



Laboratory Evaluation (Adult)

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, 24, 36, 48, 60, 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 "ALD" [-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 should be calculated using the Modification of Diet in Renal Disease (MDRD) method. If the lab does not calculate via this method then the result must be recalculated by study personnel and the result via the MDRD method should be entered into the database and used to make study-related decisions.

The following is the IDMS-traceable MDRD Study equation (for creatinine methods calibrated to an IDMS reference method) available at <http://www.nkdep.nih.gov/lab-evaluation/gfr/estimating.shtml>

$$\text{GFR (mL/min/1.73 m}^2\text{)} = 175 \times (\text{S}_{\text{cr}})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.212 \text{ if African American})$$

The equation does not require weight or height variables because the results are reported normalized to 1.73 m² body surface area, which is an accepted average adult surface area.

A MDRD calculator can be found at:

Conventional (mg/dL): <http://nkdep.nih.gov/lab-evaluation/gfr-calculators/adults-conventional-unit.asp>

SI unit (µmol/L): <http://nkdep.nih.gov/lab-evaluation/gfr-calculators/adults-SI-units.asp>

If a MDRD 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 MDRD calculator in the study chart as source documentation. If creatinine clearance is reported as "Above 60" or ">60" then report the result using the special code for above the limit [-7].

If the creatinine result is reported as below the level of detection and 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.