CLAIMS

1. A method of diagnosing a systemic lupus erythematosus (SLE) patient as undergoing a pre-flare event comprising:

(a) obtaining a blood, serum or plasma sample from a patient;

(b) assessing the level of at least one of each of the following:

(i) innate type cytokine, wherein the innate type cytokine is selected from the group consisting of IL-1α, IL-1β, INF-α, IFN-β, G-CSF, IL-7 and IL-15,

(ii) Th1 type cytokine, wherein the Th1 type cytokine is selected from the group consisting of IL-2, IL-2RA, IL-12 and IFN-γ,

(iii) Th2 type cytokine, wherein the Th2 type cytokine is selected from the group consisting of IL-4, IL-5 and IL-13, and

(iv) Th17 type cytokine, wherein the Th17 type cytokine is selected from the group consisting of IL-6, IL-17A, IL-21 and IL-23,

plus at least two each of the following:

(i) a chemokines/adhesion molecule, wherein the chemokines/adhesion molecule is selected from the group consisting of IL-8, IP-10, RANTES, MCP-1, MCP-3, MIP-1α, MIP-1β, GRO-α, MIG, Eotaxin, ICAM-1 and E-selectin,

(ii) a TNFR superfamily member, wherein the TNFR superfamily member is selected from the group consisting of TNF-α, TNFRI, TNFRII, TRAIL, Fas, FasL, BLyS, APRIL and NGFβ,

(iii) a regulatory mediator, wherein the regulatory mediator is selected from the group consisting of IL-10, TGF-β, SDF-1 and IL-1RA, and

(iv) other SLE mediator, wherein the other SLE mediator is selected from the group consisting of LIF, PAI-1, PDGF-BB, Leptin, SCF and IL-2RA;

and

(c) diagnosing said patient as undergoing a pre-flare event when the majority of innate, Th1, Th2, Th17 type cytokines, chemokines/adhesion molecules, TNFR superfamily members and other SLE mediators are elevated, and at least two regulatory mediators are reduced, as compared to an SLE patient not undergoing a pre-flare event.

2. The method of claim 1, wherein assessing comprises immunologic detection.

3. The method of claim 2, wherein immunologic detection comprises flow cytometry, ELISA, RIA or Western blot.

4. The method of claim 2, wherein immunologic detection comprises a multiplexed bead-based assay.

5. The method of claim 1, wherein assessing comprises detection of transcripts.

6. The method of claim 5, wherein detection transcripts comprises amplification of mRNA.

7. The method of claim 6, wherein said amplification comprises RT-PCR.

8. The method of claim 1, further comprising performing one or more of a SLEDA Index analysis on said patient, anti-nuclear antibody (ANA) testing in a sample from said patient and/or anti-extractable nuclear antigen (anti-ENA) in a sample from said patient.

9. The method of claim 1, further comprising taking a medical history of said patient.

10. The method of claim 1, wherein said SLE patient not undergoing a flare event is represented by a sample from the same patient during a non-flare period.

11. The method of claim 1, wherein said SLE patient not undergoing a flare is represented by a pre-determined average level.

12. A method of assessing the efficacy of a treatment for systemic lupus erythematosus (SLE) in a patient comprising:

(a) obtaining a blood, serum or plasma sample from a patient; and

(b) assessing the level of at least one of each of the following:

(i) innate type cytokine, wherein the innate type cytokine is selected from the group consisting of IL-1α, IL-1β, INF-α, IFN-β, G-CSF, IL-7 and IL-15,

(ii) Thl type cytokine, wherein the Th1 type cytokine is selected from the group consisting of IL-2, IL-2RA, IL-12 and IFN-γ,

(iii) Th2 type cytokine, wherein the Th2 type cytokine is selected from the group consisting of IL-4, IL-5 and IL-13, and

(iv) Th17 type cytokine, wherein the Th17 type cytokine is selected from the group consisting of IL-6, IL-17A, IL-21 and IL-23,

plus at least two each of the following:

