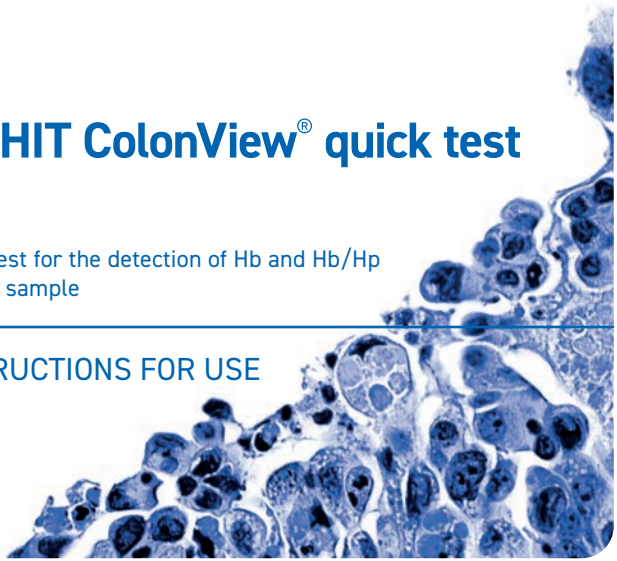
BIOHIT

Innovating for Health

BIOHIT ColonView® quick test

v2.1

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 to 30°C upon receipt

Manufacturer: Biohit Oyj Laippatie 1, FI-00880 Helsinki, Finland

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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 to 30°C
	30 determinations
	Do not reuse
	CE Mark
	Unique Device Identifier
	Material of animal origin
	Non-corrugated fiberboard (paperboard)
	Keep away from direct sunlight
	Keep dry
	This way up
	Manufacturer

INSTRUCTIONS FOR USE **English**

BIOHIT ColonView® quick test **REF 602250.02**

CONTENTS

1. INFORMATION FOR THE USER

This document provides information on the product's intended purpose, proper use and prerequisites for its use, and the established performance of the product. It is valid for BIOHIT ColonView® quick test (version 2.1), and it will be updated if the device or the provided information is changed.

The product is manufactured by:
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This instruction is the edition 15.2, and it is valid from 2025-09-12.
It applies to device version 2.1.

2. DESCRIPTION OF THE DEVICE

Trade Name	BIOHIT ColonView® quick test
Version	2.1
Basic UDI	6419587CV0010QQ
Risk Class	Low-risk IVD
Device Registry Entry Code(s) if applicable	N/A
Date of First Release	2012

BIOHIT ColonView® quick test is developed by Biohit. It is a qualitative single-use device to detect small amounts of blood in the stool. ColonView quick test aids the diagnosis of lower gastrointestinal disorders, such as colorectal cancers and large adenomas that bleed, by detecting biological markers Hemoglobin (Hb) and Hemoglobin/Haptoglobin (Hb/Hp) complex in stool samples.

ColonView quick test is a fecal immunochemical test (FIT) that detects two biological markers of fecal occult blood in stool: Hb and Hb/Hp complex. The test cassette contains two parallel test strips, one for each biomarker. The Test Cassette strip is coated with anti-human hemoglobin and anti-human haptoglobin antibodies on the Test region (T) and goat anti-mouse IgG antibodies on the Control region (C). The test result is evaluated by the intensity of the developing test bands, which are created by accumulation of colloidal gold conjugate antibody to the C and T regions of the test cassettes.

The kit includes all the necessary reagents and consumables to perform the test.

2.1 Kit Contents, Storage and Disposal

BIOHIT ColonView® quick test kit contains components for 30 tests.
Store the kit components at 2 to 30°C.

Component	Content	Stability
Test Cassette	30 pieces, Test Cassette packed in a foil bag with desiccant.	Exp. date. In-use one hour.
Sample Collection Package	30 pieces, package includes Sample Collection Tube, Specimen Collection Paper, and Sample Collection Instructions.	Exp. date. See Chapter 6 for sample stability.
Quality Control Certificate	1 piece	Exp. date.
Instructions for Use	1 piece	Exp. date.

The test cassette and sample collection equipment are single use only. Dispose unused sample diluent buffer and test cassettes (contain PVC) according to your local waste regulations. Treat used cassettes and sample collection tubes as potentially biohazardous and dispose as such according to your local waste regulations. Dispose foil bag (includes plastic), desiccant bag (silica gel) and kit box (cardboard) according to your local waste regulations.

2.2. Stability

The kit can be stored at 2 to 30°C in the up-right position until the expiration date printed on the outside of the box. Long-term storage at 2 to 8°C is recommended to minimize sample buffer evaporation Do not freeze the kit. Do not use reagents or kit components after the expiration date printed on the label.

