

CLAIMS

1. A method of predicting clinical outcome for a human subject diagnosed with colorectal cancer following surgical resection of said cancer, comprising
determining a normalized expression level of an RNA transcript of Ki-67, or an expression product thereof, in a biological sample comprising cancer cells obtained from said human subject, and;
predicting the likelihood of a positive clinical outcome for said human subject based on said normalized expression level, wherein normalized expression of an RNA transcript of Ki-67, or an expression product thereof, is positively correlated with an increased likelihood of a positive clinical outcome.
2. The method of claim 1, wherein said determining comprises determining a normalized expression level of an RNA transcript, or an expression product thereof, of one or more of BGN, FAP, and INHBA in the biological sample;
wherein normalized expression of each of BGN, FAP, and INHBA is negatively correlated with an increased likelihood of a positive clinical outcome.
3. The method of claim 1, wherein said determining comprises determining a normalized expression level of an RNA transcript, or an expression product thereof, of one or both of MYBL2 and cMYC in the biological sample;
wherein normalized expression of MYBL2 and CMYC is positively correlated with an increased likelihood of a positive clinical outcome.
4. The method of claim 1, wherein said determining comprises determining a normalized expression level of an RNA transcript, or an expression product thereof, of GADD45B in the biological sample;
wherein normalized expression of GADD45B is negatively correlated with an increased likelihood of a positive clinical outcome.

5. The method of claim 1, wherein said normalized expression level of an RNA transcript of Ki-67 is determined using a PCR-based method.
6. The method of claim 5, wherein said normalized expression level is normalized relative to the expression level of an RNA transcript of at least one-reference gene.
7. The method of any of claims 2, 3, and 4, wherein said normalized expression level is normalized relative to the expression level of an RNA transcript of at least one-reference gene.
8. The method of claim 7, wherein said normalized expression level is normalized relative to the expression level of an RNA transcript of at least one-reference gene
9. The method of claim 1, wherein said clinical outcome is expressed in terms of Recurrence-Free Interval (RFI), Overall Survival (OS), Disease-Free Survival (DFS), or Distant Recurrence-Free Interval (DRFI).
10. The method of claim 1, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colorectal cancer.
11. The method of claim 1, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colon cancer.
12. The method of claim 1, further comprising the step of creating a report summarizing said prediction.

13. A method of predicting in a human subject diagnosed with Dukes B (stage II) or Dukes C (stage III) colorectal cancer a likelihood of recurrence of colorectal cancer following surgical resection of said cancer, comprising:

determining the normalized expression level of an RNA transcript of Ki-67 in a biological sample comprising cancer cells obtained from said human subject, and;

predicting the likelihood of recurrence of colorectal cancer for the human subject based on the normalized expression level, wherein normalized expression of an RNA transcript of Ki-67 is positively correlated with decreased likelihood of recurrence of colorectal cancer.

14. The method of claim 13, wherein said determining comprises determining a normalized expression level of an RNA transcript of one or more of BGN, FAP, and INHBA in the biological sample;

wherein normalized expression of each of BGN, FAP, and INHBA is negatively correlated with a decreased likelihood of recurrence of colorectal cancer.

15. The method of claim 13, wherein said determining comprises determining a normalized expression level of an RNA transcript of one or both of MYBL2 and cMYC in the biological sample;

wherein normalized expression of MYBL2 and CMYC is positively correlated with a decreased likelihood of recurrence of colorectal cancer.

16. The method of claim 13, wherein said determining comprises determining a normalized expression level of an RNA transcript of GADD45B in the biological sample;

wherein normalized expression of GADD45B is negatively correlated with a decreased likelihood of recurrence of colorectal cancer.

17. The method of claim 13, wherein said normalized expression level is determined using a PCR-based method.

18. The method of any of claims 14, 15 and 16, wherein said normalized expression level is determined using a PCR-based method.
19. The method of claim 13, wherein, if said likelihood of recurrence of colorectal cancer is increased, said patient is subjected to further therapy following said surgical resection.
20. The method of claim 13, wherein said further therapy is chemotherapy and/or radiation therapy.
21. The method of claim 13, further comprising the step of creating a report summarizing said prediction.
22. The method of claim 13, wherein said normalized expression level is normalized relative to the expression level of an RNA transcript of at least one reference gene.
23. A report comprising:
information regarding a prediction of a clinical outcome for a human subject diagnosed with colorectal cancer following surgical resection of said cancer, wherein said prediction of clinical outcome is based on information comprising the normalized expression level of an RNA transcript of Ki-67, or an expression product thereof, in a biological sample comprising cancer cells obtained from said human subject, wherein evidence of increased normalized expression of an RNA transcript of Ki-67, or an expression product thereof, indicates a increased likelihood of a positive clinical outcome.
24. The report of claim 23, wherein said clinical outcome is expressed in terms of Recurrence-Free Interval (RFI), Overall Survival (OS), Disease-Free Survival (DFS), or Distant Recurrence-Free Interval (DRFI).

25. The report of claim 23, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colorectal cancer.
26. The report of claim 23, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colon cancer.

