

CLAIMS

What is claimed is:

1. A monoclonal antibody comprising:

a V_H CDR1 region comprising the amino acid sequence SEQ ID NO: 9; a V_H CDR2 region comprising the amino acid sequence of SEQ ID NO: 10; a V_H CDR3 region comprising the amino acid sequence of SEQ ID NO: 11; a V_L CDR1 region comprising the amino acid sequence of SEQ ID NO: 12; a V_L CDR2 region comprising the amino acid sequence of LGS; a V_L CDR3 region comprising the amino acid sequence of SEQ ID NO: 14; and

a C-terminal heavy chain sequence, wherein the C-terminal heavy chain sequence is SEQ ID NO: 8 or SEQ ID NO: 22.

2. The antibody of claim 1, wherein the antibody comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 15, and a light chain variable region comprising the amino acid sequence of SEQ ID NO: 16.

3. The antibody of claim 1 or claim 2, wherein the C-terminal heavy chain sequence is SEQ ID NO: 8.

4. The antibody of claim 1 or claim 2, wherein the C-terminal heavy chain sequence is SEQ ID NO: 22.

5. An assay comprising

(a) a solid support, wherein a first component is operably-linked to the solid support;

(b) at least one capture agent,
wherein a second component is operably-linked to the at least one capture agent,
wherein the capture agent comprises a first monoclonal antibody of any one of claims 1-4, and

(c) at least one detection agent,
wherein a detectable label is operably-linked to the detection agent, wherein the detection agent comprises a second monoclonal antibody of any one of claims 1-4,

and

wherein the first component and the second component selectively bind to one another.

6. The assay of claim 5, wherein the first component comprises streptavidin.

7. The assay of claim 5 or claim 6, wherein the second component comprises biotin.

8. An assay comprising

(a) a solid support, wherein a first component is operably-linked to the solid support;

(b) at least one capture agent, wherein a second component is operably-linked to the at least one capture agent and wherein the capture agent comprises the monoclonal antibody of any one of claims 1-4; and

(c) at least one detection agent, wherein a detectable label is operably-linked to the detection agent and wherein the detection agent comprises dupilumab; wherein the first component and the second component selectively bind to one another.

9. The assay of claim 8, wherein the first component comprises streptavidin.

10. The assay of claim 8 or 9, wherein the second component comprises biotin.

11. A method of determining a level of immunogenicity of a monoclonal antibody therapy in a subject, comprising

(a) contacting a biological sample from the subject with the assay of any one of claims 5-10 under conditions suitable to allow binding of at least one antibody in the biological sample with the at least one capture agent and to the at least one detection agent, wherein the subject has been administered the monoclonal antibody therapy prior to the contacting step,

(b) detecting a signal from the at least one detection agent, and

(c) identifying the level of immunogenicity of the subject as high when the signal from (b) is above a threshold value or

(d) identifying the level of immunogenicity of the subject as low when the signal from (b) is below the threshold value, wherein

the threshold value is a predetermined value, wherein the threshold value is a safety threshold.

12. The method of claim 11, wherein the monoclonal antibody therapy comprises an antibody of any one of claims 1-4.

13. The method of claim 11, wherein the monoclonal antibody therapy comprises dupilumab.

14. The method of any one of claims 11-13, wherein the amount of the monoclonal antibody therapy is a therapeutically-effective dose.

15. The method of any one of claims 11-14, wherein the level of immunogenicity is a baseline level.

16. The method of any one of claims 11-15, wherein the level of immunogenicity is a subsequent level.

17. The method of any one of claims 11-16, wherein the subject is a participant in a clinical trial.

18. The method of any one of claims 11-17, wherein the subject is a patient undergoing a medical treatment.

19. The method of claim 18, wherein the medical treatment is beginning and the level of immunogenicity is a baseline level.

20. The method of claim 18, wherein the medical treatment is ongoing and the level of immunogenicity is a subsequent level.

21. The method of claim 18, wherein the medical treatment is ending and the level of immunogenicity is a final level.

22. The method of any one of claims 11-21, wherein the subject is a healthy individual.

23. The method of any one of claims 11-21, wherein the subject has an inflammatory disease or disorder, an autoimmune disease or disorder, an allergic disease or disorder, an immune disease or disorder, or a benign proliferative disease or disorder.

24. The method of claim 23, wherein the subject has atopic dermatitis, asthma, allergic rhinitis, allergic conjunctivitis, eosinophilic esophagitis, nasal polyps or a combination thereof.