Claims:

1. A method for diagnosing Alzheimer's disease (AD) wherein Aβ-specific antibodies in a biological sample of a person that is suspected of having AD are detected comprising the following steps:
- contacting the sample with Aβ-aggregates or with particles having Aβ-aggregate like surfaces and allowing the Aβ-specific antibodies to bind to the Aβ-aggregates, and
- detecting the Aβ-specific antibodies bound to the Aβ-aggregates by a single particle detection technique, preferably by fluorescence activated cell sorting (FACS);
and wherein the amount of Aβ-specific antibodies detected is compared with the amount in a sample of known AD status.

2. Method according to claim 1 characterised in that the Aβ-specific antibodies are human antibodies, preferably human IgG or IgM antibodies, especially human IgG antibodies.

3. Method according to claim 1 or 2, characterised in that the Aβ-specific antibodies are autoantibodies.

4. Method according to any one of claims 1 to 3, characterised in that the Aβ-aggregates have a size of 50 nm to 15 µm, preferably from 100 nm to 10 µm, especially from 200 nm to 5 µm.

5. Method according to any one of claims 1 to 4, characterised in that the Aβ-aggregates have been prepared by incubating Aβ-1-42 peptides, Aβ-1-43 peptides, Aβ-3-42, or Aβ-p(E)3-42 peptides at a pH of 2 to 9 for at least 20 min, preferably at least 1 h, especially at least 4 h.

6. Method according to any one of claims 1 to 5, characterised in that the Aβ-aggregates are present for contacting the sample with Aβ-aggregates in an amount of 0.001 to 1 µM, preferably 0.01 to 0.1 µM.

7. Method according to any one of claims 1 to 6, characterised in that the biological sample is human blood or a sample derived from human blood, preferably human serum or human plasma; human

cerebrospinal fluid or human lymph.

8. Method according to any one of claims 1 to 7, characterised in that the Aβ-aggregates are contacted with the sample for at least 10 min, preferably from 10 min to 24 h, especially from 20 min to 2 h.

9. Method according to any one of claims 1 to 8, characterised in thata demasking step is performed on the Aβ-specific antibodies in the sample before contacting the sample with Aβ-aggregates, especially if IgM antibodies are detected.

10. Method according to any one of claims 1 to 9, characterised in that the particles having Aβ-aggregate like surfaces are beads with Aβ-aggregates immobilised on their surface, especially magnetic beads.

11. Method according to any one of claims 1 to 10, wherein the sample of known AD status is a sample of a patient with AD or a sample of a healthy person.

12. Method according to any one of claims 1 to 10, wherein the sample of known AD status is an AD status calibration curve, especially a Mini-Mental State examination (MMSE) curve.

13. Method according to any one of claims 1 to 12, wherein the detection of an amount of Aβ-specific antibodies in the sample which is lower than a threshold level is indicative of AD, wherein the threshold level is 1500 ng/ml or lower, preferably 1000 ng/ml or lower, especially 750 ng/ml or lower.

14. Method according to any one of claims 1 to 13, wherein the detected amount of Aβ-specific antibodies is correlated to a MMSE result of the same person at the same time the sample was taken from the person.

15. Method according to any one of claims 1 to 14, wherein the method is performed at least twice on samples of the same person taken at a different time and wherein preferably the detected amounts of Aβ-specific antibodies is correlated to MMSE results

of the same person at the same times the samples were taken from the person.

16. Method according to claim 15, wherein the method is performed at least once each six months, preferably at least once each three months, especially at least once each month.

17. Use of a method according to any one of claims 1 to 16 for the monitoring of AD patients, especially AD patients which are treated with medicaments for curing or ameliorating AD.

18. Use of a method according to any one of claims 1 to 16 for evaluating the risk of developing AD or for detecting early stage AD.

19. Use of a method according to any one of claims 1 to 16 for the diagnosis of Parkinson's dementia (PDD), Dementia with Lewy Bodies (DLB), Cerebral Amyloid Angiopathy (CAA), Inclusion body myositis (IBM), or chronic head trauma.

20. Kit for performing the method according to any one of claims 1 to 16 comprising

- Aβ-aggregates, and
- a sample container.

