

The method is said to comprise detecting the level of at least one microRNA (miR) selected from Mir- Group I consisting of: miR-21, miR-34a and miR-141, and detecting the level of at least one miR selected from Mir-Group II consisting of: miR-126, miR-143 and miR-145 in a test cell sample and, comparing the level of expression of said selected miRs in the test cell sample with the level of expression of the same selected miRs in a previously recorded test set.

#### SUMMARY OF THE INVENTION

**[0014]** In one embodiment the present invention includes a method for diagnosing or detecting colorectal neoplasia in a human subject comprising the steps of: obtaining one or more biological samples from the subject suspected of suffering from colorectal neoplasia; measuring an overall expression pattern or level of one or more microRNAs obtained from the one or more biological samples of the subject; and comparing the overall expression pattern of the one or more microRNAs from the biological sample of the subject suspected of suffering from colorectal neoplasia with the overall expression pattern of the one or more microRNAs from a biological sample of a normal subject, wherein the normal subject is a healthy subject not suffering from colorectal neoplasia, wherein overexpression of a combination of miR19a and miR19b, or miR19a and miR19b and miR15b is indicative of colorectal cancer. In one aspect, the method further comprises the analysis of at least one of miR18a, miR29a, or miR335 as compared to expression from the normal subject is indicative of colorectal neoplasia. In another aspect, the method further comprises the analysis of at least one of miR29a, miR92a, or miR141. In another aspect, the one or more biological samples are selected from the group consisting of one or more biological fluids, a plasma sample, a serum sample, a blood sample, a tissue sample, or a fecal sample. In another aspect, the method is capable of detecting early CRC (I-II) as accurately as advanced CRC (stage II-III), right-sided tumors and left-sided lesions. In another aspect, the method comprises confidence interval that is 90, 91, 92, 93, 94, or 95% or greater. In another aspect, the method further comprises determining of the level of expression of microRNAs that are underexpressed in colorectal neoplasia are selected from:

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hsa-miR-636;  
 hsa-miR-876-3p;  
 hsa-miR-1537;  
 hsa-miR-630;  
 hsa-miR-380\*;  
 hsa-miR-338-5p;  
 hsa-miR-573;  
 hsa-miR-182\*;  
 hsa-miR-518c\*;  
 hsa-miR-187\*;  
 hsa-miR-1233;  
 hsa-miR-449b;  
 hsa-miR-1204;  
 hsa-miR-518d-3p;  
 hsa-miR-1290;  
 hsa-miR-1449.1;  
 hsa-miR-105;  
 hsa-miR-298;  
 hsa-miR-491-5p;  
 hsa-miR-576-3p;  
 hsa-miR-590-3p;  
 hsa-miR-1257;  
 hsa-miR-1225-3p;  
 hsa-miR-127-3p;

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hsa-miR-936;  
 hsa-miR-379;  
 hsa-miR-664\*;  
 hsa-miR-548j;  
 hsa-miR-130b\*;  
 and  
 hsa-miR-515-3p.

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**[0015]** In another aspect, the method further comprises determining of the level of expression of microRNAs that are overexpressed in colorectal neoplasia are selected from:

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hsa-miR-302b;  
 hsa-miR-125a-5p;  
 hsa-miR-424;  
 hsa-miR-125b;  
 hsa-miR-100;  
 hsa-miR-768-3p:11.0;  
 hsa-miR-24;  
 hsa-miR-23a;  
 hsa-miR-1274b;  
 hsa-miR-27a;  
 hsa-miR-26b;  
 hsa-miR-30d;  
 hsa-miR-520h;  
 hsa-miR-520g;  
 hsa-miR-302a\*;  
 hsa-miR-518c;  
 hsa-miR-335;  
 hsa-miR-29a;  
 hsa-miR-152;  
 hsa-miR-191;  
 hsa-miR-17;  
 hsa-miR-19b;  
 hsa-miR-30a;  
 hsa-miR-151-5p;  
 hsa-miR-92a;  
 hsa-miR-25;  
 hsa-miR-15b;  
 hsa-miR-15a;  
 hsa-miR-30e\*;  
 hsa-miR-132\*;  
 and  
 hsa-miR-921.

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**[0016]** In another aspect, the expression level of the one or more microRNAs is measured by microarray expression profiling, PCR, reverse transcriptase PCR, reverse transcriptase real-time PCR, quantitative real-time PCR, end-point PCR, multiplex end-point PCR, cold PCR, ice-cold PCR, mass spectrometry, in situ hybridization (ISH), multiplex in situ hybridization, or nucleic acid sequencing. In another aspect, the method is used for treating a patient at risk or suffering from colorectal neoplasia, selecting an anti-neoplastic agent therapy for a patient at risk or suffering from colorectal neoplasia, stratifying a patient to a subgroup of colorectal neoplasia or for a colorectal neoplasia therapy clinical trial, determining resistance or responsiveness to a colorectal neoplasia therapeutic regimen, developing a kit for diagnosis of colorectal neoplasia or any combinations thereof. In another aspect, the overall expression pattern or level of 4, 5, 6, 7, 8, 9, 10, 12, 15, 20, 25, 30, 35, 40, 45, 50, 55 or 60 microRNAs selected from Tables 2, 3, 4, and 5, wherein the microRNAs increase the specificity of the determination, diagnosis or detection of colorectal neoplasia. In another aspect, the method further comprises the step of using the overall expression pattern or level of microRNAs for prognosis, treatment guidance, or monitoring response to treatment of the colorectal neoplasia.