Indicate the appropriate result for each test

Table 1 Blood Laboratory Tests

|  | Result | Units for test result | Proposed test result  reference 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 10^3  Age 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 10^3  Up 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 10^6  Female adults: 3.90-5.03 x 10^6 | Normal  Abnormal  Unknown |
| CBC with Differential: Hemoglobin (Hgb) |  | g/dL | Male adults: 13.2 – 17.5  Female adults: 12.0 – 16 | Normal  Abnormal  Unknown |
| CBC with Differential: Hematocrit (HCT) |  | % RBC/unit  volume 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 – 95.1  Female 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 – 15.6  Female adults: 11.9 – 15.5 | Normal  Abnormal  Unknown |
| CBC with Differential: Platelet Count |  | cells/μL | Male adults: 160 – 450 x10^3  Female 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/unit  volume 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) | TBD  Specify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) |  | Normal  Abnormal  Unknown |
| Antimitochondrial antibodies:  anti-M3 protein | TBD  Specify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) |  | Normal  Abnormal  Unknown |
| Antimitochondrial antibodies:  anti-M4 protein | TBD  Specify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) |  | Normal  Abnormal  Unknown |
| Anti-muscarinic receptor antibodies | TBD  Specify 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 | TBD  Specify test type\_\_\_\_\_\_\_\_\_ (e.g., ELISA, complement fixation test) and isotype (e.g., IgM, IgG) \_\_\_\_\_\_\_\_\_\_ | TBD | Normal  Abnormal  Unknown |
| Anti-beta-2 adrenergic antibodies | TBD  Specify 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).