

CLAIMS

1. A method of determining whether a subject suffers from, or is at risk of developing lung cancer, wherein the method comprises detecting the expression level of at least three miRNAs from a biological sample obtained from the subject, wherein the at least three miRNAs are selected from hsa-miR-1280, hsa-miR-487b-3p, hsa-miR-199b-5p, hsa-miR-205-5p, hsa-miR-16-5p, hsa-miR-320a-3p, hsa-miR-23b-3p, hsa-miR-181c-5p, hsa-miR-92a-3p, hsa-miR-210-3p, hsa-miR-342-3p, and hsa-miR-877-5p.
2. The method of Claim 1, wherein the method comprises detecting at least four, at least five, at least six, at least seven, at least eight, at least nine, at least ten, at least eleven or at least twelve miRNAs.
3. The method of Claim 1 or Claim 2, wherein the method comprises detecting the expression level of hsa-miR-1280, hsa-miR-487b-3p, hsa-miR-199b-5p, hsa-miR-205-5p, hsa-miR-16-5p, hsa-miR-320a-3p, hsa-miR-23b-3p, hsa-miR-181c-5p, hsa-miR-92a-3p, hsa-miR-210-3p, hsa-miR-342-3p, and hsa-miR-877-5p.
4. The method of any one of the preceding claims, wherein differential expression levels of the three or more miRNAs, as compared to a control, is indicative of the subject having or is at risk of developing lung cancer.
5. The method of any one of the preceding claims, the method comprising:
 - a. contacting a biological sample obtained from the subject with an isolated set of probes suitable for detecting three or more miRNAs selected from hsa-miR-1280, hsa-miR-487b-3p, hsa-miR-199b-5p, hsa-miR-205-5p, hsa-miR-16-5p, hsa-miR-320a-3p, hsa-miR-23b-3p, hsa-miR-181c-5p, hsa-miR-92a-3p, hsa-miR-210-3p, hsa-miR-342-3p, and hsa-miR-877-5p;
 - b. comparing the expression level of the three or more miRNAs in the biological sample with the level of the same miRNA in a control;
 - c. determining if said subject is suffering from or is at risk of developing lung cancer by the differential expression of the three or more miRNAs compared to the control.
6. The method of any of the preceding claims, wherein the method further comprises detecting the expression level of at least one additional biomarker from the biological sample obtained from the subject

, optionally wherein the additional biomarker is one or more biomarker selected from the group consisting of carcinoembryonic antigen (CEA), neuron-specific enolase (NSE), cancer antigen 125 (CA-125), and cytokeratin 19 fragment antigen (CYFRA 21-1).

7. The method of any one of the preceding claims, wherein the biological sample is a non-cellular biological fluid,

optionally wherein the non-cellular biological fluid is plasma and/or serum.

8. The method of any one of the preceding claims, wherein the control comprises one or more biological samples obtained from a healthy subject, a non-diseased subject, a cancer-free subject, a lung cancer-free subject, and/or a subject not suffering from, or not at risk of developing lung cancer.

9. The method of any of the preceding claims, the method further comprising an imaging test, a sputum cytology, a biopsy, or a combination thereof.

10. Use of an anti-cancer compound in the manufacture of a medicament for treating a subject suffering from lung cancer comprising:

a. determining whether a subject suffers from, or is at risk of developing lung cancer using the method of any one of Claims 1 to 11; and

b. wherein the treatment further comprises one or more therapy selected from the group consisting of surgery, and/or radiation therapy.

11. The method / use of any of the preceding claims, wherein the at least three miRNAs are detected by one or more method selected from the group consisting of sequencing, nucleic acid hybridisation, microarray, and nucleic acid amplification.

12. A kit for determining whether a subject suffers from, or is at risk of developing lung cancer, the kit comprising an isolated set of probes and/or reagents capable of detecting three or more miRNAs selected from hsa-miR-1280, hsa-miR-487b-3p, hsa-miR-199b-5p, hsa-miR-205-5p, hsa-miR-16-5p, hsa-miR-320a-3p, hsa-miR-23b-3p, hsa-miR-181c-5p, hsa-miR-92a-3p, hsa-miR-210-3p, hsa-miR-342-3p, and hsa-miR-877-5p.

13. The kit of Claim 14, wherein the isolated set of probes and/or reagents is capable of detecting hsa-miR-1280, hsa-miR-487b-3p, hsa-miR-199b-5p, hsa-miR-205-5p, hsa-miR-16-5p, hsa-miR-320a-3p, hsa-miR-23b-3p, hsa-miR-181c-5p, hsa-miR-92a-3p, hsa-miR-210-3p, hsa-miR-342-3p, and hsa-miR-877-5p, wherein the probe is selected from the group consisting of an aptamer, an antibody, an affibody, a peptide, and a nucleic acid.
14. The kit of any one of Claims 14 to 16, wherein the at least three miRNAs are detected by one or more method selected from the group consisting of sequencing, nucleic acid hybridisation, microarray, and nucleic acid amplification.
15. The kit of any one of Claims 14 to 17, wherein the kit further comprises probes and/or reagents for detecting at least one additional biomarker, wherein the biomarker is one or more selected from carcinoembryonic antigen (CEA), neuron-specific enolase (NSE), cancer antigen 125 (CA-125) and cytokeratin 19 fragment antigen (CYFRA 21-1).