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**SUBJECT** Product launching



We are happy to announce the launch of a new product of the biorapid family based on immunochromatography technology:

**biorapid FOBT 20 Test** cod. 3000-1025

FOBT stands for “Fecal Occult Blood Test. This product is intended for the qualitative detection of human haemoglobin in faeces.

Occult blood in human faeces is frequently associated with gastrointestinal diseases.

biorapid FOBT includes a dedicated extraction vial with a filter in the dropper. This unique feature removes solid particles that may affects results.

First commercial batch, L-3504, Exp. 30/03/06 will be available 1<sup>st</sup> week of January 2005.

Find enclosed a complete product information that we hope helps you in the launch of the assay.

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# Introduction

Colon cancer is the third most common type of cancer in the world. The appearance of occult blood in human faeces is frequently associated with gastrointestinal diseases, which may cause colon cancer if not treated quickly and appropriately.

Reducing the number of deaths from colorectal cancer depends on detecting and removing pre-cancerous colorectal polyps as well as detecting and treating the cancer in its early stages (See *figure 1*). Colorectal cancer can be prevented by removing precancerous polyps, which can be present in the colon for years before invasive cancer develops.

Two tests have been shown to be beneficial in screening for colorectal cancer:

- The fecal occult blood test (FOBT) is a chemical or immunological test for blood that is visually undetectable in a stool sample.
- Flexible sigmoidoscopy is a screening procedure that uses a hollow, lighted tube to visually inspect the wall of the rectum and part of the colon.

Two other tests for colorectal cancer, colonoscopy and double-contrast barium enema, are commonly used by physicians. Several scientific organizations recommend regular screening for all adults aged 50 years or older.

Recommended screening procedures include the following three tests:

- FOBT every year
- Flexible sigmoidoscopy every 5 years
- Total colon examination by colonoscopy every 10 years or by double-contrast barium enema every 5-10 years.

Traditional faecal occult blood tests detect the peroxidase-like activity of haemoglobin in the stools and rely on the tendency of colorectal cancers to bleed. Resin from Guaico plant is utilized for producing such tests. Paper filter impregnated with the resin, in front of haemoglobin in feces and with presence of a developer, produces a dark blue color, indicative of a positive sample. Sensitivity is limited because many cancers and polyps bleed intermittently, so that blood is unevenly distributed in faeces. Occult blood tests fail to detect 20-50% of cancers and up to 80% of polyps. Specificity is also low and depends on whether patients avoid dietary sources of haemoglobin and myoglobin. Red and white meats, fish, some raw vegetables, and fruits containing peroxidase may yield false positive tests. Sensitivity is increased by rehydrating the slide with a drop of water before testing, but this is at the expense of decreased specificity. A positive test requires further evaluation by colonoscopy or sigmoidoscopy and barium enema.

New generation of faecal occult blood tests utilises an immunological reaction by means of an antibody that reacts specifically to the human haemoglobin. These tests are more sensitive and specific than the chemical tests and they are not affected by diet.

# biorapid FOBT

## Rapid one-step test for the qualitative detection of human haemoglobin in faecal samples

The Faecal Occult blood test is a immunochromatographic test for the qualitative detection of human haemoglobin in faeces. Haemoglobin in faeces is indication of internal bleedings associated to pathological conditions of the gastrointestinal tract, as colon polyps, colorectal cancer, ulcerous colitis and Grohn disease. This rapid test is much more sensitive and specific than traditional guaiaco test. It is much easier to interpret the result. The biorapid FOBT results are not affected by diet.

## Methodology

**biorapid FOBT** employs a combination of coloured colloidal particles conjugated with anti-human haemoglobin monoclonal antibodies and a solid-phase coated with specific human haemoglobin monoclonal antibodies.

The faecal specimen is first treated with an extraction solution to isolate the haemoglobin. Following extraction, the only step required is to dose the extract into the sample area of the test device.

**biorapid FOBT** includes a dedicated filter dropper that removes solid faeces from the solution particles and facilitates the interpretation.

As the sample flows through the test membrane, the colloid particle conjugated with anti-human haemoglobin monoclonal antibodies, binds to the haemoglobin forming an antigen-antibody complex. This complex binds to the immobilized anti-human haemoglobin monoclonal antibodies and produces a red line if sample contains haemoglobin. The reaction mixture continues flowing through the membrane test to the control zone.



