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12 June 2007

Steve Phurrough, MD MPA
Centers for Medicare and Medicaid Services
CMS, OCSQ-CAG
7500 Security Blvd, MS-C10906
Baltimore, Maryland 21244

Dear Dr. Phurrough,

This letter is a formal request to CMS for a national coverage decision on:

Colorectal cancer screening through the identification of specific colorectal cancer associated DNA mutations and alterations by the analysis of human DNA isolated from stool

As you are well aware, colorectal cancer is the second leading cause of cancer death in the United States. Current screening options recommended by the US Preventive Services Task force include fecal occult blood testing (FOBT), flexible sigmoidoscopy and colonoscopy. Only the former is non-invasive, but problems with sensitivity and specificity limit the efficacy of FOBT in the reduction of colorectal cancer mortality. There is a great need for non-invasive colorectal screening tests with better performance characteristics than FOBT. Based on ample available data, stool-based DNA testing meets this need.

In accordance with the NCD request process published in the Federal Register, September 26, 2003 (FR Vol. 68, number 187, pages 55634-55641), we request that CMS uses the collaborative NCD development track, track one (FR Vol. 68, number 187, pg 55638, IV E).

Dr. Barry M. Berger, Vice President for Laboratory Medicine, EXACT Sciences Corporation, is the primary requestor and contact for this NCD request and may be reached at any time for additional information or clarification: 508-683-1250 Ph Office, 617-293-7738 Ph Cell, email: bberger@exactsciences.com.

Sincerely,

Jonathan Terdiman

Jonathan P. Terdiman, M.D.
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