Claims:

1. A method for diagnosing Alzheimer's disease (AD) wherein Aβ-specific antibodies in a biological sample of a person that is suspected of having AD are detected comprising the following steps:
- contacting the sample with Aβ-aggregates or with particles having Aβ-aggregate like surfaces and allowing the Aβ-specific antibodies to bind to the Aβ-aggregates; and
- detecting the Aβ-specific antibodies bound to the Aβ-aggregates by a single particle detection technique;
and wherein the amount of Aβ-specific antibodies detected is compared with the amount in a sample of known AD status.

2. Method according to claim 1 characterised in that the single particle detection technique is fluorescence activated cell sorting (FACS).

3. Method according to claim 1 or claim 2, characterised in that the Aβ-specific antibodies are human antibodies, preferably human IgG or IgM antibodies, especially human IgG antibodies.

4. Method according to any one of claims 1 to 3, characterised in that the Aβ-specific antibodies are autoantibodies.

5. Method according to any one of claims 1 to 4, characterised in that the Aβ-aggregates have a size of 50 nm to 15 µm, preferably from 100 nm to 10 µm, especially from 200 nm to 5 µm.

6. Method according to any one of claims 1 to 5, characterised in that the Aβ-aggregates have been prepared by incubating Aβ-1-42 peptides, Aβ-1-43 peptides, Aβ-3-42, or Aβ-p(E)3-42 peptides at a pH of 2 to 9 for at least 20 min, preferably at least 1 h, especially at least 4 h.

7. Method according to any one of claims 1 to 6, characterised in that the Aβ-aggregates are present for contacting the sample with Aβ-aggregates in an amount of 0.001 to 1 µM, preferably 0.01 to 0.1 µM.

8. Method according to any one of claims 1 to 7, characterised in that the biological sample is human blood or a sample derived from human blood, preferably human serum or human plasma; human cerebrospinal fluid or human lymph.

9. Method according to any one of claims 1 to 8, characterised in that the Aβ-aggregates are contacted with the sample for at least 10 min, preferably from 10 min to 24 h, especially from 20 min to 2 h.

10. Method according to any one of claims 1 to 9, characterised in thata demasking step is performed on the Aβ-specific antibodies in the sample before contacting the sample with Aβ-aggregates, especially if IgM antibodies are detected.

11. Method according to any one of claims 1 to 10, characterised in that the particles having Aβ-aggregate like surfaces are beads with Aβ-aggregates immobilised on their surface, especially magnetic beads.

12. Method according to any one of claims 1 to 11, wherein the sample of known AD status is a sample of a patient with AD or a sample of a healthy person.

13. Method according to any one of claims 1 to 11, wherein the sample of known AD status is an AD status calibration curve, especially a Mini-Mental State examination (MMSE) curve.

14. Method according to any one of claims 1 to 13, wherein the detection of an amount of Aβ-specific antibodies in the sample which is lower than a threshold level is indicative of AD, wherein the threshold level is 1500 ng/ml or lower, preferably 1000 ng/ml or lower, especially 750 ng/ml or lower.

15. Method according to any one of claims 1 to 14, wherein the detected amount of Aβ-specific antibodies is correlated to a MMSE result of the same person at the same time the sample was taken from the person.

16. Method according to any one of claims 1 to 15, wherein the

method is performed at least twice on samples of the same person taken at a different time and wherein preferably the detected amounts of Aβ-specific antibodies is correlated to MMSE results of the same person at the same times the samples were taken from the person.

17. Method according to claim 16, wherein the method is performed at least once each six months, preferably at least once each three months, especially at least once each month.

18. Use of a method according to any one of claims 1 to 17, for the monitoring of AD patients, especially AD patients which are treated with medicaments for curing or ameliorating AD.

19. Use of a method according to any one of claims 1 to 17, for evaluating the risk of developing AD or for detecting early stage AD.

20. Use of a method according to any one of claims 1 to 17, for the diagnosis of Parkinson's dementia (PDD), Dementia with Lewy Bodies (DLB), Cerebral Amyloid Angiopathy (CAA), Inclusion body myositis (IBM), or chronic head trauma.