

Duchenne Muscular Dystrophy (DMD) and Becker Muscular Dystrophy (DMD) Common Data Elements (CDEs)

The Laboratory Tests CDE recommendations have been divided into separate categories and sorted alphabetically. The recommendations are presented in different tables as shown below:

- Table 1 – **CBC with Differential**
- Table 2 – **Chemistries**
- Table 3 – **CSF**
- Table 4 – **CSF Culture**
- Table 5 – **Blood Tests**
- Table 6 – **Blood Gas Tests**
- Table 7 – **Urinalysis**
- Table 8 – **Scalp Electroencephalogram**
- Table 9 – **Immune Cell Subsets**

The tables provide an extensive list of the possible laboratory tests that may be collected in a study. While this list is broad, it is not exhaustive. The Laboratory Tests have all been recommended as supplemental or exploratory as the type of laboratory tests collected is dependent on the nature of the study and therefore none of the recommendations are considered core.

The list should be used in conjunction with the [Laboratory Tests and Tracking Case Report Form](#) (CRF).

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Table 1. CBC with Differential

CDE	General Comments	Purpose	Classification
Absolute Basophils	Measured in %	Safety	Supplemental
Absolute Eosinophils	Measured in %	Safety	Supplemental
Absolute Lymphocytes	Measured in %	Safety	Supplemental
Absolute Monocytes	Measured in %	Safety	Supplemental
Absolute Neutrophils	Measured in %	Safety	Supplemental
Basophils	Measured in cells per microliter or %	Safety	Supplemental
Blasts	Measured in cells per microliter or %	Safety	Supplemental
Eosinophils	Measured in cells per microliter or %	Safety	Supplemental
Hematocrit (HCT)	Measured in cells/mcL	Safety	Supplemental
Hemoglobin (HB)	Measured in cells/mcL	Safety	Supplemental
Hemoglobin electrophoresis	Hb A, Hb A2, Hb F, Hb S, Hb C - measured in %	Safety	Supplemental
Lymphocytes	Measured in platelets per microliter	Safety	Supplemental
Macrophages	Measured in cells per microliter or %	Safety	Supplemental
Mean corpuscular hemoglobin (MCH)	Measured in gm/dL	Safety	Supplemental
Mean corpuscular hemoglobin concentration (MCHC)	Measured in %	Safety	Supplemental
Mean corpuscular volume (MCV)	Measured in femtoliter (fL)	Safety	Supplemental
Mean platelet volume (MPV)	Measured in gm/dL	Safety	Supplemental
Metamyelocytes	Measured in cells per microliter or %	Safety	Supplemental
Monocytes	Measured in cells per microliter or %	Safety	Supplemental
Myelocytes	Measured in cells per microliter or %	Safety	Supplemental
Neutrophils	Measured in femtoliter (fL)	Safety	Supplemental
Platelet count	Measured as a count	Safety	Supplemental
Promyelocytes	Measured in cells per microliter or %	Safety	Supplemental
RBC Morphology	Measured in cells per microliter or %	Safety	Supplemental
Red Blood Cell (RBC) Count	Measured in cells/mcL; for drug trials	Safety	Supplemental
Red blood cell distribution width (RDW)	Measured in %	Safety	Supplemental
Stab cells/Band cells/Band neutrophils	Measured in cells per microliter or %	Safety	Supplemental
WBC Morphology	Measured in cells per microliter or %	Safety	Supplemental
White Blood Cell (WBC) Count	Measured in cells/mcL; for drug trials	Safety	Supplemental

