

What is claimed is:

1. A method for the diagnosis of non-small cell lung cancer (NSCLC) in a subject, the method comprising the steps of:
 - (a) detecting the expression level of at least one EML4-ALK fusion transcript in nucleic acids extracted from at least one microvesicle isolated from a biological sample from the subject,
 wherein the EML4-ALK fusion transcript is selected from the group consisting of EML4-ALK v1, EML4-ALK v2, EML4-ALK v3a, EML4-ALK v3b, EML4-ALK v3c; and
 - (b) identifying the presence of NSCLC in the subject if:
 - the detected cycle threshold (CT) value of EML4-ALK v1 is less than or equal to 31,
 - the detected CT value of EML4-ALK v2 is less than or equal to 32,
 - the detected CT value of EML4-ALK v3a is less than or equal to 32,
 - the detected CT value of EML4-ALK v3b is less than or equal to 32, or
 - the detected CT value of EML4-ALK v3c is less than or equal to 32,
 - or,
 - identifying the absence of NSCLC in the subject if:
 - the detected CT value of EML4-ALK v1 is greater than 31,
 - the detected CT value of EML4-ALK v2 is greater than 32,
 - the detected CT value of EML4-ALK v3a is greater than 32,
 - the detected CT value of EML4-ALK v3b is greater than 32, or
 - the detected CT value of EML4-ALK v3c is greater than 32.
2. The method of claim 1, wherein the biological sample is a bodily fluid.
3. The method of any one of claims 1 to 2, wherein the biological sample is plasma or serum.
4. The method of any one of claims 1-3, wherein the expression level of the at least one EML4-ALK fusion transcript is detected using qPCR.

5. The method of any one of claims 1 to 3, wherein the extracted nucleic acids comprise exosomal RNA.
6. The method of claim 5, wherein step (a) further comprises reverse transcription of the exosomal RNA.
7. The method of claim 6, wherein a control nucleic acid or control particle or combination thereof is spiked into the reverse transcription reaction.
8. The method of claim 6 or claim 7, wherein step (a) further comprises a pre-amplification step following reverse transcription of the exosomal RNA.
9. The method of claim 8, wherein the pre-amplification step comprises use of a positive amplification control.
10. The method of claim 9, wherein the positive amplification control comprises a reference DNA encoding for EML4-ALK v1, a reference DNA encoding for EML4-ALK v2, a reference DNA encoding for EML4-ALK v3, a reference DNA coding for RPL4, a reference RNA coding Qbeta, or combinations thereof.
11. The method of claim 10, wherein the positive amplification control is quantified using qPCR.
12. The method of any one of claims 8 to 11, wherein the pre-amplification step comprises use of a negative amplification control.
13. The method of claim 12, wherein negative amplification control comprises water instead of a nucleic acid template.
14. The method of any one of claims 1 to 13, wherein step (a) further comprises detecting one or more controls.
15. The method of claim 14, wherein the control is a housekeeping gene.

16. The method of claim 15, wherein the housekeeping gene is RPL4.
17. The method of claim 14, wherein the one or more controls is Qbeta spiked into the extracted nucleic acids.