# Technology Offer

**Ref.-No. M2612**

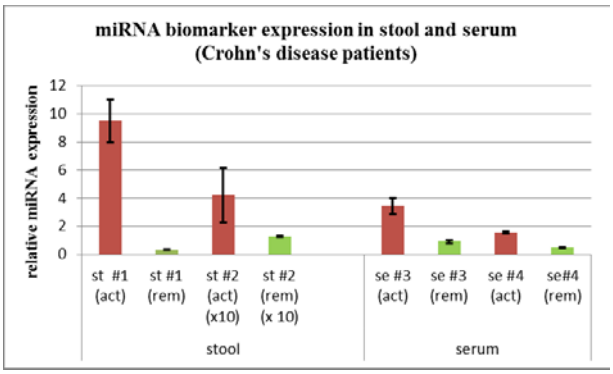
## A special miRNA as a minimal invasive biomarker for IBD

### Introduction

Inflammatory bowel diseases (IBD), such as Crohn's disease (CD) and ulcerative colitis (UC) are severe and relapsing immunologically mediated chronic disorders of the gastrointestinal tract, fuelled by continuous infection and aggravated inflammation with the risk of disabling complications due to uncontrolled inflammation. The highest reported prevalence for both diseases is estimated at more than 1400 per 100,000 in western industrialized countries and causes numerous events of sick-leaves and increasing economic pressure on health care systems. As the etiology of IBD is not fully understood in general mainly the inflammatory symptoms are treated e.g. by immune modulators such as infliximab. Accordingly the potential over-treatment of patients bears the risk of severe side-effects such as opportunistic infections making it obvious that an adequate patient-tailored use of anti-inflammatory therapy is needed. There is an urgent need for sensitive, reliable and inexpensive markers to follow non-invasively the course of disease, detectable in body fluids like serum and plasma as well as stool samples which are simple to use in clinical practice.
We focus on a particular microRNA, serving as a biomarker for IBD, to assess the course of inflammation as well as disease activity in Ulcerative colitis or in Crohn`s disease patients.
MicroRNAs (miRNAs) are small (~22–24 nucleotide), noncoding RNAs that act as master regulators of gene expression in particular in a huge variety of diseases. Actually, miRNAs are thought to contribute to the regulation of over 60% of all protein coding genes. We are able to show that the differential expression of miRNAs may distinguish disease states including CD and UC, even and particular when isolated from peripheral body fluids, what is the background of this invention.

### Invention

The present invention relates to the use of a nucleic acid molecule (microRNA) which can be used as a biomarker to distinguish acute or relapsing phase of inflammatory bowel disease. The present invention also relates to a pharmaceutical composition comprising the nucleic acid and a fragment or variant thereof which envisages monitoring of disease progression of a subject suffering from inflammatory bowel disease**.**
In addition, the present invention relates to a medicament for use in the treatment of inflammatory bowel disease by enhancing the barrier function of the intestinal mucosa which is based on the integrity of the junctional complexes.




miRNA as a biomarker for Crohn's disease in body fluids. act = acute flare, rem = remission, x10 = value has to be multiplied by 10

### New aspects and advantages of the invention

A single, short nucleic acid (microRNA) that is capable to monitor, in a sensitive, reliable and inexpensive manner, the status of inflammatory bowel diseases (IBD), such as Crohn's disease (CD) and ulcerative colitis (UC) in body fluids of patients.

### Particular important aspects include

- data from human samples (see Fig. above) as well as from two in vivo colitis mouse models which demonstrate the correlation of a specific miRNA expression with histological phenomena of IBD
- a new biomarker for IBD (Crohn's disease and ulcerative colitis
- a particular miRNA that can be used to characterize the inflammatory status of the gut
- an indicator for the disruption of epithelial barrier function
- a miRNA, which if applied therapeutically restores barrier integrity and prevents the permeability of the gastrointestinal barrier (bacterial infection)

### Patent situation

Patent applications have been filed in Australia, Canada, Europe and USA.

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