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Table 2. Chemistries

CDE	General Comments	Purpose	Classification
Alanine transaminase (ALT)	Measured in U/L	Safety	Supplemental
Albumin	Measured in g/dL	Safety	Supplemental
Alkaline phosphatase (ALP)	Measured in IU/L	Safety	Supplemental
Amylase	Measured in U/L	Safety	Supplemental
Anion gap	Ratio measured in mEq/L	Safety	Supplemental
Aspartate transaminase (AST)	Measured in IU/L	Safety	Supplemental
Bicarbonate	Measured in mmol/L (bicarbonate)	Safety	Supplemental
Bilirubin, direct (conjugated)	Measured in mg/dL	Safety	Supplemental
Bilirubin, total	Measured in mg/dL	Safety	Supplemental
Blood urea nitrogen (BUN)	Measured in mg/dL	Safety	Supplemental
Calcium	Measured in mg/dL	Safety	Supplemental
Carbon dioxide	Measured in mEq/L	Safety	Supplemental
Chloride	Measured in mEq/L	Safety	Supplemental
Creatine kinase	Measured in IU/L	Diagnosis/ Outcome	Supplemental
Ferritin	Measured in ng/mL	Safety	Supplemental
Gamma glutamyl transferase (GGT)	Measured in IU/L	Diagnosis	Supplemental
Glucose, fasting	Measured in mg/dL	Safety	Supplemental
Glucose, random	Measured in mg/dL	Safety	Supplemental
Ionized Calcium	Measured in mg/dL	Safety	Supplemental
Iron	Measured in mcg/dL	Safety	Supplemental
Lactate	Measured in IU/L	Diagnosis/ Safety	Supplemental
Lactate dehydrogenase (LDH)	Measured in IU/L	Safety	Supplemental
Lipase	Measured in IU/L	Safety	Supplemental
Magnesium	Measured in mg/dL	Diagnosis	Supplemental
Phosphate	Measured in mg/dL	Safety	Supplemental
Potassium	Measured in mEq/L	Safety/ Diagnosis/ Outcome	Supplemental
Pre-Albumin	Measured in g/dL	Safety	Supplemental
Serum creatinine	Measured in mg/dL	Safety	Supplemental
Sodium	Measured in mEq/L	Safety	Supplemental
Total Iron Binding Capacity	Measured in mcg/dL	Safety	Supplemental
Total Protein	Measured in g/dL	Safety	Supplemental
Urate	Measured in μ mol/L	Safety	Supplemental
Urea-N	Measured in mmol/L	Safety	Supplemental
Vitamin D	Measured in ng/mL	Safety	Supplemental

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Table 3. CSF

CDE	General Comments	Purpose	Classification
Albumin, CSF	Measured in mg/dL. Major CSF protein component. Originates from blood.	Diagnosis/ Safety	Supplemental
Albumin index	Measured in mg/dL. CSF to serum albumin ratio, x100. Reflects BBB permeability.	Diagnosis/ Safety	Supplemental
Cell count, CSF	Measured in cells/uL. WBC components. Predominantly mononuclears (lymphocytes, monocytes) but can also include neutrophils, eosinophils, plasma cells and other cells.	Diagnosis/ Safety	Supplemental
CSF lactate	Measured in mmol/L. CSF lactic acid level. Increased with tissue acidosis, anaerobic metabolism.	Diagnosis	Supplemental
CSF myelin basic protein (MBP)	Quantitative measure of detectable MBP like material in CSF.	Diagnosis	Supplemental
CSF PCR for viruses	Virus nucleic acid (DNA or RNA) detection in CSF.	Outcome	Supplemental
Cytopathology, CSF	Specialized technique to collect CSF cells with preserved morphology; used to detect malignant cells.	Diagnosis/ Safety	Supplemental
Differential, CSF	Measured in cells/uL.	Diagnosis/ Safety	Supplemental
Electrophoresis, Protein, CSF	Measured in mg/dL. Proteins are separated by electrophoresis to identify different fractions.		Supplemental
Glucose, CSF	Measured in mg/dL. Measures glucose level in CSF; dependent on blood level (normally 60 to 80% of blood level)	Outcome	Supplemental
IgG, CSF	Measured in mg/dL. Quantitative IgG level in CSF.	Diagnosis/ Safety	Supplemental
IgG Index, CSF	Measured in mg/dL. Measures intrathecal IgG production. Derived from ratio of CSF IgG to CSF albumin compared to serum IgG to serum albumin ratio (quantitative abnormality).	Diagnosis/ Safety	Supplemental
Lyme Disease Ab, CSF	Positive; Negative. Immunoglobulin reactivity to B Burgdorferi. Measured by ELISA and/or Western blot.	Diagnosis/ Safety	Supplemental
Protein, CSF	Measured in mg/dL. Measures total protein level in CSF predominantly albumin; reflects serum proteins with trace CNS components and intrathecal modified components.	Outcome	Supplemental

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Table 3. CSF, cont.

