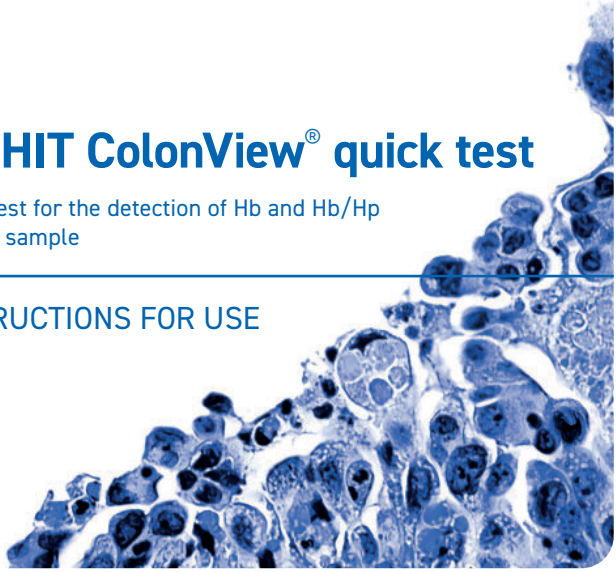
BIOHIT

Innovating for Health

BIOHIT ColonView® quick test

Quick test for the detection of Hb and Hb/Hp in fecal sample

INSTRUCTIONS FOR USE



REF 602250.02 (30 tests)

IVD CE

For *in vitro* diagnostic use
Store at 2-30°C upon receipt

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EXPLANATION OF THE SYMBOLS USED IN LABELS

Symbol	English
	For *in vitro* diagnostic use
	Catalogue number
	Batch code
	Use by (yyyy-mm-dd)
	Consult instructions for use
	Storage limitation. Store at +2...+30°C
	30 determinations
	Do not reuse
	CE Mark
	Manufacturer

INSTRUCTIONS FOR USE **English**

Note! Other languages available at www.biohithealthcare.com

BIOHIT ColonView® quick test **REF 602250.02**

CONTENTS

1. INTENDED USE AND BACKGROUND

BIOHIT ColonView® quick test is a qualitative in vitro immunochromatographic test aiding in diagnosis of lower gastrointestinal disorders, such as colorectal cancers and large adenomas that bleed, by detecting human hemoglobin (Hb) and hemoglobin/haptoglobin complex (Hb/Hp) in stool samples. The test is conducted manually or semi-automated and is intended to be used by healthcare professionals only [1,2].

ColonView Hb and Hb/Hp Fecal Occult Blood Test (FIT) test was designed to aid diagnosis of lower GI disorders, such as colorectal cancers and large adenomas that bleed. In 2012, colorectal cancer was the third most common cancer in men (746,000 cases) and the second in women (614,000 cases), with more than 690 000 annual deaths worldwide [3]. Screening for colorectal cancer reduces disease-specific mortality by increasing the cancer detection at its' early stages [4].

2. PRINCIPLE OF COLONVIEW® FIT

The Test Cassette strip is coated with anti-human hemoglobin and anti-human haptoglobin antibodies on the Test region (T) and antibodies on the Control region (C). The test result is evaluated by the intensity of the developing test bands, which are created by concentration of colloidal gold conjugate antibody to the C and T regions of the test cassettes [4].

3. SAMPLE COLLECTION AND HANDLING

Collect a random sample of stool with the Stool Collection Paper provided with the Sample Collection Package (or with a clean dry container). For the use of the Stool Collection Paper, please refer to the Sample Collection Instruction provided in the Kit. Also, using the Sample Collection Tube, please collect the sample as instructed. Too much stool in the stool collection tube results in an invalid result. The specimen(s) can be stored in the refrigerator (2-…8 °C) for up to 11 days, or at room temperature (max. 25°C) for up to 5 days.

4. WARNINGS AND PRECAUTIONS

For in vitro diagnostic use.

CAUTION: Handle stool samples as potentially biohazardous material.

