CLAIMS:

1. A method for measuring cell-mediated immune response activity in a subject, said method comprising contacting lymphocytes from the subject with at least two sets of peptides, a first set comprising at least one peptide of from about 7 to 14 amino acid residues in length and a second set comprising at least one peptide of from 16 amino acid residues or greater which peptides encompass all or part of a protein antigen and measuring the presence or elevation in the level of an immune effector molecule from immune cells wherein the presence or level of the immune effector molecule is indicative of the level of cell-mediated responsiveness of the subject.

2. The method of Claim 1 wherein the subject is a human.

3. The method of Claim 1 wherein the 7 to 14 amino acid peptides are recognized by $CD8^+$ lymphocytes and the 16 amino acid or greater peptides are recognized by $CD4^+$ lymphocytes.

4. The method of Claim 1 wherein the sample is undiluted whole blood.

5. The method of Claim 4 wherein the sample is whole blood which comprises from about 10% to 100% by volume of the sample to be assayed.

6. The method of Claim 5 wherein the whole blood comprises from about 50% to 100% by volume of the sample to be assayed.

7. The method of Claim 6 wherein the whole blood comprises from about 80% to 100% by volume of the sample to be assayed.

8. The method of Claim 1 wherein the whole blood is collected in a tube comprising heparin.

9. The method of Claim 1 wherein the immune effector molecule is a cytokine.

10. The method of Claim 11 wherein the cytokine is IFN-γ.

11. The method of Claim 1 wherein the immune effectors are detected with antibodies specific for same.

12. The method of Claim 11 wherein the immune effectors are detected using ELISA.

13. The method of Claim 12 wherein the immune effectors are detected using ELISpot.

14. The method of Claim 1 wherein the subject has an infection by a pathogenic agent selected from *Mycobacterium* species, *Staphylococcus* species, *Streptococcus* species, *Borrelia* species, *Escherichia coli*, *Salmonella* species, *Clostridium* species, *Shigella* species, *Proteus* species, *Bacillus* species, Herpes virus, Hepatitis B or C virus and Human immune deficiency virus (HIV) or a disease resulting therefrom.

15. The method of Claim 14 wherein the disease condition is an infection by *Mycobacterium tuberculosis* or tuberculosis (TB).

16. The method of Claim 15 wherein the antigen is selected from CFP10, ESAT-6, TB7.7 and TB37.6.

17. The method of Claim 1 wherein the subject has a disease condition selected from alopecia areata, ankylosing spondylitis, antiphospholipid syndrome, autoimmune Addison's disease multiple sclerosis, autoimmune disease of the adrenal gland, autoimmune hemolytic anemia, autoimmune hepatitis, autoimmune oophoritis and orchitis, Behcet's disease, bullous pemphigoid, cardiomyopathy, celiac sprue-dermatitis, chronic fatigue syndrome (CFIDS), chronic inflammatory demyelinating, chronic inflammatory polyneuropathy, Churg-Strauss syndrome, cicatricial pemphigoid, crest syndrome, cold agglutinin disease, Crohn's disease, dermatitis herpetiformis, discoid lupus, essential mixed

cryoglobulinemia, fibromyalgia, glomerulonephritis, Grave's disease, Guillain -Barre, Hashimoto's thyroiditis, idiopathic pulmonary fibrosis, idiopathic thrombocytopenia purpura (ITP), IgA nephropathy, insulin dependent diabetes (Type I), lichen planus, lupus, Meniere's disease, mixed connective tissue disease, multiple sclerosis, myasthenia gravis, myocarditis, pemphigus vulgaris, pernicious anemia, polyarteritis nodosa, polychondritis, polyglancular syndromes, polymyalgia rheumatica, polymyositis and dermatomyositis, primary agammaglobulinemia, primary biliary cirrhosis, psoriasis, Raynaud's phenomenon, Reiter's syndrome, rheumatic fever, rheumatoid arrthritis, sarcoidosis, scleroderma, Sjogren's syndrome, stiff-man syndrome, systemic lupus erythematosus, Takayasu arteritis, temporal arteritis/gianT-cell arteritis, ulcerative colitis, uveitis, vasculitis, vitiligo and inflammatory bowel disease.

