

Claims

What is claimed is:

1. A method for early diagnosing colorectal cancer in a subject, comprising (a) providing a biological sample from the subject, and (b) determining the methylation status of a target DNA sequence comprising *MROH6* in the biological sample, wherein the presence of hypermethylation in *MROH6* of the subject is indicative of colorectal cancer.

2. The method of claim 1, wherein the target DNA sequence further comprises one or more DNA sequences selected from the group consisting of *TMEM240*, *BEND5* and *SMAD3*, or any of combinations thereof; wherein the presence of hypermethylation in *TMEM240*, hypermethylation in *BEND5*, or hypomethylation in *SMAD3*, of the subject is indicative of colorectal cancer.

3. The method of claim 1, wherein the biological sample is a tissue, cell, blood, urine, serum, plasma, stool, ascites, sputum, saliva, gastric juice, bile, or oral mucosa.

4. The method of claim 2, wherein the method further comprises a step of defining a score as 1 if the presence of hypermethylation or hypomethylation of each gene and, defining a score as 0 if the absence of hypermethylation or hypomethylation of each gene, and summing the score.

5. The method of claim 1, wherein the methylation status is determined by a polymerase chain reaction; a target DNA sequence methylation specific primer for *MROH6* is used in the methylation determination; and the target DNA sequence methylation specific primer for *MROH6* has an identity of about 85% to a sequence selected from the group consisting of SEQ ID NOs: 5, and 6.

6. The method of claim 1, wherein a target DNA sequence methylation specific probe for *MROH6* is used in the methylation determination, and the target DNA sequence methylation specific probe for *MROH6* has an identity of about 85% to a sequence of SEQ ID NO: 7.

7. The method of claim 2, wherein the target DNA sequence comprises any of the following combinations of the DNA sequences: *TMEM240* and *MROH6*; *TMEM240*, *MROH6* and *BEND5*; *TMEM240*, *MROH6*, *BEND5* and *SMAD3*; *TMEM240*, *MROH6*, and *SMAD3*; *MROH6* and *BEND5*; and *MROH6*, *BEND5* and *SMAD3*.

8. The method of claim 2, wherein a target DNA sequence methylation specific primer for *TMEM240*, *BEND5*, or *SMAD3* or a combination thereof is used in the methylation determination, and wherein the target DNA sequence methylation specific primer for *TMEM240* has an identity of about 85% to a sequence selected from the group consisting of SEQ ID NOs: 1, 2, and 3; the

target DNA sequence methylation specific primer for *BEND5* has an identity of about 85% to a sequence selected from the group consisting of SEQ ID NOs: 8 to 11; and the target DNA sequence methylation specific primer for *SMAD3* has an identity of about 85% to a sequence selected from the group consisting of SEQ ID NOs: 14 to 15.

5 9. The method of claim 2, wherein a target DNA sequence methylation specific probe for *TMEM240*, *BEND5*, or *SMAD3* or a combination thereof is used in the methylation determination, and wherein the target DNA sequence methylation specific probe for *TMEM240* has an identity of about 85% to a sequence of SEQ ID NO: 4; the target DNA sequence methylation specific probe for *BEND5* has an identity of about 85% to a sequence selected from the group consisting of SEQ
10 ID NOs: 12 to 13; and the target DNA sequence methylation specific probe for *SMAD3* has an identity of about 85% to a sequence of SEQ ID NO: 16.

10. An isolated nucleic acid molecule having a sequence selected from the group consisting of: SEQ ID Nos: 5 to 7.

15 11. A kit for early diagnosing colorectal cancer in a subject, which comprises a target DNA sequence methylation specific primer pair for detection of a methylation status of a target DNA sequence comprising *MROH6*, wherein the target DNA sequence methylation specific primer pair for *MROH6* comprises SEQ ID NOs: 5 and 6.

20 12. The kit of claim 11, further comprising a target DNA sequence methylation specific probe for detection of a methylation status of a target DNA sequence comprising *MROH6*, wherein the target DNA sequence methylation specific probe for *MROH6* comprises SEQ ID NO: 7

25 13. The kit of claim 11, wherein the target DNA sequence further comprises *TMEM240*, *BEND5*, or *SMAD3*, or any combination thereof, and the kit further comprises one or more target DNA sequence methylation specific primer pairs for detection of a methylation status of *TMEM240*, *BEND5*, or *SMAD3*, or any combination thereof; and wherein the target DNA sequence methylation specific primer pair for *TMEM240* comprises SEQ ID NOs: 1 and 2 or 1 and 3; the target DNA sequence methylation specific primer pair for *BEND5* comprises SEQ ID Nos. 8 and 9 or 10 and 11; and the target DNA sequence methylation specific primer pair for *SMAD3* comprises SEQ ID Nos. 14 and 15.

30 14. The kit of claim 11, wherein the kit further comprises one or more target DNA sequence methylation specific probe for detection of a methylation status of *TMEM240*, *BEND5*, or *SMAD3*, or any combination thereof, and wherein the target DNA sequence methylation specific probe for

TMEM240 comprises SEQ ID NO: 4; the target DNA sequence methylation specific probe for *BEND5* comprises SEQ ID NO: 12 or 13; and the target DNA sequence methylation specific probe for *SMAD3* comprises SEQ ID NO: 16.