patients less than 18 years should be calculated using the Schwartz method. Patients 18 years of age and older should use the Cockcroft-Gault equation. If the lab does not calculate via this method then the result must be recalculated by study personnel and the result via the Schwartz method or Cockcroft-Gault equation, as age appropriate, should be entered into the database and used to make study-related decisions.

The Schwartz method equation is the following:
CrCl = (k * Height) / Creatinine (mg/dL)

Age Group	k
<13 years	0.55
Female, 13 to <18 years	0.55
Male, 13 to <18 years	0.70

The Cockcroft-Gault equation as follows:

Males:
Creatinine clearance = (140 - age) x weight in kg/(72 x serum creatinine)

Females:
Creatinine clearance = (140 - age) x weight in kg x 0.85/(72 x serum creatinine)

A calculator for the Schwartz method can be found at:

http://www.medcalc.com/pedigfr.html OR

http://www.globalrph.com/specialpop.cgi (accepts Candian units)

A calculator for the Cockcroft-Gault equation can be found at:

http://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation/

If a calculator is used then the result must be recorded in the patient chart to support any clinical decisions made as a result of that result. Include a printout from the calculator in the study chart as source documentation.

If the creatinine result is reported as below the level of detection and the creatinine clearance cannot be calculated, check “Not Done” for creatinine clearance.

Glucose: check “Yes” or “No” to indicate whether a fasting sample was used for testing.