18. The method of Claim 17 wherein the disease is Celiac's disease.

19. The method of Claim 18 wherein the disease is autoimmune diabetes.

20. The method of Claim 1 wherein the subject has a cancer selected from ABL1 protooncogene, AIDS related cancers, acoustic neuroma, acute lymphocytic leukaemia, acute myeloid leukaemia, adenocystic carcinoma, adrenocortical cancer, agnogenic myeloid metaplasia, alopecia, alveolar soft-part sarcoma, anal cancer, angiosarcoma, aplastic anaemia, astrocytoma, ataxia-telangiectasia, basal cell carcinoma (skin), bladder cancer, bone cancers, bowel cancer, brain stem glioma, brain and CNS tumors, breast cancer, CNS tumors, carcinoid tumors, cervical cancer, childhood brain tumors, childhood cancer, childhood leukaemia, childhood soft tissue sarcoma, chondrosarcoma, choriocarcinoma, chronic lymphocytic leukaemia, chronic myeloid leukaemia, colorectal cancers, cutaneous T-Cell lymphoma, dermatofibrosarcoma-protuberans, desmoplastic-small-round-cell-tumor, ductal carcinoma, endocrine cancers, endometrial cancer, ependymoma, esophageal cancer, Ewing's sarcoma, extra-hepatic bile duct cancer, eye cancer, eye: melanoma, retinoblastoma, fallopian tube cancer, fanconi anemia, fibrosarcoma, gall bladder cancer, gastric cancer, gastrointestinal cancers, gastrointestinal-carcinoid-tumor, genitourinary cancers, germ cell tumors, gestational-trophoblastic-

disease, glioma, gynaecological cancers, hematological malignancies, hairy cell leukaemia, head and neck cancer, hepatocellular cancer, hereditary breast cancer, histiocytosis, Hodgkin's disease, human papillomavirus, hydatidiform mole, hypercalcemia, hypopharynx cancer, intraocular melanoma, islet cell cancer, Kaposi's sarcoma, kidney cancer, Langerhan's-cell-histiocytosis, laryngeal cancer, leiomyosarcoma, leukemia, Li-Fraumeni syndrome, lip cancer, liposarcoma, liver cancer, lung cancer, lymphedema, lymphoma, Hodgkin's lymphoma, non-Hodgkin's lymphoma, male breast cancer, malignant-rhabdoid-tumor-of-kidney, medulloblastoma, melanoma, merkel cell cancer, mesothelioma, metastatic cancer, mouth cancer, multiple endocrine neoplasia, mycosis fungoides, myelodysplastic syndromes, myeloma, myeloproliferative disorders, nasal cancer, nasopharyngeal cancer, nephroblastoma, neuroblastoma, neurofibromatosis, nijmegen breakage syndrome, non-melanoma skin cancer, non-small-cell-lung-cancer-(NSCLC), ocular cancers, oesophageal cancer, oral cavity cancer, oropharynx cancer, osteosarcoma, ostomy ovarian cancer, pancreas cancer, paranasal cancer, parathyroid cancer, parotid gland cancer, penile cancer, peripheral-neuroectodermal-tumors, pituitary cancer, polycythemia vera, prostate cancer, rare-cancers-and-associated-disorders, renal cell carcinoma, retinoblastoma, rhabdomyosarcoma, Rothmund-Thomson syndrome, salivary gland cancer, sarcoma, schwannoma, Sezary syndrome, skin cancer, small cell lung cancer (SCLC), small intestine cancer, soft tissue sarcoma, spinal cord tumors, squamous-cell-carcinoma-(skin), stomach cancer, synovial sarcoma, testicular cancer, thymus cancer, thyroid cancer, transitional-cell-cancer-(bladder), transitional-cell-cancer-(renal-pelvis-/-ureter), trophoblastic cancer, urethral cancer, urinary system cancer, uroplakins, uterine sarcoma, uterus cancer, vaginal cancer, vulva cancer, Waldenstrom's-macroglobulinemia and Wilms' tumor.

21. The method of Claim 1 wherein the subject was exposed to a proteinaceous toxicant.

22. The method of any one of Claims 1 to 21 wherein the magnitude of the cell-mediated immune response correlates with the state, progression and/or severity of a disease condition.

23. Use of at least two sets of peptides, a first set comprising at least one peptide of from about 7 to 14 amino acid residues in length and a second set comprising at least one peptide of from 16 amino acid residues or greater which peptides encompass all or part of a protein antigen in the manufacture of a diagnostic assay of cell-mediated immune responsiveness by the method of incubating of the peptides with lymphocytes and detecting the presence or elevation in effector molecules.