## Kinetics of reaction

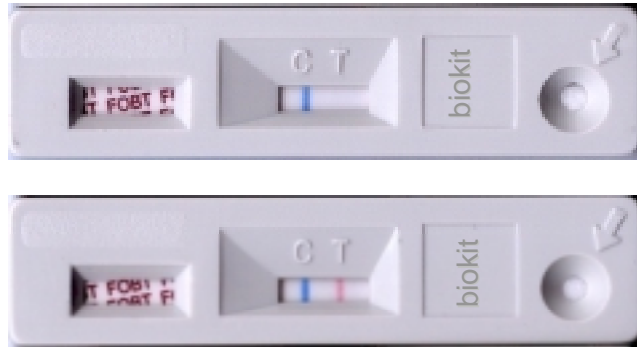
Immediately after the addition of the sample, the chromatographic process begins, which moves the latex particles along the chromatographic layer to the reacting area.

Between 1 and 5 minutes after the sample has been added, the residual particles of latex may continue to react, increasing the intensity of the signal or causing a slight signal in the case of weak positive samples with a low concentration of human haemoglobin. After 5 minutes, the flow of particles is complete and the chromatographic membrane will be washed by the remaining flow of sample, providing a greater colour band contrast. Depending on the concentration of human haemoglobin, the positive results will be obtained in less than 1 minute.

## Test description

The test is very sensitive, detecting 4 ng/ml of human haemoglobin. It is specific to the different sub-types of human haemoglobin: HbA<sub>0</sub>, HbA<sub>2</sub>, Hb<sub>S</sub>, Methaemoglobin. No cross-reaction is caused with the different animal haemoglobin present in the diet: turkey, beef, lamb, pigeon, horse, rabbit or pork. No cross-reaction has been detected with 1000 µg/ml peroxidase in the sample re-suspension buffer. The

prozone effect was not detected below  $5 \times 10^6$  ng/ml in the sample resuspension buffer.



### Material provided

- biorapid FOBT test devices.
- 1 x 50 ml of diluent buffer.
- 20 disposable stirrers.
- 20 Tip droppers with incorporated filter
- 20 Extraction vials

### Storage

The reagents will remain stable through the expiration date shown on the label if stored between 2-30°C. Do not freeze. **Very important: Do not let open the aluminium pouch if the device is not going to be used immediately.**

### Sample collection

Samples may be liquid, semi-solid or solid. Aqueous or diarrhoeic faeces are unsuitable for the test. It is important not to collect samples should any of the following circumstances arise: during menstruation, the present of bleeding haemorrhoids, patients with oral illnesses that cause haemorrhages, hiatus hernia or blood in urine. Alcohol, aspirin or other medicines in excess may cause gastrointestinal irritation leading to the presence of faecal occult blood. These types of substance must not be taken for at least 48 hours before taking the sample.

The samples must be kept at 2-8 °C for as short a time as possible before the test is carried out. For longer times, they must be frozen at -20°C. Frozen samples must be completely defrosted and allowed to reach room temperature.

It is very important to take the sample from 3-4 different places in the stool so that the possibilities of intermittent intestinal bleeding affecting the test results are minimised.

### Quality control

The Control line (C) is an internal procedural control. If the test has been performed correctly and the test device is functioning properly this line will always appear.

## Procedure

### PREPARATION OF SAMPLE

- Label an extraction vial for each sample to be tested.
- Remove the cap and the dropper **by pressing it laterally. Do not try to remove the dropper by traction.**
- Dispense 1.5 ml of the dilution buffer.
- Introduce the stirrer **vertically** in three different sites of the fecal sample to facilitate stirrer to be well impregnated of fecal material, as bleeding is frequently intermittent and blood could be not homogeneously distributed in the feces.
- Introduce the stirrer into the diluent buffer and swirl gently into the solution to complete dispersion of feces.
- Close the vial with the filter tip dropper and cap provided and previously retired.
- **Shake well manually or on a Vortex** to obtain an homogeneous suspension.