All human samples are to be treated as potentially infectious and handled according to standard precautions (e.g., GLP, GMMP, CLSI M29). Please refer to internationally or nationally recognized manuals concerning biosafety issues, such as Laboratory Biosafety Manual by World Health Organization

or Biosafety in Microbiological and Biomedical Laboratories by Centers for Disease Control and Prevention/National Institutes of Health.

Always use protective gloves and clothing when handling patient samples. Use a safety pipetting device for all liquid transfers. Read all instructions prior to performing this assay.

Components containing ProClin 300 may cause an allergic skin reaction (see Safety Data Sheet). Dispose of ProClin containing solutions according to local waste management legislation.

Any serious incident that occurs in relation to the use of this kit shall be reported immediately to the manufacturer (contact details in Chapter 13).

Reagents of different kit lots must not be mixed.

5. KIT CONTENTS, STORAGE, AND DISPOSAL OF MATERIALS PROVIDED

The Kit contains 30 tests.

The kit can be stored at 2...30°C until the expiration date printed on the outside of the box. Do not freeze or expose the kit to high humidity, or high temperatures when not in use. Do not use a test cassette that has been removed from the foil bag for more than 1 h ago, or has been damaged (e.g., after dropping).

Test cassette is single use only. Dispose unused sample diluent buffer and test cassettes (contain PVC) according to your local waste regulations. Treat used cassettes as potentially biohazardous and dispose as such according to your local waste regulations.

6. TEST PROCEDURE

1. The Test Cassette and the Sample Collection Tube containing the stool sample all be brought to room temperature (20...30°C) at least 10 minutes before testing.

2. Take the required number of Test Cassettes from the foil packaging only immediately before performing the test. Mark the Test Cassette with the name of the patient or with another form of identification.

3. Carefully shake the Sample Collection Tube to ensure that the stool sample mixes properly with the sample buffer.

4. Open the white cap of the Sample Collection Tube. Take a paper towel and break the seal of the sample collection tube. The paper towel prevents the solution from splashing while opening the tube. Hold the collection tube upright and add 3 drops of the solution into both round sample windows (S) of the Test Cassette

5. Time to results is 15 minutes. Please note when reading the test lines (T), that strongly positive results may be interpreted visually (seen by eye only) sooner than 15 minutes. Visually negative results must be interpreted exactly at 15 minutes. Results are only valid when control lines (C) are visible.

7. QUALITY CONTROL OR INTERNAL PROCEDURAL CONTROL

The test contains a procedural control. A colored line that appears in the control region (C) shows that each test is performed correctly. The background may become slightly yellowish in color during testing, depending on the color of the stool sample.

8. TEST RESULTS AND VALID TEST

Visual evaluation of positive or negative results: The test is evaluated “negative”, if a colored line appears in the control region (C) of both Hb and Hb/Hp tests and no distinguishable lines appear in the test regions (T). The test is evaluated “positive”, if two lines appear; one colored line in the control region (C) and one distinguishable line in the test region (T) in either Hb and/or Hb/Hp tests. In case of ambiguous interpretation of the test region, the same test result should be confirmed with at least two persons i.e. if two out of three test interpretations are positive, the test result is positive. If additional observants are not available, repeat the test with a new Test Cassette.

Invalid result with visual evaluation: if no line appears in the control region in either Hb and/or Hb/Hp tests, this is a sign that the test is not functioning properly, or that the test materials are not correct. In this case, repeat the test with a new Test Cassette or contact the manufacturer for technical support.