CDE	General Comments	Purpose	Classification
Oligoclonal Banding, CSF	Positive; Negative. Two or more discrete IgG electrophoretic bands in CSF not in serum. Reflects restricted intrathecal IgG production (qualitative abnormality).	Outcome	Supplemental
VDRL, CSF	Positive; Negative. Nonspecific serologic test for syphilis; Venereal Disease Research Laboratory test is used to screen CSF for reagin antibodies diagnostic for neurosyphilis.	Diagnosis/ Safety	Supplemental

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Table 4. CSF Culture

CDE	General Comments	Purpose	Classification
Bacterial, Fungal culture	Cryptococcus neoformans antigen; Mycobacteria culture. Culture of CSF to identify presence of a bacterial or fungal pathogen.	Safety	Supplemental

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Table 5. Blood Tests

CDE	General Comments	Classification
5, 10 Methylene Tetra Hydrofolate Reductase	Results reported as positive, negative or not done. Measure of enzyme which metabolizes homocysteine.	Supplemental
25-OH vitamin D3	Results reported as normal, high, or low; measured in ng/mL	Supplemental
Activated partial thromboplastin time/ partial thromboplastin time (aPTT/ PTT)	Performance indicators which measure the efficacy of coagulation pathways; measured in seconds.	Supplemental
Ammonia	Results reported as positive, negative or not done. Quantitative ammonia level.	Supplemental
Anti-Cardiolipin Antibody, IgG, IgM	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-ds DNA Antibody	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-ENA/ ANA Screen	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-Epstein-Barr VCA IgG	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-HAV Hepatitis	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-HCA Hepatitis	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-HCB Hepatitis	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-HCV Hepatitis	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-HIV 1/2 Antibody	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-HLTV-I/II antibody	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-JC	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-mycoplasma Ab	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-nuclear Antibody	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-SSA	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-SSB	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-thyroglobulin AB	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Anti-VZV	Results reported as positive, negative or not done; measured in U/mL	Supplemental
Ceruloplasmin	Measured in mg/dL	Supplemental
Cholesterol - HDL***	Measured in mg/dL (U.S.) or mmol/L (outside U.S.)	Supplemental

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Cholesterol - LDL ***	Measured in mg/dL (U.S.) or mmol/L (outside U.S.)	Supplemental
Cholesterol - triglycerides	Measured in mg/dL (U.S.) or mmol/L (outside U.S.)	Supplemental
Cholesterol - VLDL	Measured in mg/dL (U.S.) or mmol/L (outside U.S.)	Supplemental
Cholesterol, total	Measured in mg/dL (U.S.) or mmol/L (outside U.S.)	Supplemental
Classical AntiNeutrophil Cytoplasmic Antibodies	Results reported as positive, negative or not done	Supplemental
C-reactive protein (CRP)	Measured in mg/L	Supplemental
Creatine Kinase - Myocardial Bands	Measured in ng/mL	Supplemental
Creatinine Clearance	Measured in mL/min	Supplemental
D-dimer	Results reported as positive, negative or not done	Supplemental
Epstein-Barr virus (EBV) panel	Results reported as positive, negative or not done	Supplemental
Erythrocyte Sedimentation Rate	Measured in mm/hr	Supplemental
Fibrinogen	Measured in mg/dL	Supplemental
Folate, serum level	Measured in ng/mL	Supplemental
Glomerular Filtration Rate (eGFR)	Sample ranges: estimated creatinine clearance – normal 90+; mild 60-89; moderate 30-59; <15ml/min = kidney failure; measured in mL/min; required if study uses MRI with contrast	Supplemental
Glycosylated hemoglobin (HbA1c)	Results indicate "average" blood sugar over 6-12 week time; sample normal is 4%-6%; measured in %	Supplemental
GaINAc-GD1a Antibody	Positive results may indicate severe axonal GBS or AMAN	Supplemental
GD1a Antibody	Positive results may indicate severe axonal GBS or AMAN	Supplemental
GD1b Antibody	Positive results may indicate varied sensory or sensorimotor polyneuropathies	Supplemental
GM1 Antibody	Positive results may indicate multifocal motor neuropathy or acute motor neuropathies including GBS	Supplemental
GQ1b Antibody	Positive results may indicate Miller Fisher syndrome, acute ataxia and ophthalmoplegia or Bickerstaff encephalitis	Supplemental
GT1a Antibody	Diagnostic antibody generated to specific ganglioside	Supplemental
High sensitivity C Reactive Protein	Acute phase reactant elevated with inflammation; non-specific; not clear, usually is <10.0; measured in mg/L	Supplemental
HIV	Antibodies to HIV-1 and HIV-2, usually by ELISA; results reported as positive, negative or not done; positive result should be confirmed by Western Blot	Supplemental