(i) a chemokines/adhesion molecule, wherein the chemokines/adhesion molecule is selected from the group consisting of IL-8, IP-10, RANTES, MCP-1, MCP-3, MIP-1α, MIP-1β, GRO-α, MIG, Eotaxin, ICAM-1 and E-selectin,

(ii) a TNFR superfamily member, wherein the TNFR superfamily member is selected from the group consisting of TNF-α, TNFRI, TNFRII, TRAIL, Fas, FasL, BLyS, APRIL and NGFβ,

(iii) a regulatory mediator, wherein the regulatory mediator is selected from the group consisting of IL-10, TGF-β, SDF-1 and IL-1RA, and

(iv) other SLE mediator, wherein the other SLE mediator is selected from the group consisting of LIF, PAI-1, PDGF-BB, Leptin, SCF and IL-2RA;

and

(c) when the majority of innate, Thl, Th2, Th17 type cytokines, chemokines/adhesion molecules, TNFR superfamily members and other SLE mediators are reduced, and at least two regulatory mediators are elevated, as compared to a level in a previous sample from said SLE patient.

13. The method of claim 12, wherein assessing comprises immunologic detection.

14. The method of claim 13, wherein immunologic detection comprises flow cytometry, ELISA, RIA or Western blot.

15. The method of claim 13, wherein immunologic detection comprises a multiplexed bead-based assay.

16. The method of claim 12, wherein assessing comprises detection of transcripts.

17. The method of claim 16, wherein detection transcripts comprises amplification of RNA.

18. The method of claim 17, wherein said amplification comprises RT-PCR.

19. The method of claim 12, further comprising performing one or more of a SLEDA Index analysis on said patient, anti-nuclear antibody (ANA) testing in a sample from said patient and/or anti-extractable nuclear antigen (anti-ENA) in a sample from said patient.

20. The method of claim 12, further comprising taking a medical history of said patient.

21. The method of claim 12, wherein said SLE patient not undergoing a flare event is represented by a sample from the same patient during a non-flare period.

22. The method of claim 12, wherein said SLE patient not undergoing a flare is represented by a pre-determined average level.

23. A kit comprising:

(a) one or more reagents for assessing the expression of biomarkers including:

(i) at least one innate cytokine, wherein the at least one innate type cytokine is selected from the group consisting of IL-1α, IL-1β, INF-α, IFN-β, G-CSF, IL-7 and IL-15;

(ii) at least one Thl type cytokine, wherein the at least one Th1 type cytokine is selected from the group consisting of IL-2, IL-2RA, IL-12 and IFN-γ;

(iii) at least one Th2 type cytokine, wherein the at least one Th2 type cytokine is selected from the group consisting of IL-4, IL-5 and IL-13;

(iv) at least one Th17 type cytokine, wherein the at least one Th17 type cytokine is selected from the group consisting of IL-6, IL-17A, IL-21 and IL-23;

(v) at least two TNFR superfamily members, wherein the at least two TNFR superfamily members are selected from the group consisting of TNF-α, TNFRI, TNFRII, TRAIL, Fas, FasL, BLyS, APRIL and NGFβ;

(vi) at least two chemokines/adhesion molecules, wherein the at least two chemokines/adhesion molecules are selected from the group consisting of IL-8, IP-10, RANTES, MCP-1, MCP-3, MIP-1α, MIP-1β, GRO-α, MIG, Eotaxin, ICAM-1 and E-selectin;

(vii) at least two regulatory mediators, wherein the at least two regulatory mediators are selected from the group consisting of IL-10, TGF-β, SDF-1 and IL-1RA; and

(viii) at least two other SLE mediators; wherein the at least two other SLE mediators are selected from the group consisting of LIF, PAI-1, PDGF-BB, Leptin, SCF and IL-2RA;

and

(b) one or more reagents for assessing anti-nuclear antibody (ANA) testing and/or anti-extractable nuclear antigen (anti-ENA) in a biological sample.

24. The kit of claim 23, wherein said reagents are beads attached to binding ligands for each of said biomarkers.