Summary

Therefore, the present invention, as defined in the claims attached, provides for new biomarkers (i.e. a new biomarker set) suitable for assessing HIV infection, particularly at an early stage of disease. Moreover, the present disclosure also describes a method for assessing HIV in a mammalian subject, as well as a kit adapted to carry out the method.

In one aspect, the present invention refers to use of a combination of metabolites contained in a blood sample, comprising at least one acylcarnitine (AC) and at least one sphingomyelin (SM) as a biomarker set for screening and/or diagnosing HIV infection. In another aspect, the present invention refers to a method for screening and/or diagnosing HIV infection in a mammalian subject, the method comprising measuring in a blood sample obtained from the subject the amount of at least one acylcarnitine (AC) and at least one sphingomyelin (SM).

In a first example, the disclosure is directed to the use of a combination of metabolites contained in a blood sample, comprising at least one acylcarnitine (AC) and at least one sphingomyelin (SM) as a biomarker set for screening and/or diagnosing HIV.

In a further example, the disclosure is directed to the use of a combination of metabolites contained in a blood sample, comprising at least one phosphatidylcholine comprising at least one acyl-alkyl group in the molecule (PC ae), and at least two amino acids as a biomarker set for prediction of immunologic response of a mammalian subject to antiretroviral therapy and/or prognosis of HIV disease progression.

In a further example, the disclosure is directed to the use of a combination of metabolites contained in a blood sample, comprising at least the ratio of total amount of arachidonic polyunsaturated etherlipids to total amount of monounsaturated fatty acid ether lipids and the ratio of total amount of monounsaturated fatty acid ether lipids to total amount of saturated fatty acids as a biomarker set for monitoring of HIV activity in a mammalian subject.

In a further example, the present disclosure describes a method for screening and/or diagnosing HIV in a mammalian subject, the method comprising measuring in a blood sample obtained from the subject the amount of at least one acylcarnitine (AC) and at least one sphingomyelin (SM).

In a further example, the present disclosure describes a method for prediction of immunologic response of a mammalian subject to antiretroviral therapy and/or prognosis of disease progression, the method comprising measuring in a blood sample

Claims

1. Use of a combination of metabolites contained in a blood sample, comprising at least one acylcarnitine (AC) and at least one sphingomyelin (SM) as a biomarker set for screening and/or diagnosing HIV infection.

2. A method for screening and/or diagnosing HIV infection in a mammalian subject, the method comprising measuring in a blood sample obtained from the subject the amount of at least one acylcarnitine (AC) and at least one sphingomyelin (SM).

3. The method of claim 2, wherein the at least one acylcarnitine is selected from those included in Table 2 of the specification and/or the at least one sphingomyelin is selected from those included in Table 4 of the specification, respectively.

4. The method of claim 2 or 3, wherein the at least one acylcarnitine is selected from glutaconylcarnitine, methylglutarylcarnitine, octanoylcarnitine, decanoylcarnitine, and dodecanoylcarnitine.

5. The method of any one of claims 2 to 4, further comprising measuring at least one biogenic amine and/or at least one phosphatidylcholine.

6. The method of anyone of claims 2 to 5, wherein measuring the amount of at least one sphingomyelin comprises measuring the ratio of amount of hydroxysphingomyelin with acyl residue sum of C24:1 (SM(OH) C24:1) to the amount of sphingomyelin with acyl residue sum of C16:0 (SM C16:0).

7. The method according to any one of claims 2 to 6, wherein the measurement is based on a quantitative analytical method, preferably chromatography, spectroscopy, and mass spectrometry.

8. The method according to claim 7, wherein chromatography comprises GC, CE, LC, HPLC, and UHPLC; spectroscopy comprises UV/Vis, IR, and NMR; and mass analyzers/spectrometry comprises ESI or APCI-QqQ, ESI or APCI-QqTOF, MALDI-QqQ, MALDI-QqTOF, and MALDI-TOF-TOF.

9. The method according to claim 8, wherein mass analyzers/spectrometry comprises Quadrupole Mass Analyzer, Ion Trap Mass Analyzers, TOF (Time of Flight)

Mass Analyzer, Orbitrap mass analyser, Magnetic Sector Mass Analyzer, Electrostatic Sector Mass Analyzer, Ion Cyclotron Resonance (ICR) and combinations of mass analyzers, including single quadrupole (Q) and triple quadrupole (QqQ), QqTOF, TOF-TOF, Q-Orbitrap.