

Alerting on Occult Colorectal Cancer in Patients with Gallstones undergoing surgical Cholecystectomy

- Gallstones lead to inflammation of the gallbladder, biliary tract ducts, liver and pancreas, and are associated with increased risk of colorectal cancer (CRC). Even after cholecystectomy patients still have a high risk of CRC and study of occult CRC is recommended for long-term survival of patients following cholecystectomy. Not surprisingly, while cholecystectomy reduces the inflammatory state associated with gallstones, it increases the exposure of the intestine to bile, which in turn increases colonic epithelial cell proliferation and carcinogenic risk.



- PBM's scientists have identified a tumor-specific gene expression pattern in the liver of patients with CRC, whose expression level is not affected by concurrent obesity, cigarette smoking, and other pathophysiological disorders including biliary diseases such as gallstones. Among included genes are those whose expression changes occur in patients with, but not without CRC, and those associated to the metastatic disease of the liver.
- By taking advantage of this discovery, PBM's scientists have now developed a novel and sensitive laboratory test for the identification of this CRC-specific gene expression pattern in hepatic biopsies obtained during the surgical intervention of patients with gallstones. Quantitation of target hepatic genes is performed using a TaqMan Low Density Array for real-time RT-PCR.

- The laboratory test consists of a panel of hepatic molecular biomarkers strongly associated with CRC development, and whose gene expression level and pattern have been shown to be highly predictive of CRC. Therefore, the test is intended to alert on the possible occurrence of an occult CRC in patients with gallstones undergoing cholecystectomy. Positive or negative results should be interpreted in conjunction with all other available examinations on occult CRC, such as colonoscopy or CT colonoscopy.
- Positive test results should be referred to other CRC screening tests for confirmation such as blood test-liquid biopsy (Epi-proColon®), stool tests (FOBT, FIT-DNA) and imaging (colonoscopy and CT-colonography), allowing your physician to treat the CRC, if detected early. A negative test result does not guarantee absence of CRC or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient.
- This test was developed and its clinical performance features determined by PBM. It has not been cleared or approved by the FDA. It should not be regarded as investigational or for research. Final diagnosis and optimal patient management are the responsibility of the referring physician or health care provider.

PERSONA BIOMED Inc. is a clinical-stage biotech company devoted to the development of clinically-validated gene and molecular expression profiling methods for contributing to the success of personalized medicine.

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