Indicate the appropriate result for each test

Table 1 Blood Laboratory Tests

|  | Result | Units for test result | Proposed test resultreference range | Abnormal Result? |
| --- | --- | --- | --- | --- |
| NK Cell Activity\*\* |  | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Erythrocyte sedimentation rate (ESR) |  | mm/hr | 0-15 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| High sensitivity C-reactive protein (hsCRP) |  | mg/L | 0-10 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Complete blood count (CBC) with Differential:White Blood Cell (WBC) Count |  | cells/μL | Adults: 3.8 – 11.0 x 10^3Age 6- 12 yr: 4.5 – 14.0 x10^3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Lymphocyte Count |  | cells/μL | 1.00 – 4.8 x 10^3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Neutrophil Count |  | cells/μL | 1.80 – 7.00 x 10^3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Monocyte Count |  | cells/μL | 0.00 – 0.80 x 10^3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Eosinophil Count |  | cells/μL | 0.00 – 0.50 x 10^3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Basophil Count |  | cells/μL | Adults: 0.00 -– 0.30 X 10^3Up to age 15 yr: 0.00 -– 0.20 X 10^3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Red Blood Cell (RBC) Count |  | cells/μL | Male adults: 4.32 – 5.72 x 10^6Female adults: 3.90-5.03 x 10^6 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Hemoglobin (Hgb) |  | g/dL | Male adults: 13.2 – 17.5Female adults: 12.0 – 16 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Hematocrit (HCT) |  | % RBC/unitvolume of blood | Male adults: 40 – 52%Female adults: 37 – 46% | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Mean Corpuscular Volume (MCV) |  | femtoliters (fl)/cell | Male adults: 81.2 – 95.1Female adults: 81.6 – 98.3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Red Cell Distribution Width (RDW) |  | % (reflects deviation of width of RBC in a blood sample | Male adults: 11.8 – 15.6Female adults: 11.9 – 15.5 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| CBC with Differential: Platelet Count |  | cells/μL | Male adults: 160 – 450 x10^3Female adults: 160 – 450 x10^3 | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Lymphocyte Subset Panel: T cells (CD3+, CD4+, CD5+, CD7+, CD8+), B cells (CD10+, CD19+, CD20+), NK cells (CD16+, CD56+, [CD3−/(CD16+/CD56+)] |  | % of cell type/unitvolume of blood | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Immunoglobulin isotypes |  | TBD | IgA \_\_\_\_\_\_\_\_\_IgE \_\_\_\_\_\_\_\_\_IgG \_\_\_\_\_\_\_\_\_IgM \_\_\_\_\_\_\_\_\_ | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Other, specify: |  |  |  | [ ]  Normal [ ]  Abnormal [ ]  Unknown |

Table 2A Infectious Disease Laboratory Tests – Serum antibodies

| Test | Test date | Positive Result? |
| --- | --- | --- |
| Epstein-Barr virus (EBV): anti VCA IgM |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Epstein-Barr virus (EBV): anti-VCA IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Epstein-Barr virus (EBV): anti-EA-D IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Epstein-Barr virus (EBV): anti-EBNA IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Cytomegalovirus (CMV): IgM |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Cytomegalovirus (CMV): IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Human herpes virus 6 (HHV6): IgM |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Human herpes virus 6 (HHV6): IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Coxsackie B virus (CBV): IgM |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Coxsackie B virus (CBV): IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Echovirus: IgM |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Echovirus: IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| *Chlamydia pneumoniae*: IgM |  | [ ]  Yes [ ]  No [ ]  Unknown |
| *Chlamydia pneumoniae*: IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| *Mycoplasma pneumoniae*: IgM |  | [ ]  Yes [ ]  No [ ]  Unknown |
| *Mycoplasma pneumoniae*: IgG |  | [ ]  Yes [ ]  No [ ]  Unknown |
| Tick-borne diseases (TBD): IgM(Lyme disease/*Borrelia burgdorferi*, *Anaplasma phagocytophilum, Coxiella burnetii, Babesia microti,* Powassan virus) |  | [ ]  Yes (specify which TBD yielded positive results):[ ]  No (specify which TBD were tested and found to be negative):[ ]  Unknown |
| Tick-borne diseases (TBD): IgG(Lyme disease/*Borrelia burgdorferi*, *Anaplasma phagocytophilum, Coxiella burnetii, Babesia microti,* Powassan virus) |  | [ ]  Yes (specify which TBD yielded positive results)[ ]  No (specify which TBD were tested and found to be negative)[ ]  Unknown |
| Parvovirus: IgM |  | [ ]  Yes (specify which parvovirus strain yielded positive results):[ ]  No (specify which parvovirus strains were tested and found to be negative):[ ]  Unknown |
| Parvovirus: IgG |  | [ ]  Yes (specify which parvovirus strain yielded positive results):[ ]  No (specify which parvovirus strains were tested and found to be negative):[ ]  Unknown |
| Mycotoxin/fungal (IgE antibodies unless otherwise specified) |  | [ ]  Yes (specify which mycotoxins/fungi yielded positive results):[ ]  No (specify which mycotoxins/fungi were tested and found to be negative):[ ]  Unknown |
| Lipopolysaccharides (LPS): IgA, IgM or IgG |  | [ ]  Yes (specify bacterial source/type of LPS and whether IgA, IgM and/or IgG positive\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)[ ]  No (specify which were tested and whether IgA, IgM and/or IgG was found to be negative\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)[ ]  Unknown |

