CLAIMS

1. A method for diagnosing Alzheimer's Disease (AD), Neurodegeneration in Down's Syndrome (NDS) or Mild Cognitive Impairment (MCI) in a subject, the method comprising:

(a) detecting the amount of glutaminyl cyclase (QC), or an isoform thereof, in a biological sample obtained from said subject; and

(b) comparing the detected amount of QC in the biological sample with an amount of QC characteristic of a normal control;

whereby an elevated amount of QC in said biological sample relative to the normal control is a positive indicator of AD, NDS or MCI .

2. The method of claim 1, comprising:

(a) detecting the amount of glutaminyl cyclase (QC), or an isoform thereof, in a biological sample obtained from said subject; and

(b) further detecting the amount of Aβ N3pE-X,

(c) comparing the detected amount of QC and Aβ N3pE-X in the biological sample with an amount of QC and Aβ N3pE-X characteristic of a normal control;

whereby an elevated amount of QC and Aβ N3pE-X in said biological sample relative to the normal control is a positive indicator of AD, NDS or MCI, and

wherein X is an integer selected from 38, 40 and 42.

3. The method according to any of the preceding claims, wherein said biological sample is serum, plasma, urine or cerebrospinal fluid.

4. The method according to any of the preceding claims, wherein the amount of QC is detected by immunoturbidimetric assay, immunofluorescence, immunodiffusion, enzyme-linked immunosorbent assay (ELISA), radioimmunoassay (RIA), Western blot, protein activity assay, Northern Blot, PCR, high performance liquid chromatography (HPLC) , mass spectrometry (MS), gas chromatography (GC), GC-MS, LC-MS, or LC-MS/MS.

5. The method according to any one of the preceding claims, wherein the amount of QC, or an isoform thereof, is detected on the basis of the protein level or the mRNA level of said QC or isoform thereof.

6. The method according to any of the preceding claims, wherein the amount of QC is detected using an antibody that specifically binds to QC, or an isoform thereof.

7. The method according to any of the preceding claims, wherein the amount of QC is detected by measuring the enzymatic activity of QC, or an isoform thereof.

8. The method according to any one of the preceding claims, wherein not only a single form of the N-terminally truncated and pyroglutamated amyloid beta peptides but a combination of Aβ N3pE-42 and/or Aβ N3pE-40 and/or Aβ N3pE-38, and pGluABri and/or pGluADan is detected together with QC.

9. The method according to any one of the preceding claims, comprising:

(a) contacting said biological sample with an antibody that binds to glutaminyl cyclase (QC), or its isoforms ;

(b) allowing the antibody and QC to form an immune complex; and

(c) detecting the amount of immune complex formed as an indication of the amount of QC in said biological sample; and

(d) comparing the detected amount to a sample from normal control subject; whereby a detected amount that is elevated relative to the normal control is a positive indicator of a neurodegenerative disease.