

## Laboratory Tests – Immune Module

[Study Name/ID pre-filled]

Site Name:

Subject ID:

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	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Erythrocyte sedimentation rate (ESR)		mm/hr	0-15	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
High sensitivity C-reactive protein (hsCRP)		mg/L	0-10	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Complete blood count (CBC) with Differential: White Blood Cell (WBC) Count		cells/ $\mu$ L	Adults: $3.8 - 11.0 \times 10^3$ Age 6- 12 yr: $4.5 - 14.0 \times 10^3$	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Lymphocyte Count		cells/ $\mu$ L	$1.00 - 4.8 \times 10^3$	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Neutrophil Count		cells/ $\mu$ L	$1.80 - 7.00 \times 10^3$	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Monocyte Count		cells/ $\mu$ L	$0.00 - 0.80 \times 10^3$	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Eosinophil Count		cells/ $\mu$ L	$0.00 - 0.50 \times 10^3$	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown

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	Result	Units for test result	Proposed test result reference range	Abnormal Result?
CBC with Differential: Basophil Count		cells/ $\mu$ L	Adults: 0.00 – 0.30 X 10 <sup>3</sup> Up to age 15 yr: 0.00 – 0.20 X 10 <sup>3</sup>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Red Blood Cell (RBC) Count		cells/ $\mu$ L	Male adults: 4.32 – 5.72 x 10 <sup>6</sup> Female adults: 3.90-5.03 x 10 <sup>6</sup>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Hemoglobin (Hgb)		g/dL	Male adults: 13.2 – 17.5 Female adults: 12.0 – 16	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Hematocrit (HCT)		% RBC/unit volume of blood	Male adults: 40 – 52% Female adults: 37 – 46%	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Mean Corpuscular Volume (MCV)		femtoliters (fl)/cell	Male adults: 81.2 – 95.1 Female adults: 81.6 – 98.3	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Red Cell Distribution Width (RDW)		% (reflects deviation of width of RBC in a blood	Male adults: 11.8 – 15.6 Female adults: 11.9 – 15.5	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
CBC with Differential: Platelet Count		cells/ $\mu$ L	Male adults: 160 – 450 x10 <sup>3</sup> Female adults: 160 – 450 x10 <sup>3</sup>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> 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	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown

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	Result	Units for test result	Proposed test result reference range	Abnormal Result?
Immunoglobulin isotypes		TBD	IgA _____ IgE _____ IgG _____ IgM _____	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Other, specify:				<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown

Table 2A Infectious Disease Laboratory Tests – Serum antibodies

Test	Test date	Positive Result?
Epstein-Barr virus (EBV): anti VCA IgM		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Epstein-Barr virus (EBV): anti-VCA IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Epstein-Barr virus (EBV): anti-EA-D IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Epstein-Barr virus (EBV): anti-EBNA IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cytomegalovirus (CMV): IgM		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cytomegalovirus (CMV): IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

## Laboratory Tests – Immune Module

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Test	Test date	Positive Result?
Human herpes virus 6 (HHV6): IgM		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Human herpes virus 6 (HHV6): IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Coxsackie B virus (CBV): IgM		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Coxsackie B virus (CBV): IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Echovirus: IgM		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Echovirus: IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<i>Chlamydia pneumoniae</i> : IgM		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<i>Chlamydia pneumoniae</i> : IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<i>Mycoplasma pneumoniae</i> : IgM		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<i>Mycoplasma pneumoniae</i> : IgG		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