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CDE	General Comments	Classification
Homocysteine	Elevated levels associated with B12, folic acid, and pyridoxine deficiencies; sample elevated level is > 10.4 $\mu\text{mol/L}$, or > 140 $\mu\text{g/dl}$; measured in $\mu\text{mol/L}$ or ug/dL	Supplemental
Human T-cell lymphotropic virus type 1 (HTLV-1)	Antibodies to retrovirus HTLV-1, typically screen with ELISA, confirmation with Western blot positive, negative, sometimes provides titers	Supplemental
Human T-cell lymphotropic virus type 2 (HTLV-2)	Antibodies to retrovirus HTLV-2, positive, negative, sometimes provides titers	Supplemental
Insulin-like Growth Factor-1 (IGF-1)	IGF-1 levels can be measured in the blood in 10-1000 ng/ml amounts.	Supplemental
Lyme disease Ab, Serum	Antibodies to Borrelia Burgdorferi, screen with ELISA, confirmation with Western blot; results reported as positive, negative or not done	Supplemental
Methylmalonic acid	Elevated levels associated with B12 deficiency; sample normal range 73-271 nmol/L ; often elevated non-specifically in elderly; measured in nmol/L	Supplemental
Paraneoplastic panel	Test for autoantibodies often associated with cancers; includes ANNA 1(Hu); ANNA 2 (Ri), ANNA 3, anti-Yo (against Purkinje cells); Purkinje cell Tr, CRMP-5 IgG, amphiphysin Ab, AGNA1, antibodies to voltage gated potassium channels, AChR binding and antibodies against ganglionic neuronal antigens, often NMO IgG, and others; results reported as positive or negative, and sometimes provided as titers	Supplemental
Pregnancy test, blood	Test for beta subunit of human chorionic gonadotropin; results reported as positive, negative or not done; sensitive to as low as 1 mIU/ml serum	Supplemental
Pregnancy test, urine	Test for beta subunit of human chorionic gonadotropin; results reported as positive, negative or not done; sensitive to as low as 10 mIU/ml	Supplemental
Prothrombin time (PT)	Measures extrinsic coagulation pathway (functional assay of Factors I, II, V, VII and X); Sample normal range is 11-16 seconds; measured in seconds	Supplemental
Prothrombin time/ international normalised ratio (PT/INR)	Ratio of PT tested to PT of normal controls, used to standardize PT sample normal range is 0.8-1.2; measured as a ratio	Supplemental
Protoplasmic-staining AntiNeutrophil Cytoplasmic Antibodies (ANCA)	Autoantibodies to cytoplasmic antigens in neutrophils; positive in several types of vasculidites, e.g. Wegner's, Churg-Strauss; usually given as titers	Supplemental
Rapid plasma reagin (RPR/VDRL)	Screening test for antibodies to syphilis in blood; most sensitive in Secondary Syphilis, less sensitive in primary and tertiary syphilis; should be confirmed with the more specific FTA-ABS test	Supplemental

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CDE	General Comments	Classification
Rapid plasma reagin (RPR; syphilis)	See above, RPR has largely replaced the older VDRL test; results reported as positive, negative or not done	Supplemental
Rheumatoid factor	IgM autoantibody against Fc portion of self IgG; can bind to IG to form immune complexes; positive in 80% of patients with Rheumatoid Arthritis, 70% of patients with Sjogren's Syndrome, in 5-10% healthy controls	Supplemental
serum IgA	Isotype of Ig; sample normal range is 70-370 measured in mg/dL	Supplemental
serum IgE	Isotype of Ig; upper limit of normal not well defined; measured in mg/dL	Supplemental
serum IgG	Isotype of Ig; sample normal range is 700-1450; measured in mg/dL	Supplemental
serum IgM	Isotype of Ig; sample normal range is 30-210; measured in mg/dL	Supplemental
Serum Pregnancy (if applicable)	Results reported as positive, negative or not done	Supplemental
Serum protein electrophoresis with immunofixation	Screening test for disease such as multiple myeloma, macroglobulinemia, amyloidosis. Separation of major serum proteins by electrophoresis, with identification by immune methods; total protein : 6.4-8.3; albumin 3.5-5.0; alpha-1globulin 0.1-0.3; alpha-2-globulin 0.6-1.0; beta globulin 0.7-1.2; gamma globulin 0.7-1.6 g/dL; measured in g/dL	Supplemental
Stool Guaiac	Test for fecal occult blood, using alpha-guaiaconic acid and hydrogen peroxide; iron supplements and various foods can alter results results reported as positive, negative or not done	Supplemental
Sulfatide Antibody	Positive results may indicate chronic sensory neuropathies	Supplemental
TB Skin testing	0.1ml purified protein derivative of T.B. Positive is >15mm induration; >10mm in immunosuppressed persons, negative <10mm. Can be false positive after BCG vaccination. Can be falsely negative; read as mm of induration at 48-72hr.	Supplemental
Thrombin time	Measured in seconds	Supplemental
Thyroid stimulating hormone (TSH)	Measured in mIU/L	Supplemental
Thyroxine (T4), free	Measured in mcg/dL; ordered and reported when TSH is <0.40 mIU/mL or >4.00 mIU/mL	Supplemental
Total T4	Measured in mcg/dL; normal range is approximately 4.5 to 12.5	Supplemental
Toxicology screen	Results reported as positive, negative or not done	Supplemental
Troponin I	Measured in µg/L	Supplemental
Troponin T	Measured in µg/L	Supplemental

