In some aspects, the present invention provides an immunoassay device comprising: a membrane having a Z-AAT protein capture area defined by a capture antibody immobilized thereto, wherein the capture antibody is an anti-Z-AAT protein antibody.

In one aspect, there is provided an immunoassay device comprising:

i) a membrane having a Z-AAT protein capture area defined by a capture antibody specific for Z-AAT protein immobilized thereto;

ii) a sample application area and a flow path from the sample application area to the Z-AAT protein capture area; and

iii) a conjugate structure located in the flow path, wherein the conjugate structure comprises a detection reagent specific for the Z-AAT protein, the detection reagent being mobile or mobilizable;

wherein the capture antibody is selected from the group consisting of monoclonal antibody LG96 produced by hybridoma cells deposited under Accession No. DSM ACC3092, and monoclonal antibody MG97 produced by hybridoma cells deposited under Accession No. DSM ACC3093; and

wherein the detection reagent is a detector antibody selected from the group consisting of monoclonal antibody LG96 produced by hybridoma cells deposited under Accession No. DSM ACC3092, and monoclonal antibody MG97 produced by hybridoma cells deposited under Accession No. DSM ACC3093.

In one aspect, there is provided a method for determining whether a mammal is a PiZ gene carrier, the method comprising performing an immunochromatographic assay of a sample from the mammal to be tested, using the device as defined above, wherein the assay comprises:

binding of the Z-AAT protein to the capture antibody, and

detecting a complex that is formed between the capture antibody, the Z-AAT protein, and the detection reagent,

wherein detecting the complex indicates that the mammal is a PiZ carrier.

In one aspect, there is provided a kit comprising the device as defined above, wherein the detector antibody is labeled with a a reporter moiety conjugated thereto.

In one aspect, there is provided a monoclonal antibody, or an antigen-binding fragment thereof, that specifically binds to Z-AAT protein, wherein the monoclonal antibody is produced by a hybridoma on deposit under an Accession Number selected from the group consisting of DSM ACC3092 (LG96) and DSM ACC3093 (MG97).

In one aspect, there is provided a hybridoma cell line that produces a monoclonal antibody as defined above and is on deposit under an Accession Number selected from the group consisting of DSM ACC3092 (LG96) and DSM ACC3093 (MG97).

In other aspects, the present invention provides an immunoassay device for determining the presence or amount of a Z-AAT protein in a fluid sample. The device comprises:

a sample application area;

a microporous membrane having a Z-AAT protein capture area defined by a capture antibody immobilized thereto, wherein the capture antibody is LG96 or antigen-binding fragment thereof;

a flow path from the sample application area to the Z-AAT protein capture area, wherein the presence or amount of a Z-AAT protein in a fluid sample can be determined by formation of a complex between the capture antibody and the Z-AAT protein that may be present in the fluid sample; and

a conjugate structure located in the flow path, wherein the conjugate structure comprises a detection reagent specific for the Z-AAT protein, the detection reagent being mobile or mobilizable, wherein the detection reagent is gold-conjugated LG96 or a gold-conjugated antigen-binding fragment thereof.

In one aspect, a method for detecting a Z-AAT protein in a subject is provided. The method comprises:

applying a biological sample from the subject to the immunoassay device of present invention; and

detecting a complex that is formed between the capture antibody and the Z-AAT protein that may be present in the fluid sample, wherein detection of the complex indicates the presence of the Z-AAT protein in the sample.

In another aspect, the present invention provides a method for determining a PiZ gene carrier. The method comprises subjecting a sample from a subject to immunochromatography using a device in accordance with the present invention; and determining binding of an analyte to a capture antibody, wherein binding of the analyte to the capture antibody indicates that the subject is a PiZ carrier.

In some aspects, the present invention provides a method for diagnosing a condition or disease associated with AAT deficiency. The method comprises subjecting a sample from a

We claim:

1. An immunochromatograhic device comprising a membrane having a capture antibody bound thereto at a test zone, wherein the capture antibody is capable of binding with an analyte, wherein the analyte is a Z-AAT protein present in a sample from a PiZ gene carrier.

2. The device of claim 1, wherein the capture antibody is monoclonal antibody LG96.

3. The device of claim 1, wherein the capture antibody is monoclonal antibody MG97.

4. The device of claim 1 further comprising a conjugate structure fluidly coupled to the membrane at a proximal end, wherein the conjugate structure comprises a detector antibody having a reporter moiety conjugated thereto.

5. The device of claim 4, wherein the detector antibody is monoclonal antibody LG96.

6. The device of claim 5, wherein the capture antibody is monoclonal antibody MG97.

7. The device of claim 4, wherein the capture antibody is monoclonal antibody MG97 and the detector antibody is monoclonal antibody LG96.

8. The device of claim 4, wherein the capture antibody is monoclonal antibody LG96 and the detector antibody is monoclonal antibody LG96.

9. The device of claim 4, wherein the conjugate structure is a conjugate pad that partially overlays the membrane at the proximal end of the membrane.

