

A TRULY TUMOR-SPECIFIC EPITOPE CARRIED BY BG-A ANTIGEN FOR CANCER DIAGNOSIS AND TREATMENT

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Background: In the US alone, 154,000 new cases of colorectal cancer (CRC) are diagnosed each year. Unfortunately, a third of those patients will die due to diagnosis at late stages – the 5-year survival rate is 11%, compared to 91% for those who are diagnosed with only localized CRC. A colonoscopy is the current standard of care, yet, is underutilized because of the invasive nature of the exam. CEA and CA199 blood tests have been developed but have poor sensitivity and specificity. There is a strong need for a non-invasive and sensitive test to diagnose and monitor CRC.

Technology Description: A blood test that measures a truly tumor-specific biomarker, incompatible blood group A (BG-A) antigen, in colorectal cancer patients with blood type O and B. Healthy individuals with blood type O and B have BG-H and BG-B antigen, but have no BG-A antigen in their body. However, in colorectal cancer, tumor cells can produce and express BG-A antigen. The incompatible BG-A antigen becomes a strict tumor-specific biomarker in colorectal cancer patients with O and B blood types.

The inventors have identified a novel immune epitope on the BG-A molecules and created a monoclonal antibody Mab CRC-A1 for this epitope. An ExoELISA assay which measures solid or exosome-bound tumor antigens in serum has been developed as well. Flow cytometry analysis of the Mab CRC-A1 has shown that Mab CRC-A1 also reacts to AML cells in patients with blood type B, indicating that this blood test is not limited to only colon and ovarian cancers, but could be utilized for any cancer of pre-cancer expressing incompatible BG-A antigen.

Key Advantages:

- Excellent sensitivity and specificity: 100% and 100% respectively for BG-B patients, and 100% and 80% respectively for BG-O patients
- Exosomes are abundant and stable, allowing for tumor detection at an earlier stage than currently existing assays
- Mab CRC-A1 is a candidate for the development of immunotherapeutic agents (e.g. BITE and CAR)
- Non-invasive
- Affordable test

Patent: Pending