The following are the recommendations of the NMD CDE Demographics, Medical History, and Lab Tests Subgroup. The CDE recommendations have been divided into separate categories and 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 list should be used in conjunction with the Laboratory Tests and Tracking Case Report Form (CRF).

Table 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 |
| Metamylocytes | 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  |

Table 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 μmol/L | Safety | Supplemental |
| Urea-N | Measured in mmol/L | Safety | Supplemental |
| Vitamin D | Measured in ng/mL | Safety | Supplemental  |

Table 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  |
| 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 neurosyphyilis. | Diagnosis/ Safety | Supplemental |

Table 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 |

Table 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 |
| 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 opthalmoplegia 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 |
| Homocysteine | Elevated levels associated with B12, folic acid, and pyridoxine deficiencies; sample elevated level is > 10.4 μmol/L, or> 140 μg/dl; measured in μmol/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, amphyiphysin 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 1mIU/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 10mIU/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 normalized 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 |
| 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 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 mlU/L or >4.00 mlU/L | Supplemental |
| Total T4 | Measured in mcg/dL; normal range is approximately 4.5 to 12.5 mcg/dL | 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 |
| 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 |

Table Blood Gas Tests

|  |  |  |  |
| --- | --- | --- | --- |
| CDE | General Comments | Purpose | Classification |
| Acidity/ pH |  Intentionally Left Blank | Safety | Supplemental |
| Partial pressure of oxygen (PO2) | Measured in mmHg | Safety | Supplemental |
| Partial pressure of carbon dioxide (PCO2) | Measured in mmHg | Safety | Supplemental |
| Whole blood bicarbonate (HCO3) | Intentionally Left Blank | Safety | Supplemental |
| FIO3 | Intentionally Left Blank | Safety | Supplemental |

Table 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 |

Table 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 |

Table 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) | Intentionally Left Blank | Other/Safety | Exploratory |
| CD14+ (monocytes) | Intentionally Left Blank | Other/Safety | Exploratory |
| CD4/CD8 ratio | Intentionally Left Blank | Other/Safety | Exploratory |
| CD20 | Intentionally Left Blank | Other/Safety | Exploratory |
| Other mononuclear subsets | Intentionally Left Blank | Other/Safety | Exploratory |