The open-vial stability (in-use) of the test cassette is one hour, during which the test cassette can be used at room temperature (20 to 30°C). Do not use a test cassette that has been removed from the foil bag more than 1 h ago, or has been damaged (e.g., after dropping).

3. SPECIFICATION OF THE TARGET

The analytes are hemoglobin (Hb) and hemoglobin/haptoglobin complex (Hb/Hp) which are blood components. Hemoglobin (Hb) is composed of two pairs of peptide chains, known as α- and β-globins, along with four heme groups, each containing an iron atom. When hemoglobin is free in the bloodstream, it can dissociate into α-β dimers. These dimers are then bound by haptoglobin (Hp), a protein that plays a crucial role in capturing free hemoglobin from lysed red blood cells. The resulting Hb/Hp complex is stable which is essential for the effective retrieval and clearance of hemoglobin from the bloodstream[1]. Detection of these analytes is the basis for the identification of occult blood in stool samples in ColonView quick test. Occult blood testing is a common diagnostic tool used to screen gastrointestinal disorders, including colorectal cancer and gastrointestinal bleeding[2,3].

4. INDICATION FOR USE

Fecal occult blood (FOB) tests are used to detect small amounts of blood in the stool. ColonView Hb and Hb/Hp immunochemical FOB test was designed to aid diagnosis of lower GI disorders, such as colorectal cancers and large adenomas that bleed[4]. 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[5]. In 2022, annual deaths by colorectal cancer already exceeded 900 000 deaths worldwide and was also the second leading cause of cancer death[6]. Fecal immunochemical tests (FITs) are increasingly used for colorectal cancer (CRC) screening and their use is supported by international associations[2,3]. Screening for colorectal cancer reduces disease-specific mortality by increasing the cancer detection at early stages[1]. Hb/Hp is sensitive in early detection of adenomas before they develop into carcinomas[1, 7-9].

5. INTENDED USE

BIOHIT ColonView® quick test is a qualitative in vitro immunochromatographic test aiding the 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 and is intended to be used by healthcare professionals only.

6. INTENDED TARGET GROUP AND SPECIMEN

Species	Human
Specimen type	Feces
Preservation	Fresh (stored in buffer)
Indication	Risk for gastrointestinal disorders by detection of fecal occult blood.
Age	Adults, 18–88 years
Specimen stability	11 days at 2 to 8°C, or 3 days at RT (max. 25°C).

6.1. Specimen collection

For sample collection, please refer to the Sample Collection Instructions provided with the Sample Collection Kit. In brief, test 3 different stool samples over no more than 3 days. Collect each stool sample using the Stool Collection Paper provided in the Sample Collection Package (or a clean dry container). For each stool sample, using the Sample Collection Tube, collect a random sample by inserting the applicator stick into three different areas of the stool. Fill the grooves of the sample collection stick. Ensure that the grooves are filled with sample, excess stool will be removed by the tube collar.The specimen(s) can be stored in the refrigerator (2 to 8°C) for up to 11 days, or at room temperature (max. 25°C) for up to 3 days. Samples should be delivered to the laboratory within 24 hours to ensure that weak positive samples remain positive.

False positive results may occur in the event of failure to follow separate sample collection instructions. Unless advised by an attending physician, sample collection is not recommended if there is mucus or visible blood in stool, visible blood in urine, during menstruation or for 3 days before or after menstruation, during constipation, or while taking rectal or blood-thinning medication or high doses of NSAIDs (e.g. aspirin, ibuprofen).

If the patient is unable to provide solid stool samples, watery stool can be weighed (19 mg) or pipetted into the tube (19 µl). The estimated stool concentration in the diluted sample is 12.7 mg/ml in 1.5 ml buffer. The dilution factor 12.7 may be used in ng/ml to µg/g stool transformations i.e. Hb 15 ng/ml corresponds to Hb 1.2 µg/g stool.

7. INTENDED USER GROUP AND USE ENVIRONMENT

The BIOHIT ColonView® quick test is intended to be used and interpreted by healthcare professionals only, required education level depends on local regulations. The procedure for execution of the test and result analysis is set out in chapter 12.

The ColonView quick test is intended to be used in a laboratory or by a healthcare professional. To support proper visual analysis of the test line, sufficient lighting should be ensured. The kit should be used at 20 to 30°C and stored at 2 to 30°C.

8. LIMITATIONS

The BIOHIT ColonView® quick test is validated for the intended use with specimen specifications indicated in chapter 6, by an intended user in the intended use environment described in chapter 7. Other sample materials,

users or use environments are not supported.

The correct method for performing the test is described in chapter 12. Failure to follow the instructions may result in an incorrect result. Pay attention to the expiry date and in-use stability. Do not mix components from different kit lots.

9. 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.

