WHAT IS CLAIMED IS:

1. An isolated antibody or antigen-binding fragment thereof, wherein the antibody is produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by Patent Deposit Designation PTA-10432, and the fragment is an antigen-binding fragment of the antibody produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432.

2. The antibody or fragment of claim 1, wherein the fragment is a Fab fragment or a $F(ab')_2$ fragment.

3. The antibody or fragment of claim 1 or 2, wherein the antibody or fragment thereof is glycosylated.

4. The antibody or fragment of any one of claims 1-3, wherein the fragment comprises one or more of the complementary determining regions of the light or heavy chain of the antibody produced by the hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10432.

5. A hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10432.

6. A method of quantitating a level of human soluble ST2 in a sample from a subject, the method comprising:

contacting the sample with an antibody or fragment of any one of claims 1-4; and

detecting binding of the antibody or fragment to human soluble ST2.

7. A method of quantitating a level of human soluble ST2 in a sample from a subject, the method comprising:

contacting sample with (i) an antibody produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by the Patent Deposit Designation PTA-10431 or an antigen-binding fragment thereof, and (ii) an antibody produced by a

hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432 or an antigen-binding fragment thereof; and

detecting the binding of the antibody or fragment of (i) and the binding of the antibody or fragment of (ii) to human soluble ST2.

8. A method of predicting the risk of death within one year in a subject, the method comprising:

obtaining a sample from a subject; and

determining the level of human soluble ST2 in the sample using an antibody or fragment of any one of claims 1-4;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has an increased risk of death within one year, and a decreased or an equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has a decreased risk of death within one year.

9. A method of predicting the risk of death within one year in a subject, the method comprising:

determining a level of human soluble ST2 in the sample using (i) an antibody produced by the hybridoma deposited at the American Type Culture Collection (ATCC) and designed by Patent Deposit Designation PTA-10431 or an antigen-binding fragment thereof, and (ii) an antibody produced by a hybridoma desposited at the ATCC and designed by Patent Deposit Designation PTA-10432 or an antigen-binding fragment thereof;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has an increased risk of death within one year, and a decreased or equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has a reduced risk of death within one year.

10. A method of determining whether to discharge or to initiate or continue treatment of a subject on an inpatient basis, the method comprising:

obtaining a sample from a subject; and

determining the level of human soluble ST2 in the sample using an antibody or fragment of any one of claims 1-4;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that inpatient treatment of the subject should be initiated or continued, and a decreased or an equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 in the sample indicates that the subject should be discharged.

11. A method of determining whether to discharge or to initiate or continue treatment of a subject on an inpatient basis, the method comprising:

obtaining a sample from a subject; and

detecting a level of human soluble ST2 in the sample using (i) an antibody produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designed by Patent Deposit Designation PTA-10431 or an antigen-binding fragment thereof, and (ii) an antibody produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432 or an antigen-binding fragment thereof;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that inpatient treatment of the subject should be initiated or continued, and a decreased or an equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 in the sample indicates that the subject should be discharged.

12. A method of selecting a subject for participation in a clinical study, the method comprising:

obtaining a sample from a subject;

determining the level of human soluble ST2 in the sample using an antibody or fragment of any one of claims 1-4; and

selecting the subject for participation in a clinical study if the subject's level of human soluble ST2 relative to a reference level of human soluble ST2 indicates that the subject should be selected for participation in a clinical study.

13. A method of selecting a subject for participation in a clinical study, the method comprising:

obtaining a sample from a subject;

determining a level of human soluble ST2 in the sample using (i) an antibody produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by Patent Deposit Designation PTA-10431 or an antigen-binding fragment thereof, and (ii) an antibody produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432 or an antigen-binding fragment thereof; and

selecting the subject for participation in a clinical study if the subject's level of human soluble ST2 relative to a reference level of human soluble ST2 indicates that the subject should be selected for participation in a clinical study.

14. The method of claim 12 or 13, wherein the presence of an elevated level of human soluble ST2 indicates that the subject should be selected for participation in a clinical study.

15. The method of any one of claims 6-14, wherein the subject is undiagnosed or is not presenting with two or more symptoms of a disease selected from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

16. The method of any one of claims 6-14, wherein the subject has been diagnosed as having a disease selected from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

17. The method of any one of claims 6-14, wherein the subject has been identified as being at risk of developing a disease selected from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

18. The method of any one of claims 6-17, wherein the subject has one or more of: hypertriglyceridemia, hypercholesterolemia, hypertension, and a body mass index of $\geq$30.

