

# Product Data for Colon Polyps Prevention Test

- an immunochromatographic assay for qualitative determination of human Hemoglobin in feces

## **Introduction**

Test principle  
Interpretation  
Limitation

## **Performance**

Sensitivity  
Specificity and cross-reactions

## **Correlation**

Colon Polyps Prevention Test vs. Haemoccult vs.  
colonoscopy

## **Real Time Stability Data**

# References

## Introduction:

The Colon Polyps Prevention Test is a rapid, convenient and practically very hygienic method for detecting fecal occult blood, which may be indicative of gastrointestinal diseases associated with bleeding such as colorectal carcinoma, Crohn's disease, ulcerative colitis, and colon polyps.

## **PRINCIPLES OF THE PROCEDURE**

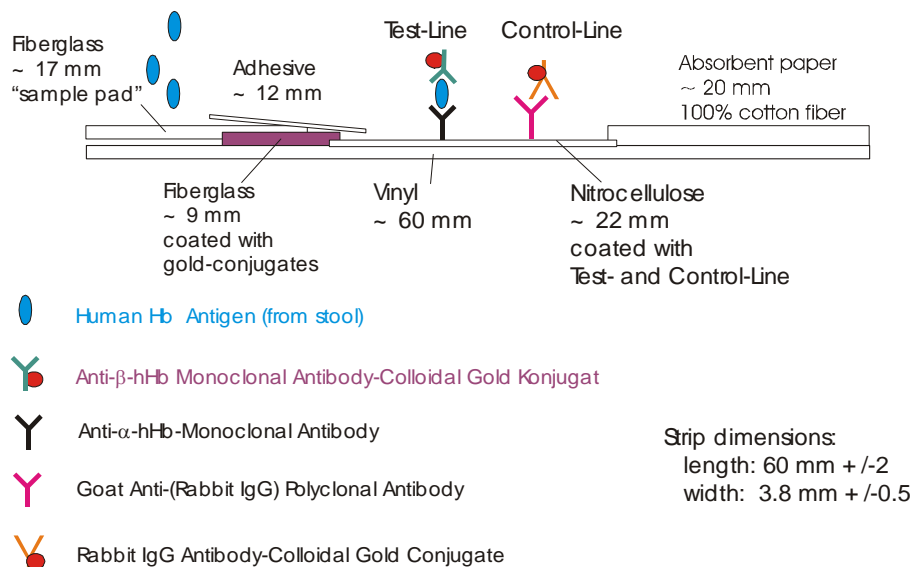
Colon Polyps Prevention Test incorporates a monoclonal antibody-colloidal gold conjugate specific to  $\beta$ -hHB to bind to hHB and a surface coated with monoclonal antibodies specific to  $\alpha$ -hHB to capture the complex. As the test strip in the test cassette is in contact with the specimen buffer mixture, the antibody coated surface captures intact hHB bound to the antibody-colloidal gold conjugate forming a complex and giving a colored test line. In the absence of intact hHB in the sample, independent unbound conjugate binds to an antibody in the control area and appears as purple color band confirming the correct test performance.

Detection Limit: 0,05  $\mu$ g hHB / ml Buffer resp.  $\sim$ 0,03 mg hHB / g Stuhl

Incubation time: RESULTS 5 MINUTES AFTER APPLICATION OF SPECIMEN

Active Ingredients: Bovine Serum Albumin  
Goat Anti-(Rabbit IgG) Polyclonal Antibody  
Anti- $\alpha$ -hHB Monoclonal Antibody  
Rabbit IgG Colloidal Gold Conjugate  
Anti- $\beta$ -hHB Monoclonal Antibody-Colloidal Gold Conjugate

Buffer: Bovine Serum Albumin  
Sodium Azide  
Sodium Dibasic Phosphate  
Sodium Chloride





Conclusions: The minimum detectable concentration of hHB is 0,05 µg / ml buffer or ~0,03mg hHB / g stool. The test is capable of qualitative testing hHB at a concentration of 0,05 µg / ml – 500 µg / ml or 0,03-60 mg / g stool.

**The Colon Polyps Prevention Test is specific to human hemoglobin. Positive and negative specimens containing the following potentially interfering substances were tested with no effect on test result:**

Substance	Concentration	Comments
Chicken HB	500 µg / ml	PASS
Pork HB	500 µg / ml	PASS
Beef HB	2000 µg / ml	PASS
Goat HB	500 µg / ml	PASS
Horse HB	500 µg / ml	PASS
Rabbit HB	500 µg / ml	PASS
Horseradish Peroxidase	2000 µg / ml	PASS

No interference from common stools has been observed.

## **Correlation Study**

For the purpose of this study the immunochromatographic Colon Polyps Prevention Test was compared to a extremely widely used test for fecal occult blood, namely HAEMOCCULT, that is based on the guaiac method and to a reference method, namely COLONOSCOPY.

**251 patients completed all 3 test procedures  
and the following results were obtained:**

Colon Polyps Prevention Test		Haemoccult		Colonoscopy			
+	69	+	29	+	26		
			-	40	-	3	
		-	182	+	2	+	1
				-	180	-	1
		+	34	+	33		
		-	146	-	7		
Sum	251	Sum	251	Sum	251		

		+	-	Total
Colonoscopy +	Colon Polyps Prevention Test	59	35	94
	Haemoccult	27	67	94
Colonoscopy -	Colon Polyps Prevention Test	10	147	157
	Haemoccult	4	153	157
Sum				251

## **SENSITIVITY**

The sensitivity is the estimate of the percent of true positives for the Colon Polyps Prevention Test, that is, the percent of the positive reference results which are positive by the Colon Polyps Prevention Test.

Therefore the relative sensitivity of Colon Polyps Prevention Test when compared to the reference method (colonoscopy) is calculated as follows:

$$59/94 * 100 = 63\%.$$

*The sensitivity of Haemoccult in this test is  $27/94 * 100 = 28,7\%$ .*

One has to note here, that colonoscopy is only able to find bleeding sources in the colon area, but not at all more anterior regions. This can be seen as reason for virtually false positive results of Colon Polyps Prevention Test. Additionally due to this fact sensitivity is actually not an allowed attribute for comparison. But generally, for screening tests high sensitivity is desired.

## **SPECIFICITY**

The specificity is the percent of true negatives for the Colon Polyps Prevention Test test, that is, the percent of the negative reference results which are negative by the Colon Polyps Prevention Test.

The specificity of Colon Polyps Prevention Test when compared to the reference method (colonoscopy) is calculated as follows:

$$147/157 * 100 = 94\%$$

*The specificity of Haemoccult in this test is  $153/157 * 100 = 97\%$ .*

**Real Time Stability Test Results for Colon Polyps Prevention Test,  
stored at 15°C – 28°C  
Tested over 18 months**

L O T 1	Type	Sample	Rep- licate	Real Time Stability (Months)																	
				0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Visual Assay	Negative Control	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
		2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Visual Assay	0,05 µg hHB / ml	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
		2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

L O T 2	Type	Sample	Rep- licate	Real Time Stability (Months)																	
				0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Visual Assay	Negative Control	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
		2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Visual Assay	0,05 µg hHB / ml	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
		2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

L O T 3	Type	Sample	Rep- licate	Real Time Stability (Months)																	
				0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Visual Assay	Negative Control	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
		2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Visual Assay	0,05 µg hHB / ml	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
		2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

**REFERENCES:**

1. Kutter, D., Kremer, A., Aspesberro, F., and Gallego, F., Department des Sciences, Centre Universitaire de Luxembourg, Z.med.Lab.diagn. 32, 3/4 (1991)