24. A method of allowing a user to determine the status of cell-mediated immunoresponsiveness of a subject, the method including:

(a) receiving data in the form of levels or concentrations of an immune effector molecule which relative to a control provide a correlation to the state of cell-mediated immunoresponsiveness from the user *via* a communications network, the immune effector molecule measured after exposure of lymphocytes to at least two sets of peptides, a first set comprising at least one peptide of from about 7 to 14 amino acid residues in length and a second set comprising at least one peptide of from 16 amino acid residues or greater which peptides encompass all or part of a protein antigen;

(b) processing the subject data *via* univariate or multivariate analysis to provide an immunoresponsiveness value;

(c) determining the status of the subject in accordance with the results of the immunoresponsiveness value in comparison with predetermined values; and

(d) transferring an indication of the status of the subject to the user *via* the communications network.

CLAIMS:

1. A method for measuring cell-mediated immune response activity in a subject, said method comprising contacting whole blood containing lymphocytes which comprises from 50% to 100% by volume of a sample to be assayed from the subject with a first and second set of peptides wherein the first set comprises at least one peptide of from about 7 to 14 amino acid residues in length and the second set comprises at least one peptide of from 16 amino acid residues or greater which peptides encompass all or part of a protein antigen and measuring the presence or elevation in the level of an immune effector molecule from immune cells wherein the presence or level of the immune effector molecule is indicative of the level of cell-mediated responsiveness of the subject.

2. The method of Claim 1 wherein the subject is a human.

3. The method of Claim 1 wherein the 7 to 14 amino acid peptides are recognized by $CD8^+$ lymphocytes and the 16 amino acid or greater peptides are recognized by $CD4^+$ lymphocytes.

4. The method of Claim 1 wherein the sample is undiluted whole blood.

5. The method of Claim 1 or 4 wherein the whole blood is collected in a tube comprising heparin.

6. The method of Claim 1 wherein the immune effector molecule is a cytokine.

7. The method of Claim 6 wherein the cytokine is IFN-γ.

8. The method of Claim 1 wherein the immune effector molecule is detected with antibodies specific for same.

9. The method of Claim 8 wherein the immune effector molecule is detected using ELISA.

10. The method of Claim 9 wherein the immune effector molecule is detected using ELISpot.

11. The method of Claim 1 wherein the subject has an infection by a pathogenic agent selected from *Mycobacterium* species, *Staphylococcus* species, *Streptococcus* species, *Borrelia* species, *Escherichia coli*, *Salmonella* species, *Clostridium* species, *Shigella* species, *Proteus* species, *Bacillus* species, Herpes virus, Hepatitis B or C virus and Human immune deficiency virus (HIV) or a disease resulting therefrom.

12. The method of Claim 11 wherein the infection is by *Mycobacterium tuberculosis* or tuberculosis (TB).

13. The method of Claim 12 wherein the antigen is selected from CFP10, ESAT-6, TB7.7 and TB37.6.

14. The method of Claim 1 wherein the subject has Celiac's disease.

15. The method of Claim 1 wherein the subject has autoimmune diabetes.

16. The method of Claim 1 wherein the subject has cancer.

17. The method of Claim 1 wherein the subject was exposed to a proteinaceous toxicant.

18. The method of any one of Claims 1 to 17 wherein the magnitude of the cell-mediated immune response correlates with the state, progression and/or severity of a disease condition.

19. Use of at least two sets of peptides, a first set comprising at least one peptide of from about 7 to 14 amino acid residues in length and a second set comprising at least one peptide of from 16 amino acid residues or greater which peptides encompass all or part of

a protein antigen in the manufacture of a diagnostic assay of cell-mediated immune responsiveness by the method of incubating of the peptides with lymphocytes and detecting the presence or elevation in effector molecules.

20. A method of allowing a user to determine the status of cell-mediated immunoresponsiveness of a subject, the method including:

(a) receiving data in the form of levels or concentrations of an immune effector molecule which relative to a control provide a correlation to the state of cell-mediated immunoresponsiveness from the user *via* a communications network, the immune effector molecule measured after exposure of whole blood containing lymphocytes which comprises from 50% to 100% by volume of a sample to be assayed from the subject with a first and second set of peptides wherein the first set comprises at least one peptide of from about 7 to 14 amino acid residues in length and the second set comprises at least one peptide of from 16 amino acid residues or greater which peptides encompass all or part of a protein antigen;

(b) processing the subject data *via* univariate or multivariate analysis to provide an immunoresponsiveness value;

(c) determining the status of the subject in accordance with the results of the immunoresponsiveness value in comparison with predetermined values; and

(d) transferring an indication of the status of the subject to the user *via* the communications network.