10. The device of claim 4 further comprising a blood separation system for receiving the sample, wherein the blood separation system is fluidly coupled to the conjugate structure.

11. The device of claim 10, wherein the blood separation system partially overlays the conjugate pad.

12. The device of claim 10 further comprising a distal structure fluidly coupled to the membrane at a distal end of the membrane, wherein the distal structure is configured to provide sufficient flow-through of the sample from the proximal to the distal end of the membrane.

13. The device of claim 12, wherein the distal structure is an adsorbent pad configured to provide sufficient flow-through of the sample from the proximal end of the membrane to at least a control zone by capillary action.

14. The device of claim 1, wherein the membrane further comprises a control zone having a control antibody bound thereto, wherein the control antibody is capable of binding with a detection reagent.

15. The device of claim 14, wherein the control antibody is an anti-mouse IgG.

16. A method for determining a PiZ gene carrier, the method comprising:

subjecting a sample from a subject to immunochromatography using the device of claim 1; and

determining binding of the analyte to the capture antibody, wherein binding of the analyte to the capture antibody indicates that the subject is a PiZ carrier.

17. The method of claim 16, wherein the capture antibody is monoclonal antibody LG96 or MG97.

18. The method of claim 16, wherein the PiZ carrier has a phenotype that is any allelic combination having a PiZ allele.

19. The method of claim16, wherein the capture antibody is monoclonal antibody MG97 and the detector antibody is monoclonal antibody LG96.

20. The device of claim 16, wherein the capture antibody is monoclonal antibody LG96 and the detector antibody is monoclonal antibody LG96.

21. The method of claim 18, wherein the phenotype is PiZZ, PiMZ, PiSZ, or PiZ/Null.

22. A method for diagnosing a condition or disease associated with AAT deficiency, the method comprising:

subjecting a sample from a subject to immunochromatography using the device of claim 1; and

determining binding of the analyte to the capture antibody, wherein binding of the analyte to the capture antibody indicates that the subject has the condition or disease.

23. A method for determining a subject's predisposition to developing a condition or disease associated with AAT deficiency, the method comprising:

subjecting a sample from a subject to immunochromatography using the device of claim 1; and

determining binding of the analyte to the capture antibody, wherein binding of the analyte to the capture antibody is indicative of the subject's predisposition to developing the condition or disease.

24. An immunoassay device comprising: a membrane having a Z-AAT protein capture area defined by a capture antibody immobilized thereto.

25. The device of claim 24, wherein the capture antibody is LG96 or fragment thereof.

26. The device of claim 24, wherein the capture antibody is MG97 or fragment thereof.

27. The device of claim 24 further comprising a sample application area and a flow path from the sample application area to the Z-AAT protein capture area, wherein the presence or amount of a Z-AAT protein in a fluid sample can be determined by formation of a complex between the capture antibody and the Z-AAT protein that may be present in the fluid sample.

28. The device of claim 27 further comprising a conjugate structure located in the flow path, wherein the conjugate structure comprises a detection reagent specific for the Z-AAT protein, the detection reagent being mobile or mobilizable.

29. The device of claim 28, wherein the detection reagent is a detector antibody.

30. The device of claim 29, wherein the detector antibody is LG96 or fragment thereof.

31. The device of claim 29, wherein the detector antibody is MG97 or fragment thereof.

32. The device of claim 29, wherein the detector antibody is labeled with a reporter moiety.

33. The device of claim 29, wherein the detector antibody is a gold-conjugated detector antibody.

34. The device of claim 27, wherein a source of the fluid sample is capillary blood, serum, or plasma.

35. An immunoassay device for determining the presence or amount of a Z-AAT protein in a fluid sample, the device comprising:

a sample application area;

a microporous membrane having a Z-AAT protein capture area defined by a capture antibody immobilized thereto, wherein the capture antibody is LG96 or antigen-binding fragment thereof;

a flow path from the sample application area to the Z-AAT protein capture area, wherein the presence or amount of a Z-AAT protein in a fluid sample can be determined by formation of a complex between the capture antibody and the Z-AAT protein that may be present in the fluid sample; and

a conjugate structure located in the flow path, wherein the conjugate structure comprises a detection reagent specific for the Z-AAT protein, the detection reagent being mobile or mobilizable, wherein the detection reagent is gold-conjugated LG96 or a gold-conjugated antigen-binding fragment thereof.

36. A method for detecting a Z-AAT protein in a subject, the method comprising:

applying a biological sample from the subject to the immunoassay device of claim 35; and

detecting a complex that is formed between the capture antibody and the Z-AAT protein that may be present in the fluid sample, wherein detection of the complex indicates the presence of the Z-AAT protein in the sample.

37. A method for determining the presence of a Z-AAT protein in a biological sample, the method comprising:

providing the biological sample and a first antibody in a mixed state on a membrane having a second antibody bound thereto at a test zone, wherein each of the first and the second antibody is capable of binding to the Z-AAT protein; wherein capture of the second antibody at the test zone indicates the presence of the Z-AAT protein in the sample.