Table 2B Infectious Disease Laboratory Tests – PCR, Other

|  |  |  |  |
| --- | --- | --- | --- |
| Test | Test Type | Sample Type | Positive Result? |
| Epstein-Barr virus (EBV) | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |
| Cytomegalovirus (CMV) | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |
| Coxsackie B virus (CBV) | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |
| Human herpes virus 6 (HHV6) | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |
| Echovirus | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |
| *Chlamydia pneumoniae* | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |
| *Mycoplasma pneumoniae* | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |
| Tick-borne diseases (TBD)  | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes (specify which TBD yielded positive results)[ ]  No (specify which TBD were tested and found to be negative)[ ]  Unknown |
| Parvovirus | [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Serum [ ]  PBMC [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes (specify which parvovirus strains yielded positive results)[ ]  No (specify which parvovirus strains were tested and found to be negative)[ ]  Unknown |
| Giardia | [ ]  Antigen test [ ]  PCR [ ]  Other (specify\_\_\_\_\_\_\_\_\_)[ ]  Unknown | [ ]  Stool [ ]  Other (specify\_\_\_\_\_\_\_\_\_\_) | [ ]  Yes [ ]  No [ ]  Unknown |

Table 3 Autoimmunological and Other Immune Profiling Laboratory Tests

| Test | Result | Unit for Result | Abnormal Result? |
| --- | --- | --- | --- |
| Cytokines: TGFbeta | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Cytokines: Interleukin 6 (IL-6) | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Cytokines: Interleukin 1 beta (IL-1b) | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Cytokines: Tumor necrosis factor-alpha (TNF-alpha) | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Cytokines: Interferon gamma (IFN-gamma) | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Cytokines: Interleukin 8 (IL-8) | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Antinuclear antibodies (ANA): IgM | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Antinuclear antibodies (ANA): IgG |  |  | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Rheumatoid Factor (RF) antibodies: IgM | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Rheumatoid Factor (RF) antibodies: IgG | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Antimitochondrial antibodies:anti-cardiolipin antibodies (ACA) | TBDSpecify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) |  | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Antimitochondrial antibodies:anti-M3 protein | TBDSpecify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) |  | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Antimitochondrial antibodies:anti-M4 protein | TBDSpecify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) |  | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Anti-muscarinic receptor antibodies | TBDSpecify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test), specificity (which muscarinic receptor, if known) \_\_\_\_\_\_\_\_\_\_ and isotype (e.g., IgM, IgG) \_\_\_\_\_\_\_\_\_\_\_ | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Anti-beta-1 adrenergic antibodies | TBDSpecify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) and isotype (e.g., IgM, IgG) \_\_\_\_\_\_\_\_\_\_ | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Anti-beta-2 adrenergic antibodies | TBDSpecify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) and isotype (e.g., IgM, IgG) \_\_\_\_\_\_\_\_\_\_ | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Anti-streptolysin O antibodies | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |
| Anti-DNase B antibodies | TBD | TBD | [ ]  Normal [ ]  Abnormal [ ]  Unknown |

Table 4 Hypersensitivity Lab Tests

|  |  |  |
| --- | --- | --- |
| Test | Result | Unit for Result |
| Eosinophils | TBD | TBD |
| Tryptase | TBD | TBD |
| Food-based IgG skin test | TBD | TBD |
| Food-based IgE skin test | TBD | TBD |

## General Instructions

Laboratory tests are routinely administered in clinical trials of pharmacological interventions to assess subject safety. Laboratory tests may also be used to determine an individual’s eligibility for a study.

Laboratory results may be received via electronic files directly from central study laboratories or recorded manually on case report forms if the study is using a local lab. In either scenario, it is recommended that the Laboratory Test form be used to record when samples were collected (date and time) so that the laboratory tests results can be matched with the samples collected for each subject.

Important note: None of the data elements included on this CRF Module are considered Core (i.e., required for all ME/CFS studies to collect). All data elements are considered Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study, unless specified by an asterisk.

\*\*Element is classified as Supplemental – Highly Recommended

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

1. Test – Indicate the name of each laboratory test that is run on the specimen. See the data dictionary for additional information on coding the test name using Logical Observation Identifiers Names and Codes (LOINC).
2. Result – Record the numeric or alpha-numeric results for each laboratory test.
3. Unit for Result – Record the units of the numeric results for each laboratory test are measured in. See the data dictionary for additional information on coding the unit of measure using Unified Code for Units of Measure (UCUM).