19. The method of any one of claims 8-18, wherein the reference level of human soluble ST2 is a threshold level of human soluble ST2 that is an average level or a percentile level of human soluble ST2 in a healthy patient population.

20. The method of claim 19, wherein the healthy patient population is a healthy male patient population.

21. The method of claim 19, wherein the healthy patient population is a healthy female patient population.

22. The method of any one of claims 8-18, wherein the reference level is a level of human soluble ST2 present in a sample of a subject not presenting with two or more symptoms of a disease.

23. The method of any one of claims 8-18, wherein the reference level of human soluble ST2 present in a sample of a subject not diagnosed as having a disease selected from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

24. The method of any one of claims 6-23, wherein the sample comprises blood, serum, or plasma.

25. The method of claim 8 or 9, wherein the subject has at least one or more of the following symptoms: chest pain or discomfort, shortness of breath, nausea, vomiting, eructation, sweating, palpitations, lightheadedness, fatigue, and fainting.

26. A kit comprising an antibody or antigen-binding fragment thereof of any one of claims 1-4.

27. The kit of claim 26, wherein the kit further comprises an isolated antibody produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10431 or an antigen-binding fragment thereof.

28. The kit of claim 26, wherein the antibody or fragment has a K_D for binding to human soluble ST2 equal to or less than 8.59×10^{-10} M as determined by surface plasmon resonance (SPR).

29. The kit of any of claims 26-28, wherein the kit is provided as an enzyme-linked immunosorbent assay.

30. The kit of any of claims 26-29, further comprising a recombinant human soluble ST2 isolated from a human cell.

31. The kit of claim 30, wherein the human cell is a human embryonic kidney cell.

WHAT IS CLAIMED IS:

1. An isolated antibody or antigen-binding fragment thereof, wherein the antibody or fragment thereof is produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by Patent Deposit Designation PTA-10431 or PTA-10432.

2. The antibody or fragment of claim 1, wherein the antibody or fragment thereof is chimeric.

3. The antibody or fragment of claim 1, wherein the antibody or fragment thereof is humanized.

4. The antibody or fragment of any one of claims 1-3, wherein the fragment is a Fab fragment or a $F(ab')_2$ fragment.

5. The antibody or fragment of any one of claims 1-4, wherein the antibody or fragment thereof is glycosylated.

6. The antibody or fragment of any one of claims 1-5, wherein the antibody or fragment thereof comprises one or more of the complementary determining regions of the light or heavy chain of the antibody produced by the hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10431 or PTA-10432.

7. The antibody or fragment of any one of claims 1-6, wherein the antibody is the antibody produced by the hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10431, or is an antigen-binding fragment of the antibody produced by the hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10431.

8. The antibody or fragment of any one of claims 1-6, wherein the antibody is the antibody produced by the hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10432, or is an antigen-binding fragment of the antibody produced by

the hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10432.

9. A hybridoma selected from the group consisting of: the hybridoma deposited at the American Type Culture Collection (ATCC) and designated by the Patent Deposit Designation PTA-10431 and the hybridoma deposited at the ATCC and designated by the Patent Deposit Designation PTA-10432.

10. A method of quantitating a level of human soluble ST2 in a sample from a subject, the method comprising:

contacting the sample with an antibody or fragment thereof of any one of claims 1-8; and

detecting binding of the antibody or fragment thereof to human soluble ST2.

11. A method of quantitating a level of human soluble ST2 in a sample from a subject, the method comprising:

contacting the sample with (i) an antibody or fragment produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by Patent Deposit Designation PTA-10431, and (ii) an antibody or fragment produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432; and

detecting binding of the antibody or fragment of (i) and the binding of the antibody or fragment of (ii) to human soluble ST2.

12. A method of predicting the risk of death within one year in a subject, the method comprising:

obtaining a sample from a subject; and

determining a level of human soluble ST2 in the sample using an antibody or fragment thereof of any one of claims 1-8;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has an increased risk of death within one year, and a decreased or an equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has a decreased risk of death within one year.

13. A method of predicting the risk of death within one year in a subject, the method comprising:

obtaining a sample from a subject; and

determining a level of human soluble ST2 in the sample using (i) an antibody or fragment produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by Patent Deposit Designation PTA-10431, and (ii) an antibody or fragment produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has an increased risk of death within one year, and a decreased or an equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that the subject has a decreased risk of death within one year.