### TEST PROCEDURE

- Allow test devices and specimens to reach room temperature before using.
- Remove the test device from the pouch and place it on a flat surface.
- Label test device with patient name or identification number.
- Dispense 4 drops of the fecal extraction on the sample well of the test device. **It is important to let the first drop to absorb into the membrane before the next drop is added.**
- Read the result at 5 minutes after sample addition.
- Do not interpret the test after 10 minutes.

## Interpretation of the results

### POSITIVE

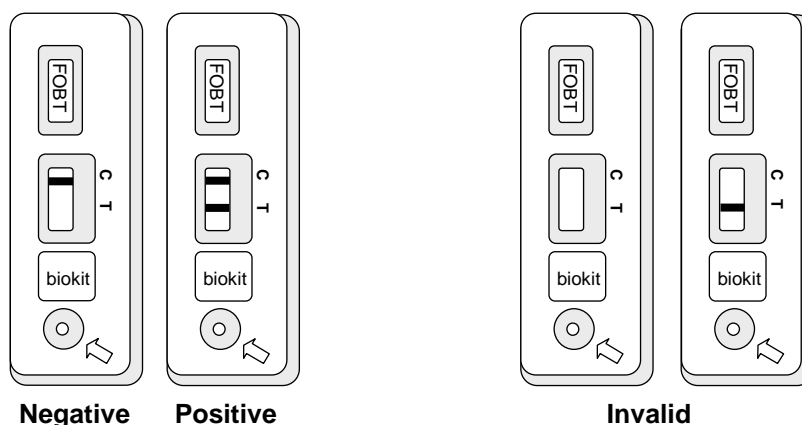
- The test result is positive if a red line appears in the window (T) together with the control line (C).
- The relative intensity of the Test line is variable depending on the concentration present in the sample.

### NEGATIVE

- If only the blue control line (C) is visible, the test result is negative.

### INVALID

- If no coloured lines appear or if only a test line is visible, the test is invalid. The sample should be retested using another test device.



### **Limitations of the procedure**

The test should be used for the detection of haemoglobin only in faecal samples. The significance of results must be evaluated in relation to the patient's clinical symptoms.

An excess of faecal sample may cause a prozone effect, conducting false negative results.

An excess of faecal sample may also cause to appear brown lines. In this case repeat the test with a higher dilution of the sample.

A negative result does not exclude the presence of haemoglobin in the sample.

## **Features and benefits biorapid FOBT**

<b>Features</b>	<b>Benefits</b>
<b>Lateral flow assay</b>	- Easiest method compared to guaiaco test
<b>Performance</b>	- Excellent sensitivity - Better specificity compared with guaiaco test
<b>Monoclonal antibody</b>	- No cross reaction with other animal haemoglobins
<b>Easy reading</b>	- Objective results - Little variation in performance and interpretation among individual users - Sharp bands - No background
<b>Filter in tip dropper</b>	- Removes solid particles from extracted samples - Avoids splashes when gas or skim is produced after vortex
<b>Small number of test presentation</b>	- Suitable for small customers
<b>Room temperature conservation</b>	- No extra refrigeration equipment need

# Performance characteristic

## Sensitivity: Detection limit

The internal standard of reference was prepared using the Sigma A<sub>0</sub> Haemoglobin ref. H0267, purified by hydrophobic interaction chromatography and diluted in the Tris/HCl saline buffer with detergents and germicide. The measurements are taken according to the instructions of the kit.

Measurements are taken in a similar manner to the W.H.O. international standard to see the calibration between both standards.

### Internal standard

ng/ml	Result (5')
64	+
32	+
16	+
8	+
4	+
2	±
1	-
0.5	-
0	-

### W.H.O. standard

ng/ml	Result (5')
64	+
32	+
16	+
8	+
4	+
2	±
1	-
0.5	-
0	-

Under such conditions, the detection limit using this internal standard of reference is 4 ng/ml. It can be seen that the correlation between the two standards is excellent and, therefore, the detection limit is 4 ng/ml.