This kit contains proteins from bovine origin (buffer) and goat, rabbit and murine origin (test cassette). Some of these might cause allergic skin reactions and/or allergy or asthma symptoms or breathing difficulties if inhaled.

Always use protective gloves and clothing when handling patient samples. Goggles/face shield are additionally recommended. 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 on the back cover of this IFU) and the competent authority of the Member State in which the user and/or the patient is established.

Reagents of different kit lots must not be mixed. Do not re-use the test cassette.

Gastrointestinal bleeding may be due to several gastrointestinal (GI) disorders such as diverticulitis, Crohn's disease, colitis, polyps and colorectal cancer. The clinical diagnosis should only be made by a qualified professional after evaluation of clinical symptoms and all laboratory findings.

Avoid having sample on the tip of the collection stick. Too much stool in the stool collection tube may result in an incorrect result.

10. CALIBRATION AND QUALITY CONTROL

No international reference material is available for fecal occult blood testing that is metrologically traceable to SI. Each test lot is calibrated by the manufacturer to represent clinically relevant fecal occult blood concentrations (Hb 0 – 500 µg/ml, Hb/Hp 0 – 100 µg/ml).

11. METROLOGICAL TRACEABILITY OF MEASUREMENTS

As there is no recognized reference material or method for Hb or Hb/Hp biomarkers, value assignment of the test is assigned gravimetrically to established Biohit internal calibrators and controls. The original value assignment of ColonView quick test was conducted with a hemoglobin powder (for Hb) and with a blood sample (for Hb/Hp)[8] which were diluted to reach defined concentrations for clinically relevant cut-offs. The determined cut-off values and clinical utility of the test were evaluated in a clinical study[6].

12. HOW TO USE COLONVIEW QUICK TEST

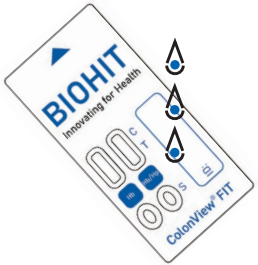
Read the complete assay procedure before starting.

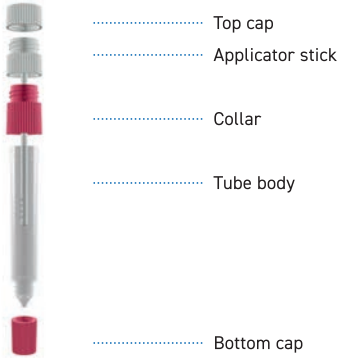
1. Bring the Test Cassette and the Sample Collection Tube containing the stool sample to room temperature (20 to 25°C) at least 10 minutes before testing.

2. Take the required number of Test Cassettes from the foil packaging, preferably, immediately before performing the test but at latest within one hour. Place the test cassettes on a flat horizontal surface. 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 red Bottom cap of the Sample Collection Tube. This will be used to seal the tube for storage (optional). Hold the collection tube upright and add 3 drops of the solution into both round sample windows (S) of the Test Cassette by squeezing the middle of the tube gently. Too many or too few drops may result in an incorrect result.





Tip: For sample storage, replace the bottom cap and discard the “fecal trap” i.e. the red Collar and the white Applicator stick from the tube body. Then screw the white Top cap tightly onto the top of the tube body.

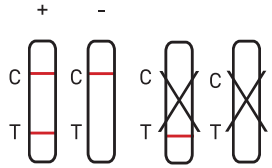
5. Time to results is 15 minutes. Please note when reading the test lines (T), that strongly positive results may be interpreted visually (seen by eye only) sooner than 15 minutes. Visually negative results must be interpreted exactly at 15 minutes. Results are only valid when control lines (C) are visible.

12.1. How to Interpret the Results

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). In case of a negative result, the presence of fecal occult blood can be excluded.

· 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 Hb and/or Hb/ Hp tests. In case of a positive result, the presence of fecal occult blood is confirmed.



Ambiguous interpretation / invalid results:

· In case of ambiguous interpretation of the test region, the same test result should be confirmed by at least two other persons, i.e., if two out of three test interpretations are positive, the test result is positive. If additional operators 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.

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

As with any diagnostic procedure, the ColonView quick test results must be interpreted together with each patient's clinical presentation and any other anamnestic information available to the physician.

