**Claims**

1. Use of a calibrator material comprising mammalian bodily fluid to calibrate an immunoassay for detection of autoantibodies.

2. Use according to claim 2 wherein the calibrator material comprises human bodily fluid.

3. Use according to claim 1 or claim 2 wherein the calibrator material does not comprise any blood products selected from the group consisting of serum, whole blood and plasma.

4. Use according to any one of claims 1 to 3 wherein the calibrator material comprises a drainage fluid, exudate or transudate.

5. Use according to any one of claims 1 to 4 wherein the calibrator material comprises bodily fluid collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated.

6. Use according to claim 5 wherein the calibration material comprises pleural fluid collected from one or more subjects with cancer.

7. Use according to claim 5 wherein the calibration material comprises ascites fluid collected from one or more subjects with cancer.

8. Use according to any one of claims 1 to 7 wherein the immunoassay is for detection of autoantibodies to cancer.

9. Use according to any one of claims 1 to 7 wherein the immunoassay is for detection of autoantibodies to early neoplastic change.

10. A method of calibrating an immunoassay for detection of autoantibodies which comprises:
(a) contacting each of a plurality of different dilutions of a calibration material comprising a mammalian bodily fluid with an antigen specific for an autoantibody, wherein said mammalian bodily fluid is known to contain autoantibodies immunologically specific for the antigen;
(b) detecting the amount of specific binding between said antigen and autoantibody present in the calibration material; and
(c) plotting or calculating a curve of the amount of said specific binding versus the dilution of the calibration material for each dilution of calibration material used in step (a), thereby calibrating an immunoassay using said antigen for detection of said autoantibody.

11. The method of claim 10 wherein the calibration material comprises human bodily fluid.

12. The method of claim 10 or claim 11 wherein the calibrator material does not comprise any blood products selected from the group consisting of serum, whole blood and plasma.

13. The method of any one of claims 10 to 12 wherein the calibrator material comprises a drainage fluid, exudate or transudate.

14. The method of any one of claims 10 to 13 wherein the calibrator material comprises bodily fluid collected from one or more subjects with cancer.

15. The method of any one of claims 10 to 14 wherein the calibration material comprises bodily fluid collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated.

16. The method of claim 15 wherein the calibration material comprises pleural fluid collected from one or more subjects with cancer.

17. The method of claim 4 wherein the calibration material comprises ascites fluid collected from one or more subjects with cancer.

18. The method of any one of claims 11 to 17 wherein the calibration material comprises human bodily fluid which is known to contain native human autoantibodies which are immunologically specific for a tumour marker protein.

19. The method of any one of claims 10 to 18 wherein the antigen of part (a) is used at a concentration greater than 20nM.

20. The method of claim 19 wherein the antigen of part (a) is used at a concentration in the range of from 20nM to 180nM.

21. The method of claim 19 wherein the antigen of part (a) is used at a concentration in the range of from 50nM to 160nM.

22. A set of calibration standards for use in calibrating an immunoassay for detection of autoantibodies, wherein each calibration standard in said set comprises a different dilution of a mammalian bodily fluid, said mammalian bodily fluid being known to contain native human autoantibodies.

23. A set of calibration standards as claimed in claim 22 wherein said mammalian bodily fluid is a human bodily fluid.

24. A set of calibration standards as claimed in claim 22 or claim 23 wherein the mammalian bodily fluid does not comprise any blood products selected from the group consisting of serum, whole blood and plasma.

25. A set of calibration standards as claimed in any one of claims 22 to 24 wherein the mammalian bodily fluid is a drainage fluid, exudate or transudate.

26. A set of calibration standards as claimed in any one of claims 22 to 25 wherein the mammalian bodily fluid is fluid collected from one or more subjects with cancer.

27. A set of calibration standards as claimed in any one of claims 22 to 26 wherein the mammalian bodily fluid is bodily fluid collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated.

28. A set of calibration standards as claimed in claim 27 wherein the mammalian bodily fluid comprises pleural fluid collected from one or more subjects with cancer.