38. The method of claim 37, wherein the first antibody is LG96.

39. The method of claim 37, wherein the first antibody is MG97.

40. The method of claim 37, wherein the second antibody is LG96.

41. The method of claim 37, wherein the second antibody is MG97.

42. A kit comprising:

(a) the device of claim 1; and

(b) a detector antibody having a reporter moiety conjugated thereto.

43. The kit of claim 42, comprising a capture antibody that is monoclonal antibody LG96 or MG97.

44. The kit of claim 42, wherein the detector antibody is monoclonal antibody LG96 or MG97, wherein the antibody is labeled with a reporter moiety.

Claims

1. An immunoassay device comprising:

i) a membrane having a Z-AAT protein capture area defined by a capture antibody specific for Z-AAT protein immobilized thereto;

ii) a sample application area and a flow path from the sample application area to the Z-AAT protein capture area; and

iii) a conjugate structure located in the flow path, wherein the conjugate structure comprises a detection reagent specific for the Z-AAT protein, the detection reagent being mobile or mobilizable;

wherein the capture antibody is selected from the group consisting of monoclonal antibody LG96 produced by hybridoma cells deposited under Accession No. DSM ACC3092, and monoclonal antibody MG97 produced by hybridoma cells deposited under Accession No. DSM ACC3093; and

wherein the detection reagent is a detector antibody selected from the group consisting of monoclonal antibody LG96 produced by hybridoma cells deposited under Accession No. DSM ACC3092, and monoclonal antibody MG97 produced by hybridoma cells deposited under Accession No. DSM ACC3093.

2. The device of claim 1, wherein the presence or amount of a Z-AAT protein in a fluid sample can be determined by formation of a complex between the capture antibody and the Z-AAT protein that may be present in the fluid sample.

3. The device of claim 1, wherein the immunoassay device is an immunochromatograhic device comprising the membrane having the capture antibody bound thereto at a test zone, wherein a conjugate structure is fluidly coupled to the membrane at a proximal end, and wherein the detector antibody has a reporter moiety conjugated thereto.

4. The device of claim 3, wherein the conjugate structure is a conjugate pad that partially overlays the membrane at the proximal end of the membrane.

5. The device of claim 3, further comprising a blood separation system for receiving the sample, wherein the blood separation system is fluidly coupled to the conjugate structure.

6. The device of claim 5, wherein the blood separation system partially overlays the conjugate pad.

7. The device of claim 5 further comprising a distal structure fluidly coupled to the membrane at a distal end of the membrane, wherein the distal structure provides sufficient flow-through of the sample from the proximal to the distal end of the membrane.

8. The device of claim 7, wherein the distal structure is an adsorbent pad which provides sufficient flow-through of the sample from the proximal end of the membrane to at least a control zone by capillary action.

9. The device of claim 1, wherein the membrane further comprises a control zone having a control antibody bound thereto, wherein the control antibody is capable of binding with a detection reagent.

10. The device of claim 9, wherein the control antibody is an anti-mouse IgG.

11. A method for determining whether a mammal is a PiZ gene carrier, the method comprising performing an immunochromatographic assay of a sample from the mammal to be tested, using the device of claim 3, wherein the assay comprises:

binding of the Z-AAT protein to the capture antibody, and

detecting a complex that is formed between the capture antibody, the Z-AAT protein, and the detection reagent,

wherein detecting the complex indicates that the mammal is a PiZ carrier.

12. The method of claim 11, wherein the PiZ carrier has a phenotype that is any allelic combination having a PiZ allele.

13. The method of claim 12, wherein the phenotype is PiZZ, PiMZ, PiSZ, or PiZ/Null.

14. A kit comprising the device of claim 1, wherein the detector antibody is labeled with a a reporter moiety conjugated thereto.

15. A monoclonal antibody, or an antigen-binding fragment thereof, that specifically binds to Z-AAT protein, wherein the monoclonal antibody is produced by a hybridoma on deposit under an Accession Number selected from the group consisting of DSM ACC3092 (LG96) and DSM ACC3093 (MG97).

16. The monoclonal antibody of claim 15 produced by the hybridoma having Accession Number DSM ACC3092 (LG96), or an antigen-binding fragment thereof.

17. The monoclonal antibody of claim 15 produced by the hybridoma having Accession Number and DSM ACC3093 (MG97), or an antigen-binding fragment thereof.

18. The monoclonal antibody or the antigen-binding fragment thereof of claim 15, wherein the antibody or fragment is labeled.

19. A hybridoma cell line that produces a monoclonal antibody of claim 15 and is on deposit under an Accession Number selected from the group consisting of DSM ACC3092 (LG96) and DSM ACC3093 (MG97).

20. The hybridoma cell line of claim 17 deposited under ATCC Accession Number DSM ACC3092 (LG96).

21. The hybridoma cell line of claim 17 deposited under ATCC Accession Number DSM ACC3093 (MG97).