14. A method of determining whether to discharge or to initiate or continue treatment of a subject on an inpatient basis, the method comprising:

obtaining a sample from a subject; and

determining a level of human soluble ST2 in the sample using an antibody or fragment thereof of any one of claims 1-8;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that inpatient treatment of the subject should be initiated or continued, and a decreased or an equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 in the sample indicates that the subject should be discharged.

15. A method of determining whether to discharge or to initiate or continue treatment of a subject on an inpatient basis, the method comprising:

obtaining a sample from a subject; and

determining a level of human soluble ST2 in the sample using (i) an antibody or fragment produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by Patent Deposit Designation PTA-10431, and (ii) an antibody or fragment produced

by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432;

wherein an elevated level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 indicates that inpatient treatment of the subject should be initiated or continued, and a decreased or an equal level of human soluble ST2 in the sample compared to a reference level of human soluble ST2 in the sample indicates that the subject should be discharged.

16. A method of selecting a subject for participation in a clinical study, the method comprising:

obtaining a sample from a subject;

determining a level of human soluble ST2 in the sample using an antibody or fragment thereof of any one of claims 1-8; and

selecting the subject for participation in a clinical study if the subject's level of human soluble ST2 relative to a reference level of human soluble ST2 indicates that the subject should be selected for participation in a clinical study.

17. A method of selecting a subject for participation in a clinical study, the method comprising:

obtaining a sample from a subject;

determining a level of human soluble ST2 in the sample using (i) an antibody or fragment produced by a hybridoma deposited at the American Type Culture Collection (ATCC) and designated by Patent Deposit Designation PTA-10431, and (ii) an antibody or fragment produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432; and

selecting the subject for participation in a clinical study if the subject's level of human soluble ST2 relative to a reference level of human soluble ST2 indicates that the subject should be selected for participation in a clinical study.

18. The method of claim 16 or 17, wherein the presence of an elevated level of human soluble ST2 indicates that the subject should be selected for participation in a clinical study.

19. The method of any one of claims 10-18, wherein the subject is undiagnosed or is not presenting with two or more symptoms of a disease selected from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

20. The method of any one of claims 10-18, wherein the subject has been diagnosed as having a disease selected from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

21. The method of any one of claims 10-18, wherein the subject has been identified as being at risk of developing a disease selected from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

22. The method of any one of claims 10-21, wherein the subject has one or more of: hypertriglyceridemia, hypercholesterolemia, hypertension, and a body mass index of ≥ 30.

23. The method of any one of claims 12-22, wherein the reference level of human soluble ST2 is a threshold level of human soluble ST2 that is an average level or a percentile level of human soluble ST2 in a healthy patient population.

24. The method of claim 23, wherein the healthy patient population is a healthy male patient population.

25. The method of claim 23, wherein the healthy patient population is a healthy female patient population.

26. The method of any one of claims 12-22, wherein the reference level is a level of human soluble ST2 present in a sample of a subject not presenting with two or more symptoms of a disease.

27. The method of any one of claims 12-22, wherein the reference level is a level of human soluble ST2 present in a sample of a subject not diagnosed as having a disease selected

from the group consisting of heart failure, coronary artery disease, cardiovascular disease, acute coronary syndrome, renal insufficiency, and stroke.

28. The method of any one of claims 10-27, wherein the sample comprises blood, serum, or plasma.

29. The method of claim 12 or 13, wherein the subject has at least one or more of the following symptoms: chest pain or discomfort, shortness of breath, nausea, vomiting, eructation, sweating, palpitations, lightheadedness, fatigue, and fainting.

30. A kit comprising an antibody or antigen-binding fragment thereof of claims 1-8.

31. The kit of claim 30, wherein the kit contains (i) an antibody or fragment produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10431, and (ii) an antibody or fragment produced by a hybridoma deposited at the ATCC and designated by Patent Deposit Designation PTA-10432.

32. The kit of claim 30, wherein the antibody or fragment has a K_D for binding to human soluble ST2 equal to or less than 8.59×10^{-10} M.

33. The kit of any one of claims 30-32, wherein the kit is provided as an enzyme-linked immunosorbent assay.

34. The kit of any one of claims 30-33, further comprising a recombinant human soluble ST2 isolated from a human cell.

35. The kit of claim 34, wherein the human cell is a human embryonic kidney cell.