## Detection limit in human faeces

A pool of negative faeces resuspended in the diluent buffer is formed: Tris/HCl saline buffer with detergents and germicides and Sigma A<sub>0</sub> ref. H0267 human haemoglobin purified by hydrophobic chromatography is added at different concentrations to evaluate the analytical sensitivity and the detection limit under these conditions. These same dilutions are tested after 120 minutes at 37 °C and at 4-8 °C.

<b> biorapid FOBT</b>			
A <sub>0</sub> Hb Faecal pool ng/ml	Time 0	Time 120' 4-8 °C	Time 120' 37 °C
	Result (5')	Result (5')	Result (5')
64	+	+	+
32	+	+	±
16	+	+	-
8	+	+	-
4	+	+	-
2	+	+	-

It is seen that the faecal haemoglobin is degraded in time and that this degradation is proportional to the temperature at which the faecal haemoglobin is to be found. Therefore, it is recommended that, once obtained from the patient, the samples must be kept cool until analysis, which should not be delayed.

The following table shows the results obtained when different types of faeces are tested following the equipment instructions.

The evaluation is carried out with very positive and weakly positive faeces and their serial dilutions:

Sample	dilution	Result (5')
Very positive faeces	1/1	+
	1/2	+
	1/4	+
	1/8	+
	1/16	+
	1/32	+
	1/64	+
	1/128	+
	1/256	+
	1/512	±
	1/1024	δ

Sample	dilution	Result (5')
Weak positive faeces	1/1	+
	1/2	±
	1/4	δ
	1/8	-
	1/16	-
	1/32	-
	1/64	-
	1/128	-
	1/256	-
	1/512	-
	1/1024	-

Under such conditions, the detection limit for a strong positive sample corresponds to the 1/512 dilution, while for a weak positive sample it is 1/2. The extensive difference obtained between the dilutions of the two faeces confirms that the presence of haemoglobin in faeces can be extremely variable and, therefore, the amount of intestinal bleeding very different, depending on the different clinical conditions of patients.

## Prozone effect

To determine the maximum Haemoglobin concentration affecting test effectiveness (Prozone effect), an internal standard heavily enriched in Sigma A<sub>0</sub> reference: H0267 human haemoglobin with 5,000,000 ng/ml is used.

Sigma Haemoglobin		Batch 1
5,000,000 ng/ml		+
Sample	dilution	Result (5')
Very positive faeces	1/1	+
	1/2	+
	1/4	+
	1/8	+
	1/16	+
	1/32	+
	1/64	+
	1/128	+
	1/256	+
	1/512	±
	1/1024	-

Sample	dilution	Result (5')
<b>Weak positive faeces</b>	1/1	+
	1/2	±
	1/4	-
	1/8	-
	1/16	-
	1/32	-
	1/64	-
	1/128	-
	1/256	-
	1/512	-
	1/1024	-

## Specificity

**biorapid FOBT** is subjected to an interference study using the chemical substances described in the table below, which showed that under no circumstances does it show any interference on negative or positive samples at the amounts tested.

The chemical substances indicated below were added to a negative faeces sample and another faeces sample with 4 ng/ml of haemoglobin previous added to it and they were then evaluated after 5 minutes according to the instructions. The results are indicated in the table:

	Concentration mg/dl	biorapid FOBT	
		Positive sample 4 ng/ml	Negative sample
		Result after adding interfere substance	
Acetaminophenol / Paracetamol	20	+	-
Acetylsalicylic Acid	20	+	-
Ampicillin	40	+	-
Ascorbic Acid / Vitamin C	100	+	-
Atropine	40	+	-
Caffeine	40	+	-
Gentisic Acid	40	+	-
Glucose	2000	+	-
Urea	4000	+	-
Uric Acid	10	+	-
Bilirubin	30	+	-
Peroxidase (Horseradish)	1000	+	-

## Specificity with animal haemoglobins

**biorapid FOBT** was subjected to an evaluation with haemoglobins from animals, which are commonly present in our diet. The amounts indicated in the table were added to a negative faeces sample and the evaluation was made after 5 minutes.

HAEMOGLOBIN	Concentration µg/ml	biorapid FOBT
		Negative sample
BOVINE	1000	-
OVINE	1000	-
PORCINE	1000	-
PIGEON	500	-
TURKEY	1000	-
RABBIT	1000	-
HORSE	1000	-
CHICKEN	Coagulated and lysed blood	-

# Comparison with other methods

## 1. Immunochromatographic methods

A panel of 42 fecal positive and 7 negative samples were tested in parallel with biorapid FOBT, and two additional immunochromatographic devices.

