

Technical Product Data Sheet

Product name	BIOHIT ColonView quick test
Cat. N:o	602 250.02
Kit Size	30 tests
Kit Contents	30 test cassettes, 30 sample collection tubes, 1 Instruction for Use, 30 Instructions for sample collection, 30 Sample collection papers
Intended Use	The Biohit ColonView quick test detects human Hb and Hb/Hp complex from faeces. For <i>in vitro</i> diagnostic use
Method	Immunochromatographic Lateral Flow device
Sample type	Faeces
Reading of the result	Visual or instrument (Quick Test Reader) read
Time to result	15 minutes (Strongly positive results may be evaluated visually sooner. NOTE: The control line must be visible. Reader evaluation must be done exactly at 15 minutes.)
Test Performance	For adenoma and carcinoma (Vasilyev, Table 2): Sensitivity 97.3% (93.9-99.1), Specificity 85.1% (77.2-91.1) PPV 91.4% (86.6-94.9), NPV 95.1% (88.9-98.4) AUC= 0.912 (0.877-0.947) Cut off (detection limit): Hb 15 ng/ml, Hb/Hp: 4 ng/ml
Kit Storage	2 - 30 °C
Sample Storage	11 days in refrigerator (2-8 °C), 5 days at room temperature (max. 25 °C)
Quality	CE IVD This product has been manufactured according to ISO 9001/ ISO 13485 quality management protocols.
Registered trademark	ColonView Hb and Hb/Hp Test is a registered trademark of Biohit Oyj.
Literature	<ul style="list-style-type: none">• Vasilyev S, Smirnova E, Popov D, Semenov A, Eklund C, Hendolin P, Paloheimo L, Syrjänen K. A New-Generation Fecal Immunochemical Test (FIT) Is Superior to Quaiac-based Test in Detecting Colorectal Neoplasia Among Colonoscopy Referral Patients. <i>Anticancer Res.</i> 2015; 35:2873-80.• Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: http://globocan.iarc.fr, accessed on 02/2014.• Whitlock EP, Lin J, Liles E, Beil T, Fu R, O'Connor E, Thompson RN, Cardenas T. Screening for Colorectal Cancer: An updated Systematic Review. Evidence Synthesis No. 65, Part 1. AHRQ Publication No. 08-05124EF-1. Rockville, Maryland, Agency for Healthcare Research and Quality, October 2008.• Hewitson P, Glasziou P, Irwig L, Towler B, Watson E. Screening for colorectal cancer using the faecal occult blood test, Hemoccult. <i>Cochrane Database Syst Rev.</i> 2007;CD001216.• Kronborg O, Jorgensen OD, Fenger C, Rasmussen M. Randomized study of biennial screening with a faecal occult blood test: results after nine screening rounds. <i>Scand J Gastroenterol</i> 2004;39:846-851.• Ransohoff DF and Lang CA. Improving the Fecal Occult- Blood Test. <i>The New England Journal of Medicine</i> 1996; 334 (3): 189-190.