29. A set of calibration standards as claimed in claim 27 wherein the mammalian bodily fluid comprises ascites fluid collected from one or more subjects with cancer.

30. A set of calibration standards as claimed in any one of claims 22 to 29 wherein the mammalian bodily fluid is human bodily fluid which is known to contain native human autoantibodies immunologically specific for a tumour marker protein.

31. An immunoassay kit for detection of autoantibodies, said kit comprising a set of calibration standards according to any one of claims 22 to 30 and an immunoassay reagent comprising an antigen immunologically specific for said autoantibodies.

32. Use according to any one of claims 1 to 4 wherein the immunoassay is for detection of autoantibodies to benign autoimmune disease.

CLAIMS

1. Use of a calibrator material comprising mammalian bodily fluid to calibrate an immunoassay for detection of autoantibodies, wherein said calibrator material comprises a drainage fluid, exudate or transudate.

2. Use according to claim 1 wherein the calibrator material
a) comprises human bodily fluid, or
b) comprises bodily fluid collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated.

3. Use according to claim 2 wherein the calibration material comprises
a) pleural fluid collected from one or more subjects with cancer, or
b) ascites fluid collected from one or more subjects with cancer.

4. Use according to any one of claims 1 to 3 wherein the immunoassay is for
a) detection of autoantibodies to cancer, or
b) for detection of autoantibodies to early neoplastic change.

5. A method of calibrating an immunoassay for detection of autoantibodies which comprises:
(a) contacting each of a plurality of different dilutions of a calibration material comprising a mammalian bodily fluid with an antigen specific for an autoantibody, wherein said mammalian bodily fluid is known to contain autoantibodies immunologically specific for the antigen and wherein said calibrator material comprises a drainage fluid, exudate or transudate;
(b) detecting the amount of specific binding between said antigen and autoantibody present in the calibration material; and
(c) plotting or calculating a curve of the amount of said specific binding versus the dilution of the calibration material for each dilution of calibration material used in step (a), thereby calibrating an immunoassay using said antigen for detection of said autoantibody.

6. The method of claim 5 wherein the calibration material

a) comprises human bodily fluid,

b) comprises bodily fluid collected from one or more subjects with cancer, or

c) comprises bodily fluid collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated.

7. The method of claim 6 wherein the calibration material comprises

a) pleural fluid collected from one or more subjects with cancer, or

b) ascites fluid collected from one or more subjects with cancer.

8. The method of any one of claims 5 to 7 wherein the calibration material comprises human bodily fluid which is known to contain native human autoantibodies which are immunologically specific for a tumour marker protein.

9. The method of any one of claims 5 to 8 wherein the antigen of part (a) is used at a concentration

a) greater than 20nM,

b) in the range of from 20nM to 180nM, or

c) in the range of from 50nM to 160nM.

10. An immunoassay kit for detection of autoantibodies, said kit comprising a set of calibration standards for use in calibrating an immunoassay for detection of autoantibodies, wherein each calibration standard in said set comprises a different dilution of a mammalian bodily fluid, said mammalian bodily fluid being known to contain native human autoantibodies, and wherein the mammalian bodily fluid is a drainage fluid, exudate or transudate and an immunoassay reagent comprising an antigen immunologically specific for said autoantibodies.

11. An immunoassay kit as claimed in claim 10 wherein said mammalian bodily fluid

a) is a human bodily fluid,

b) is a fluid collected from one or more subjects with cancer, or

c) is bodily fluid collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated.

12. An immunoassay kit as claimed in claim 11 wherein the mammalian bodily fluid comprises

a) pleural fluid collected from one or more subjects with cancer, or

b) ascites fluid collected from one or more subjects with cancer.

13. An immunoassay kit as claimed in any one of claims 10 to 12 wherein the mammalian bodily fluid is human bodily fluid which is known to contain native human autoantibodies immunologically specific for a tumour marker protein.

14. Use according to claim 1 or 2 wherein the immunoassay is for detection of autoantibodies to benign autoimmune disease.