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CDE	General Comments	Classification
Vitamin B12, Serum level	Measured in ng/L	Supplemental
Vitamin D, 25 hydroxy	Measured in ng/mL or nmol/L	Supplemental
β 2- glycoprotein Antibody IgG, IgM	Measured in SGU and SMU, respectively	Supplemental

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Table 6. Blood Gas Tests

CDE	General Comments	Purpose	Classification
Acidity/ pH		Safety	Supplemental
Partial pressure of oxygen (PO ₂)	Measured in mmHg	Safety	Supplemental
Partial pressure of carbon dioxide (PCO ₂)	Measured in mmHg	Safety	Supplemental
Whole blood bicarbonate (HCO ₃)		Safety	Supplemental
FIO ₃		Safety	Supplemental

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Table 7. Urinalysis

CDE	General Comments	Purpose	Classification
Albumin, urine	Measured in g/dL	Safety	Supplemental
Bacteria	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Bilirubin, urine	Measured in mg/dL	Safety	Supplemental
Blood	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Casts	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Clarity	Normal result = Clear	Safety	Supplemental
Color	Normal result = Yellow	Safety	Supplemental
Creatinine, urine	Measured in mg/dL	Safety	Supplemental
Crystals	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Culture, urine	Measured in units/mL	Safety	Supplemental
Epithelial cells	Normal result = Few or None	Safety	Supplemental
Glomerular Filtration Rate	Measured in mL/min	Safety	Supplemental
Glucose, urine	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Hemoglobin	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Ketones	Measured in mg/dL	Safety	Supplemental
Leukocyte esterase	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Leukocytes	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Myoglobin	Reported as positive or negative	Safety	Supplemental
Nitrite	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
pH		Safety	Supplemental
Protein	Measured in mg/dL	Safety	Supplemental
Red cell/microscopic RBC	Measured in cells/high power field (HPF); Normal = Trace or None.	Safety	Supplemental
Specific gravity		Safety	Supplemental
Urine cast/LPF	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
Urine Protein Electrophoresis	Reported as description of what protein was found in urine	Safety	Supplemental
Urobilinogen	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental
White cell/microscopic WBC	Measured in cells/high power field (HPF); Normal = Trace or None.	Safety	Supplemental
Yeast	Reported as present or absent; normal result = Absent, abnormal result = Present	Safety	Supplemental

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Table 8. Scalp Electroencephalogram

CDE	General Comments	Purpose	Classification
Activating procedures used	Permissible values: Sleep; Hyperventilation; Photic stimulation; Unknown; Other, specify	Diagnosis/ Safety	Supplemental
Routine EEG and Sleep-deprived EEG	Permissible values: Awake; Asleep; Unresponsive state; Indeterminate; Other, specify	Diagnosis/ Safety	Supplemental

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Table 9. Immune Cell Subsets

CDE	General Comments	Purpose	Classification
CD2+	T cell % and number	Other/Safety	Exploratory
CD2+DR	T cell % and number	Other/Safety	Exploratory
CD3+ (T cells)	T cell % and number	Other/Safety	Exploratory
CD3+/CD4+	T cell % and number	Other/Safety	Exploratory
CD4+DR	T cell % and number	Other/Safety	Exploratory
CD3+/CD8+	T cell % and number	Other/Safety	Exploratory
CD8+DR	T cell % and number	Other/Safety	Exploratory
CD19+ (B cells)	B cell % and number	Other/Safety	Exploratory
CD3-/CD56+ (NK cells)		Other/Safety	Exploratory
CD14+ (monocytes)		Other/Safety	Exploratory
CD4/CD8 ratio		Other/Safety	Exploratory
CD20		Other/Safety	Exploratory
Other mononuclear subsets		Other/Safety	Exploratory