## Laboratory Tests – Immune Module

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Test	Test date	Positive Result?
Tick-borne diseases (TBD): IgM (Lyme disease/ <i>Borrelia burgdorferi</i> , <i>Anaplasma phagocytophilum</i> , <i>Coxiella burnetii</i> , <i>Babesia microti</i> , Powassan virus)		<input type="checkbox"/> Yes (specify which TBD yielded positive results): <input type="checkbox"/> No (specify which TBD were tested and found to be negative): <input type="checkbox"/> Unknown
Tick-borne diseases (TBD): IgG (Lyme disease/ <i>Borrelia burgdorferi</i> , <i>Anaplasma phagocytophilum</i> , <i>Coxiella burnetii</i> , <i>Babesia microti</i> , Powassan virus)		<input type="checkbox"/> Yes (specify which TBD yielded positive results) <input type="checkbox"/> No (specify which TBD were tested and found to be negative) <input type="checkbox"/> Unknown
Parvovirus: IgM		<input type="checkbox"/> Yes (specify which parvovirus strain yielded positive results): <input type="checkbox"/> No (specify which parvovirus strains were tested and found to be negative): <input type="checkbox"/> Unknown
Parvovirus: IgG		<input type="checkbox"/> Yes (specify which parvovirus strain yielded positive results): <input type="checkbox"/> No (specify which parvovirus strains were tested and found to be negative): <input type="checkbox"/> Unknown
Mycotoxin/fungal (IgE antibodies unless otherwise specified)		<input type="checkbox"/> Yes (specify which mycotoxins/fungi yielded positive results): <input type="checkbox"/> No (specify which mycotoxins/fungi were tested and found to be negative): <input type="checkbox"/> Unknown
Lipopolysaccharides (LPS): IgA, IgM or IgG		<input type="checkbox"/> Yes (specify bacterial source/type of LPS and whether IgA, IgM and/or IgG positive _____) <input type="checkbox"/> No (specify which were tested and whether IgA, IgM and/or IgG was found to be negative _____) <input type="checkbox"/> Unknown

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Table 2B Infectious Disease Laboratory Tests – PCR, Other

Test	Test Type	Sample Type	Positive Result?
Epstein-Barr virus (EBV)	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Cytomegalovirus (CMV)	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Coxsackie B virus (CBV)	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Human herpes virus 6 (HHV6)	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Echovirus	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<i>Chlamydia pneumoniae</i>	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<i>Mycoplasma pneumoniae</i>	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

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[Study Name/ID pre-filled]

Site Name:

Subject ID:

Tick-borne diseases (TBD)	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes (specify which TBD yielded positive results) <input type="checkbox"/> No (specify which TBD were tested and found to be negative) <input type="checkbox"/> Unknown
Parvovirus	<input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Serum <input type="checkbox"/> PBMC <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes (specify which parvovirus strains yielded positive results) <input type="checkbox"/> No (specify which parvovirus strains were tested and found to be negative) <input type="checkbox"/> Unknown
Giardia	<input type="checkbox"/> Antigen test <input type="checkbox"/> PCR <input type="checkbox"/> Other (specify _____) <input type="checkbox"/> Unknown	<input type="checkbox"/> Stool <input type="checkbox"/> Other (specify _____)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

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Table 3 Autoimmunological and Other Immune Profiling Laboratory Tests

Test	Result	Unit for Result	Abnormal Result?
Cytokines: TGFbeta	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Cytokines: Interleukin 6 (IL-6)	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Cytokines: Interleukin 1 beta (IL-1b)	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Cytokines: Tumor necrosis factor-alpha (TNF-alpha)	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Cytokines: Interferon gamma (IFN-gamma)	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Cytokines: Interleukin 8 (IL-8)	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Antinuclear antibodies (ANA): IgM	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Antinuclear antibodies (ANA): IgG			<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Rheumatoid Factor (RF) antibodies: IgM	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Rheumatoid Factor (RF) antibodies: IgG	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown



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Test	Result	Unit for Result	Abnormal Result?
Antimitochondrial antibodies: anti-cardiolipin antibodies (ACA)	TBD Specify test type _____ (e.g., ELISA, complement fixation test)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Antimitochondrial antibodies: anti-M3 protein	TBD Specify test type _____ (e.g., ELISA, complement fixation test)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Antimitochondrial antibodies: anti-M4 protein	TBD Specify test type _____ (e.g., ELISA, complement fixation test)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> 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	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Anti-beta-1 adrenergic antibodies	TBD Specify test type _____ (e.g., ELISA, complement fixation test) and isotype (e.g., IgM, IgG) _____	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Anti-beta-2 adrenergic antibodies	TBD Specify test type _____ (e.g., ELISA, complement fixation test) and isotype (e.g., IgM, IgG) _____	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Anti-streptolysin O antibodies	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
Anti-DNase B antibodies	TBD	TBD	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown

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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

## Laboratory Tests – Immune Module Instructions

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### 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.

- a. 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).
- b. Result – Record the numeric or alpha-numeric results for each laboratory test.
- c. 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).