9. ANALYTICAL PERFORMANCE CHARACTERISTICS

Performance Test	Results
Analytical sensitivity (cut-off, imprecision at the concentration near the cut-off)	**Hb:** Cut-off, C50 = 15 ng/ml C5 = 9 ng/ml (-40% from cut-off) C95 = 21 ng/ml (+40% from cut-off) **Hb/Hp:** Cut-off, C50 = 4 ng/ml C5 = 2 ng/ml (-50% from cut-off) C95 = 6 ng/ml (+50% from cut-off)
Analytical specificity (interference)	**The results from tested substances showed no interference:** - Bilirubin up to 400 µg/ml - Horse radish peroxidase up to 20 mg/ml - Triglycerides up to 15 mg/ml - Albumin (human) up to 2 mg/ml - Iron (dietary supplement) up to 2 mg/ml - Secretory Immunoglobulin A (sIgA) up to 600 ng/ml
Accuracy of measurement: Trueness of measurement (bias)	Bias calculated between CVQT and comparative method as positive, negative and overall percent agreement: **Hb:** PPA: 100% (95% CI; 94,2% – 100%) NPA: 82,9% (95% CI; 72,4% – 89,9%) OPA: 90,9% (95%CI; 84,8% – 94,7%) **Hb/Hp:** PPA: 100% (95% CI; 94,2% – 100%) NPA: 85,7% (95% CI; 75,7% – 92,1%) OPA: 92,4% (95%CI; 86,6% – 95,8%)
Hook	There is no hook effect observed up to 500 µg/ml hemoglobin and up to 100 µg/ml hemoglobin/haptoglobin complex.

10. CLINICAL PERFORMANCE

The clinical sensitivity and specificity of BIOHIT ColonView quick test was evaluated in a clinical study of 300 colonoscopy-referral patients [4]. Three fecal samples were tested, and all subjects were examined by diagnostic colonoscopy with biopsy verification. The quick test was interpreted as positive if any of the three samples were positive for either Hb or Hb/Hp complex.

The sensitivity (SE) of ColonView quick test for adenoma and carcinoma together was determined to be 97.3%, and specificity (SP) 85.1%. Positive predictive value (PPV) was 91.4% (86.6.2-94.9) and negative predictive value (NPV) 95.1% (88.9-98.4). For adenoma, the corresponding figures were SE 94.5%, SP 85.1%, PPV 83.5 and NPV 95.1%. For carcinoma, the corresponding figures were SE 100%, SP 85.1%, PPV 84.8% and NPV 100%.

Comparison With Other Methods

The ColonView test was compared with the conventional guaiac-based test (Hemoccult SENSA®) in detection of fecal occult blood as surrogate of clinically significant colorectal neoplasia (4). For the combined adenoma and carcinoma endpoint, the HemoccultSENSA test had sensitivity of 58.3% and specificity of 96.5%, while the ColonView tests had 97.2% sensitivity and 85.8% specificity.

11. REFERENCES

1. Immunoassay for fecal human hemoglobin, http://www.google.com/patents/US4427769
2. Aggressive innovation and patenting strategy http://www.biohithealthcare.com/resource/files/media/articles/biohit-innovation-patenting-strategy.pdf
3. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, 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.
4. 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. Anticancer Res 2015; 35:2873-2880.

12. DATE OF ISSUE

BIOHIT ColonView® quick test

Instructions for Use
Version 14, 06-2024 (SA)

13. WARRANTY

Biohit shall remedy all defects discovered in any Product (the “Defective Product”) that result from unsuitable materials or negligent workmanship and which prevent the mechanical functioning or intended use of the Products including, but not limited to, the functions specified in Biohit’s specifications for the Products. ANY WARRANTLY WILL, HOWEVER, BE DEEMED AS VOID IF FAULT IS FOUND TO HAVE BEEN CAUSED BY MALTREATMENT, MISUSE, ACCIDENTAL DAMAGE, INCORRECT STORAGE OR USE OF THE PRODUCTS FOR OPERATIONS OUTSIDE THEIR SPECIFIED LIMITATIONS OR OUTSIDE THEIR SPECIFICATIONS, CONTRARY TO THE INSTRUCITONS GIVEN IN THE INSTRUCTION MANUAL.

The period of this warranty is defined in the instruction manual of the Products and will commence form the date the relevant Product is shipped by Biohit. This Biohit Diagnostic kit has been manufactured according to ISO 9001/ ISO 13485 quality management protocols.

In case of interpretation disputes the English text applies.

In case of any serious incident in relation to the product, contact the manufacturer.

14. ORDERING INFORMATION

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NOTES

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