PLASMA MICRORNAS FOR THE DETECTION OF EARLY COLORECTAL CANCER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Ser. No. 61/550,148, filed Oct. 21, 2011, the entire contents of which are incorporated herein by reference.

TECHNICAL FIELD OF THE INVENTION

[0002] The present invention relates in general to the field of colorectal cancer detection, and more particularly, to plasma microRNAs for the detection of early colorectal cancer.

STATEMENT OF FEDERALLY FUNDED RESEARCH

[0003] None.

INCORPORATION-BY-REFERENCE OF MATERIALS FILED ON COMPACT DISC

[0004] None.

BACKGROUND OF THE INVENTION

[0005] Without limiting the scope of the invention, its background is described in connection with colorectal cancers.

[0006] U.S. Patent Application No. 20100317533 (Lou et al. 2010) provides a panel of biomarkers of tumor metastasis comprising any two of carbonic anhydrase-9 (CAIX), vascular endothelial growth factor C (VEGF-C), ephrin A5 (EFNA5), eph receptor B2 (EPHB2), transforming growth factor beta 3 (TGF-β3), pyruvate dehydrogenase kinase isoenzyme-3 (PDK3), carbonic anhydrase-12 (CAXII), keratin 14 (KRT14), hypoxia inducible factor 1 alpha subunit (HIF-1α), or tenascin C (TNC). CAIX, VEGF-C, EFNA5, EPHB2, TGF-β3 or PDK3 may be indicators of moderate metastatic potential, while CAXII, KRT14, HIF-1α, or TNC may be indicators of high metastatic potential. There is also provided a method of determining risk of tumor metastasis using the aforementioned biomarkers is also provided. The biomarkers may be used in diagnosis, prognosis, treatment selection, or to test putative therapeutics. The biomarkers may be used to assess malignancies or cancers having hypoxic regions, such as breast cancer.

[0007] U.S. Patent Application No. 20100120898 (Croce et al. 2010) discloses methods and compositions for the diagnosis, prognosis and treatment of Hepatocellular carcinoma (HCC). Also provided are methods of identifying anti-HCC agents. The Croce application provides a method diagnosing whether a subject has, or is at risk for developing, hepatocellular carcinoma (HCC), comprising measuring the level of at least one miR gene product in a test sample from the subject, wherein an alteration in the level of the miR gene product in the test sample, relative to the level of a corresponding miR gene product in a control sample, is indicative of the subject either having, or being at risk for developing, HCC.

[0008] U.S. Pat. No. 7,939,255, issued to Chung is directed to diagnostic methods for colorectal cancer. Briefly, the patent discloses a diagnostic method and a kit for prognosis assessment of colorectal cancer (CRC) with a tumor suppressor gene to be used for diagnosis of colorectal cancer (CRC), wherein the method comprises: identifying recurrently altered regions (RAR) on a chromosome; and detecting genomic alterations in the RAR. It is said that the invention makes it possible to perform early diagnosis as well as prognosis assessment for various cancers and tumors including colorectal cancer (CRC).

[0009] Publication No. WO2011076147, entitled, Plasma-Based Micro-RNA Biomarkers And Methods For Early Detection of Colorectal, filed by Li, a diagnostic kit of molecular markers in blood for diagnosing colorectal cancer, and/or monitoring the therapeutic effect for treating colorectal cancer is disclosed. The kit is said to comprise a plurality of nucleic acid molecules, and each nucleic acid molecule encodes a microRNA biomarker, wherein one or more of the plurality of nucleic acid molecules are differentially expressed in plasma of patient and healthy control, and the one or more differentially expressed nucleic acid molecules together represent a nucleic acid expression biomarker that is indicative for the presence of colorectal cancer. The invention is said to further provide corresponding methods using such nucleic acid expression biomarkers for identifying colorectal cancer as well as for preventing or treating such a condition. Finally, the invention provides a pharmaceutical composition for the prevention and/or treatment of colorectal cancer.

[0010] Publication No. WO2011076142, entitled, Compositions And Methods For MicroRNA Expression Profiling in Plasma of Colorectal, also filed by Li, is said to teach compositions and methods for microRNA (miRNA) expression profiling in plasma of colorectal cancer. In particular, the invention is said to relate to a diagnostic kit of molecular markers in blood for diagnosing colorectal cancer, monitoring the cancer therapy and/or treating colorectal cancer that includes a plurality of nucleic acid molecules, each nucleic acid molecule encoding a microRNA sequence, wherein one or more of the plurality of nucleic acid molecules are differentially expressed in plasma of colorectal cancer and healthy control plasma, and wherein the one or more differentially expressed nucleic acid molecules together represent a nucleic acid expression signature that is indicative for the presence of colorectal cancer. The invention is said to further relate to corresponding methods of using such nucleic acid expression signatures for identifying colorectal cancer as well as for preventing or treating such a condition. Finally, the invention is directed to a pharmaceutical composition for the prevention and/or treatment of colorectal cancer.

[0011] Publication No. WO2011088226, entitled, Detection Of Gastrointestinal Disorders, filed by, Christine, is said to teach methods and systems for characterizing a phenotype by detecting microRNAs, vesicles, or biomarkers that are indicative of disease or disease progress. The disease can be a gastrointestinal disorder, such as colorectal cancer. The microRNAs, vesicles, or biomarkers can be detected in a bodily fluid.

[0012] Publication No. WO2010004562, entitled, Methods And Compositions For Detecting Colorectal Cancer, filed by Baruch, is said to teach a method for conducting minimally-invasive early detection of colorectal cancer and/or of colorectal cancer precursor cells, by using microRNA molecules associated with colorectal cancer, as well as various nucleic acid molecules relating thereto or derived thereof.

[0013] Finally, Publication No. WO2011012136, entitled, A Method For Classifying A Human Cell Sample As Cancerous, filed by Fog, et al., is said to teach a method for discriminating between cancer and non-cancer samples is described.