CLAIMS

1. A method of predicting clinical outcome for a human subject diagnosed with colorectal cancer following surgical resection of said cancer, comprising
determining a normalized expression level of an RNA transcript of Ki-67, or an expression product thereof, in a biological sample comprising cancer cells obtained from said human subject, and;
predicting the likelihood of a positive clinical outcome for said human subject based on said normalized expression level, wherein normalized expression of an RNA transcript of Ki-67, or an expression product thereof, is positively correlated with an increased likelihood of a positive clinical outcome.
2. The method of claim 1, wherein said determining comprises determining a normalized expression level of an RNA transcript, or an expression product thereof, of one or more of BGN, FAP, and INHBA in the biological sample;
wherein normalized expression of each of BGN, FAP, and INHBA is negatively correlated with an increased likelihood of a positive clinical outcome.
3. The method of claim 1, wherein said determining comprises determining a normalized expression level of an RNA transcript, or an expression product thereof, of one or both of MYBL2 and cMYC in the biological sample;
wherein normalized expression of MYBL2 and CMYC is positively correlated with an increased likelihood of a positive clinical outcome.
4. The method of claim 1, wherein said determining comprises determining a normalized expression level of an RNA transcript, or an expression product thereof, of GADD45B in the biological sample;
wherein normalized expression of GADD45B is negatively correlated with an increased likelihood of a positive clinical outcome.
5. The method of claim 1, wherein said normalized expression level of an RNA transcript of Ki-67 is determined using a PCR-based method.

6. The method of claim 5, wherein said normalized expression level is normalized relative to the expression level of an RNA transcript of at least one-reference gene.
7. The method of any of claims 2, 3, and 4, wherein said normalized expression level of an RNA transcript of one or more of BGN, FAP, INHBA, MYBL2, CMYC, and GADD45B is determined using a PCR-based method and wherein said normalized expression level is normalized relative to the expression level of an RNA transcript of at least one-reference gene.
8. The method of claim 1, wherein said method comprises determining a normalized expression level of an expression product of an RNA transcript of Ki-67, and wherein said normalized expression level of an expression product of an RNA transcript of Ki-67 is normalized relative to the expression level of an expression product of an RNA transcript of at least one reference gene.
9. The method of claim 1, wherein said clinical outcome is expressed in terms of Recurrence-Free Interval (RFI), Overall Survival (OS), Disease-Free Survival (DFS), or Distant Recurrence-Free Interval (DRFI).
10. The method of claim 1, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colorectal cancer.
11. The method of claim 1, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colon cancer.
12. The method of claim 1, further comprising the step of creating a report summarizing said prediction.
13. A method of predicting in a human subject diagnosed with Dukes B (stage II) or Dukes C (stage III) colorectal cancer a likelihood of recurrence of colorectal cancer following surgical resection of said cancer, comprising:

determining the normalized expression level of an RNA transcript of Ki-67 in a biological sample comprising cancer cells obtained from said human subject, and;

predicting the likelihood of recurrence of colorectal cancer for the human subject based on the normalized expression level, wherein normalized expression of an RNA transcript of Ki-67 is positively correlated with decreased likelihood of recurrence of colorectal cancer.

14. The method of claim 13, wherein said determining comprises determining a normalized expression level of an RNA transcript of one or more of BGN, FAP, and INHBA in the biological sample;

wherein normalized expression of each of BGN, FAP, and INHBA is negatively correlated with a decreased likelihood of recurrence of colorectal cancer.

15. The method of claim 13, wherein said determining comprises determining a normalized expression level of an RNA transcript of one or both of MYBL2 and cMYC in the biological sample;

wherein normalized expression of MYBL2 and CMYC is positively correlated with a decreased likelihood of recurrence of colorectal cancer.

16. The method of claim 13, wherein said determining comprises determining a normalized expression level of an RNA transcript of GADD45B in the biological sample;

wherein normalized expression of GADD45B is negatively correlated with a decreased likelihood of recurrence of colorectal cancer.

17. The method of claim 13, wherein said normalized expression level is determined using a PCR-based method.

18. The method of any of claims 14, 15 and 16, wherein said normalized expression level is determined using a PCR-based method.

19. The method of claim 13, wherein, if said likelihood of recurrence of colorectal cancer is increased, said patient is subjected to further therapy following said surgical resection.
20. The method of claim 13, wherein said further therapy is chemotherapy and/or radiation therapy.
21. The method of claim 13, further comprising the step of creating a report summarizing said prediction.
22. The method of claim 13, wherein said normalized expression level is normalized relative to the expression level of an RNA transcript of at least one reference gene.
23. A report comprising:
information regarding a prediction of a clinical outcome for a human subject diagnosed with colorectal cancer following surgical resection of said cancer, wherein said prediction of clinical outcome is based on information comprising the normalized expression level of an RNA transcript of Ki-67, or an expression product thereof, in a biological sample comprising cancer cells obtained from said human subject, wherein evidence of increased normalized expression of an RNA transcript of Ki-67, or an expression product thereof, indicates an increased likelihood of a positive clinical outcome.
24. The report of claim 23, wherein said clinical outcome is expressed in terms of Recurrence-Free Interval (RFI), Overall Survival (OS), Disease-Free Survival (DFS), or Distant Recurrence-Free Interval (DRFI).
25. The report of claim 23, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colorectal cancer.
26. The report of claim 23, wherein said colorectal cancer is Dukes B (stage II) or Dukes C (stage III) colon cancer.