13. ANALYTICAL PERFORMANCE OF COLONVIEW QUICK TEST

Performance Test	Results
Specimen type (stability)	**Stability of 13 positive stool samples showed:** - 11 days storage at 2 to 8°C - 3 days storage at room temperature - All weak positive samples remained positive when analyzed within 24 hours
Analytical sensitivity (cut-off, imprecision at a concentration near the cut-off) CLSI EP12-A2 EP12-Ed3	**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) CLSI EP07-Ed3E CLSI EP12-Ed3 CLSI EP37-Ed1E	**The results from the following 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 - Mucin up to 2 mg/ml - Pancreatic amylase up to 40 U/ml - Calprotectin up to 50 µg/ml - Myeloperoxidase up to 200 ng/ml **Other human hemoglobin variants were detected by the Hb test:** - Sickle cell hemoglobin-S (HbS)
Accuracy of measurement: Clinical performance (bias) CLSI EP12-A2 CLSI EP12-Ed3	Bias calculated between CVQT and comparative method as positive, negative and overall percent agreement: Hb: PPA: 98.6% (95% CI; 92.4 to 99.8%) NPA: 82.0% (95% CI; 69.2% to 90.2%) OPA: 91.7% (95%CI; 85.5% to 95.4%) Hb/Hp: PPA: 95.8% (95% CI; 88.3% to 98.6%) NPA: 82.0% (95% CI; 69.2% to 90.2%) OPA: 90.1% (95%CI; 83.5% to 94.2%)
Accuracy of measurement: Precision (within-laboratory) CLSI EP12-Ed3	Five days, two operators and three lots tested: - Hb samples ≤ 9 ng/ml and ≥ 21 ng/ml - Hb/Hp samples ≤ 2 ng/ml and ≥ 6 ng/ml can be expected to yield consistently negative and positive results with 95-% confidence, respectively.

Accuracy of measurement: Precision (reproducibility) CLSI EP12-Ed3	Five days and three sites tested: - Hb samples ≤ 9 ng/ml and ≥ 21 ng/ml - Hb/Hp samples ≤ 2 ng/ml and ≥ 6 ng/ml can be expected to yield consistently negative and positive results with 95-% confidence, respectively.
Hook	There is no hook effect (false negative) observed up to 500 µg/ml hemoglobin and up to 100 µg/ml hemoglobin/hapto-globin complex with samples: **Hb:** 50 ng/ml, 100 ng/ml, 300 ng/ml, 1000 ng/ml, 500 µg/ml, 2 mg/ml, 6 mg/ml, 8 mg/ml, 10 mg/ml **Hb/Hp:** 20 ng/ml, 40 ng/ml, 200 ng/ml, 1000 ng/ml, 100 µg/ml, 300 µg/ml, 500 µg/ml, 800 µg/ml, 1000 µg/ml
Kit real-time stability CLSI EP25-AE CLSI EP25-Ed2	No difference in performance after 18 months storage at 2 to 30°C.
Use environment	Storage and operating conditions showed no difference in performance at negative (Hb 9 ng/ml; Hb/Hp 2 ng/ml) and positive samples (Hb 21 ng/ml; Hb/Hp 6 ng/ml): - Temperatures between 20 to 30°C - Humidity between 10% to 80% Test cassettes were opened at 0h and 1h.

14. CLINICAL PERFORMANCE OF COLONVIEW QUICK TEST

The clinical sensitivity and specificity of BIOHIT ColonView® quick test (CVQT) was evaluated in two separate clinical studies of colonoscopy-referral patients[1,9]. Three fecal samples were tested, and all subjects were examined by diagnostic colonoscopy with biopsy verification. Clinical performance presented for carcinoma and adenoma.

Study	Target name	AUC	Sensi-tivity	Speci-ficity	PPV	NPV
CARCINOMA						
300 Patients[1]	CVQT Hb	0.946	98.9%	90.4%	89.5%	99.0%
	CVQT Hb/Hp	0.917	100%	83.3%	83.3%	100%
368 Patients[9]	CVQT Hb	0.782	91.9%	64.5%	35.8%	97.4%
	CVQT Hb/Hp	0.768	91.9%	61.6%	34.0%	97.2%
ADENOMA						
300 Patients[1]	CVQT Hb	0.842	78.0%	90.4%	86.6%	83.7%
	CVQT Hb/Hp	0.884	93.4%	83.3%	81.7%	94.1%
368 Patients[9]	CVQT Hb	0.544	44.2%	64.5%	53.1%	56.1%
	CVQT Hb/Hp	0.516	41.7%	61.6%	49.6%	53.8%

AUC = area under the curve, PPV = positive predictive value,
NPV = negative predictive value.

15. SERVICE AND MAINTENANCE

As the test device is a reagent kit with single use disposables, there are no service or maintenance requirements

16. TROUBLESHOOTING

Manufacturer's Customer Support productsupport@biohit.fi will offer assistance with the test system and answer questions concerning the performance. Any serious incident that has occurred in relation to the device must be reported immediately to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

17. ATTACHMENTS

BIOHIT ColonView® quick test, Sample Collection Instructions.

18. REFERENCES

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19. CHANGE HISTORY

Version	v15.2
Change description	Sample collection tube has been changed. Update of analytical and clinical performance. Sample stability and delivery time updated. Added version number for the kit.
Product version	2.1

NOTES

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