

A4 Central Laboratory Results Methods

Digital electrocardiograms (ECG) and clinical laboratory tests were among the safety assessments collected during the longitudinal phase of the A4 study. The results of these components utilized designated central laboratories to process the test results which were stored electronically in Lilly's Clinical Laboratory Results Modernization (CLRM) system. The following datasets were produced from the CLRM system:

	Filename	File label
1	clrm_ecg.csv	Clinical Laboratory Results Modernization (CLRM) - ECG
2	clrm_lab.csv	Clinical Laboratory Results Modernization (CLRM) - Laboratory Tests

Note: These safety assessments were only collected for the A4 study. LEARN longitudinal data is not available in these datasets.

1. Electrocardiogram (ECG) Methods

12-lead digital ECGs were collected as replicates (triplicates) and electronically transmitted to a designated central ECG laboratory. A cardiologist at the central ECG laboratory conducted full overreads on 1 of the replicates (including all intervals). Additional safety reads of the ECG replicates were performed to report any clinically significant finding were not present on the fully overread ECG. Data from the overreads are included in this clrm_ecg.csv dataset.

2. Clinical Laboratory Tests Methods

A variety of laboratory specimens were collected to determine whether subjects meet inclusion/exclusion criteria and to monitor subject health. During infusion visits, clinical sites were instructed to collect any blood samples before beginning infusion. The following laboratory tests results were reported:

Laboratory Test	
Hematology	Hemoglobin, Hematocrit, Erythrocyte count, MCV, MCHC, Leukocytes (WBC), Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets
Coagulation Panel	PT, INR, PTT
CSF	Glucose, Protein, Cell count with differential
Urinalysis	Color, Specific gravity, pH, Protein, Glucose, Ketones, Blood, Leukocyte esterase
Clinical Chemistry Serum Concentrations	Sodium, Potassium, Chloride, Total bilirubin, Direct bilirubin, Alkaline phosphatase, ALT/SGPT, AST/SGOTd, GGT, BUN, Creatinine, Uric acid, Phosphorus, Calcium, Glucose (nonfasting or fasting), Total protein, Albumin, Cholesterol, CK
Other Tests	APOE genotyping, Serologies (if needed), C-reactive protein, HbA1c