- 1.- FOBT. Biomedics.
- 2.- Hexagon OBTI test. Human

Discrepant samples were treated with a monoclonal antibody to human haemoglobin as an inhibitory method.

	HUMAN	BIOMEDICS	Biorapid FOBT		HUMAN	BIOMEDICS	Biorapid FOBT
1	-	-	-	26	+	+	+
2	+	+	+	27	+	+	+
3	+	+	+	28	+	+	+
4	+	+	+	29	-	-	-
5	ND	ND	ND	30	-	-	-
6	+	+	+	31	-	-	-
7	+	+	+	32	+	+	+
8	+	+	+	33	-	-	+
9	+	+	+	34	+	+	+
10	+	+	+	35	+	+	+
11	+	+	+	36	-	+	+
12	-	+	+	37	+	+	+
13	-	+	+	38	+	+	+
14	-	-	+	39	+	+	+
15	+	+	+	40	-	+	+
16	+	+	+	41	+	+	+
17	+	+	+	42	-	-	+
18	+	+	+	43	-	-	-
19	+	+	+	44	+	+	+
20	-	+	+	45	-	-	-
21	+	+	+	46	-	+	+
22	-	-	+	47	-	-	+
23	-	-	+	48	-	-	+
24	-	+	+	49	-	+	+
25	-	-	-	50	+	+	+
+	15	19	22	+	12	16	20
-	9	5	2	-	13	9	5

	NEGATIVE	POSITIVE	TOTAL
<b>HUMAN</b>	22	27	49
<b>BIOMEDICS</b>	14	35	49
<b>biorapid FOBT</b>	7	42	49
<b>REFERENCE</b>	7	42	49

		HUMAN	
		+	-
REFERENCE	+	27	15
	-	0	7

	Sensitivity	Specificity
<b>HUMAN</b>	64,2 %	100 %

		BIOMEDICS	
		+	-
REFERENCE	+	35	7
	-	0	7

	Sensitivity	Specificity
BIOMEDICS	83,3 %	100 %

		biorapid FOBT	
		+	-
REFERENCE	+	42	0
	-	0	7

	Sensitivity	Specificity
biorapid FOBT	100 %	100 %

### Summary of results

	SENSITIVITY	SPECIFICITY	VPN	VPP
HUMAN	64,2 %	100 %	31,8 %	100 %
BIOMEDICS	83,3 %	100 %	50 %	100 %
biorapid FOBT	100 %	100 %	100 %	100 %

## 2. Comparison with classical guaiaco test

**biorapid FOBT** was tested in comparison with Hemocult Sensa II (Beckman-Coulter). Hemocult Sensa II is a modification of the guaiaco test. Haemo group of the haemoglobin has a peroxidase activity, able to decompose the peroxide of hydrogen contained in the reagent test, able to produce a coloured reaction.

This is a test designed to be performed by the patient himself, to be sent by mail to a reference lab. On the lab, the results are not stable and colour disappears few minutes later.

Haemocult sensitivity claimed by manufacturer is 75% when there is 0.3 mg of haemoglobin per gram of faeces. (Daily loss of 2-3 ml of blood). Sensitivity rises almost 100% when daily loss is 10 ml.

Specificity of the assay is affected by haemoglobin of other animal species present in diet and for other group of proteins that include the hemo group, such as peroxidases present in ingested fruits and vegetables. In addition there are endogenous microperoxidases from the own individual that may produce non-specific reactions.

Specificity of the Hemocult is lower than the immunological test and also conditioned to a strict follow-up of a 72 hours diet before testing

**biorapid FOBT** and Hemocult II SENSAs (Beckman Coulter) were tested with a panel of 15 positive and negative samples discrepant from other methods.

Neutralization method by monoclonal anti-human haemoglobin was used to characterized the samples.

	<b>NEGATIVE</b>	<b>POSITIVE</b>	<b>TOTAL</b>	<b>SENSITIVITY</b>	<b>SPECIFICITY</b>
<b>biorapid FOBT</b>	5	15	20	100 %	100 %
<b>HEMOCCULT</b>	12	8	20	53,3 %	100 %
<b>REFERENCE</b>	5	15	20		



# bioKIT

## biorapid FOBT

Made in SPAIN by:  
**BIOKIT, S.A.**  
08186 Lliçà d'Amunt  
**BARCELONA**



3300-3312-12/04

<b>GARANTÍA DE CALIDAD</b>	
Fecha	14-12-04
V.º B.º	—

**CE**

REF 3000-1025

# **biorapid FOBT**

## **Rapid one-step test for the qualitative detection of occult blood in feces.**

### **Summary**

Fecal occult blood test is an immunochromatographic test for the qualitative detection of human hemoglobin in feces. Hemoglobin in feces is an indication of internal bleedings associated to pathological conditions of the gastrointestinal tract, as colon polyps, colorectal cancer, ulcerous colitis and Crohn disease. This test is much more sensitive and specific than the traditional gualacco test and easier to perform. The FOBT results are not affected by the diet of patients.

### **Principle**

biorapid FOBT employs a combination of coloured latex particles coated with anti-human hemoglobin monoclonal antibodies and solid-phase specific anti-human hemoglobin antibodies. Following the extraction of the fecal sample, the only step required is to dose the extract into the sample well of the test device. As the sample flows through the test membrane, the latex-conjugated with anti-human hemoglobin monoclonal antibodies, binds to the human hemoglobin of the sample forming an antigen-antibody complex. This complex binds to the anti-human hemoglobin monoclonal antibodies immobilized on the test zone (T) producing a red line if the sample contains hemoglobin. The reaction mixture continues flowing through the membrane test to the control zone (C) forming a second coloured blue line indicating the proper performance of the test.

### **Components**

[REF] 3000-1025.

- [TEST] 20 biorapid FOBT test devices.
- [DIL] 1 x 50 ml of diluent buffer. Contains < 0.1% sodium azide.
- [VIALS] 20 extraction vials with tip droppers and filters.
- [STIRRERS] 20 disposable stirrers.

### **Precautions**

biorapid FOBT is intended for IN VITRO diagnostic use.

Sodium azide may react with lead or copper pipes and plumbing creating highly explosive metal azides. Flush drains with water thoroughly after disposing of the remains of reagents.

Because no test method can offer complete assurance of the absence of infectious agents, this product should be handled with caution.

All specimens should be handled as if they were capable of transmitting infectious agents.

Do not use test devices if the aluminum pouch has been damaged during storage.

Dispose all used materials in a suitable biohazardous waste container.

### **Storage**

The reagents will remain stable through the expiration date shown on the label if stored between 2-30°C. Do not freeze.

### **Sample collection**

Fecal samples should be collected in clean and dry containers, free of detergents. Avoid contamination from water and/or other substances coming from the collection. Once collected, specimens should be stored at 2-8°C. If the test is not performed within 24 hours of sample collection, the specimens should be stored at -20°C, without diluting or other manipulations.

It is recommended **NOT** to use the fecal samples in the following situations:

- Menstrual period.
- Presence of bleeding hemorrhoids.
- Presence of blood in urine.
- Bleedings by other origins (nasal, dental surgery...).
- Intestinal bleedings by ingestion of alcohol, aspirin, anti-inflammatory and other substances that can produce gastrointestinal mucosal irritation. It is recommendable to discontinue prescription some days before the analysis in feces of the treated patients.

## Quality control

The Control line (C) is an internal procedural control. If the test has been performed correctly and the test device is functioning properly this line will always appear.

## Procedure

### PREPARATION OF SAMPLE

- Label an extraction vial for each sample to be tested.
- Remove the cap and the tip dropper of the vial by pressing it laterally.
- Dispense 1.5 ml of the dilution buffer into the vial.
- Introduce the stirrer vertically in three different sites of the fecal sample to facilitate stirrer to be well impregnated of fecal material, as bleeding is frequently intermittent and blood could be not homogeneously distributed in the feces.
- Introduce the stirrer into the diluent buffer and swirl gently into the solution to complete dispersion of feces.
- Close the vial with the filter tip dropper and cap provided and previously retired.
- Shake well manually or on a Vortex to obtain an homogeneous suspension.

## Test procedure

- Allow test devices and specimens to reach room temperature before using.
- Remove the test device from the pouch and place it on a flat surface.
- Label test device with patient name or identification number.
- Dispense 4 drops of the fecal extraction on the sample well of the test device. It is important to let the first drop to absorb into the membrane before the next drop is added.
- Read the result at 5 minutes after sample addition.
- Do not interpret the test after 10 minutes.

## Interpretation of the results

### POSITIVE

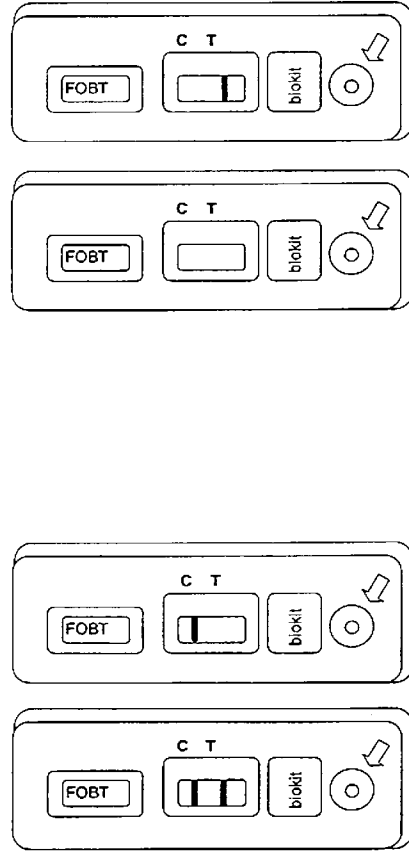
The test result is positive if a red line appears in the window (T) together with the control line (C). The relative intensity of the test line is irrelevant to the test result.

### NEGATIVE

If only the blue control line (C) is visible, the test result is negative.

### INVALID

If no colored lines appear or if only a test line is visible, the test is invalid. The sample should be retested using another test device.



POSITIVE

NEGATIVE

INVALID

## Limitations of the procedure

The test should be used for the detection of hemoglobin only in fecal samples. The significance of results must be evaluated in relation to the patient's clinical symptoms. An excess of fecal sample may cause a prozone effect that can give false negative results. A negative result does not exclude the presence of hemoglobin in the sample.

## Performance characteristics

### Analytical sensitivity

The detection limit of the biorapid FOBT has been evaluated in front of the WHO International Standard for hemoglobin ref. 89/686 and has been of 4 ng/ml of human HbA<sub>2</sub>.

### Diagnostic sensitivity

Comparative studies with other diagnostic methods have shown that the sensitivity of biorapid FOBT is around 98%.

### Specificity

It has been demonstrated that biorapid FOBT specificity is higher than 97%. The use of monoclonal antibodies assures a high degree of specificity for the detection of human hemoglobin (A<sub>0</sub>, A<sub>2</sub>, S and metahemoglobin) and does not react with animal hemoglobin coming from regular ingestion.

## Interfering substances

The following substances and concentrations do not affect the expected test results.

	Concentration mg/dl
Acetaminophen / Paracetamol	20
Acetylsalicylic acid	20
Ampicillin	40
Ascorbic acid / Vitamin C	100
Atropine	40
Caffeine	40
Gentisic acid	40
Glucose	2000
Urea	4000
Uric acid	10
Bilirubin	30
Peroxidase (Horseradish)	1000

# biorapid FOBT

20 TESTS

REF 3000-1025

qualitative test for detection of human HEMOGLOBIN  
in faeces / test cualitativo para la detección de  
HEMOGLOBINA humana en heces



## biorapid FOBT

DIL

50 ml

IVD

LOT L-2004  
2005-06-26



## biorapid FOBT

TEST

IVD

LOT L-2004  
2005-06-26



IVD



CE



20

TEST

1 x 50 ml

DIL

20

VIALS

20

STIRRERS



## biorapid FOBT

REF 3000-1025



8 436003 076124

LOT L-2004

2005-06-26

GARANTÍA DE CALIDAD

Fecha 22-11-04

V.º B.º