

(Revised 10/18/2002)

Product Name:	Hämoglobin-Haptoglobin Combo-Test DIMDI-Reg-Nr.: DE/CA22/1116-185-IVD	KGST173	Max Reading Time	10'
Product Format:	Cassette		Specimen:	Human Stool
Lot Number:	201011088		Exp Date:	2013-04
			Quantity:	

Raw materials:

1. All reagents and raw materials used in the manufacture of the one step tests are qualified for use by many different parameters.
 2. Only qualified materials are released to manufacturing for product preparation. 3. All the reagents are uniformly dissolved in the solution during the production process.

Visual Result Description:

Positive: 2 colored lines visible in the result window within the maximum reading time.
 Negative: 1 colored lines visible in the result window within the maximum reading time.
 Invalid: No lines visible in the result window within the maximum reading time.

Storage: Product must be stored at room temperature avoid direct sunlight.

Functional Quality Inspection:

The functional ability of the product is tested by randomly chosen samples from the finished products. Follow the procedure specified in the insert.

Detailed visual test results

		positive control							
ITEM	Sensitivity	1		2		3		4	
		C	T	C	T	C	T	C	T
Hb	50 ng/ml	30"	1'36"	32"	1'38"	30"	1'36"	32"	1'38"
Hb/Hp	80 ng/ml	34"	1'37"	36"	1'39"	34"	1'37"	34"	1'39"
		negative control							
ITEM	negative control	5		6		7		8	
		C	T	C	T	C	T	C	T
Hb	-Human Stool	29"	-	31"	-	29"	-	31"	-
Hb/Hp	-Human Stool	28"	-	30"	-	28"	-	30"	-

Conclusion: Pass x Not Pass

This batch of the product is assigned to the following lot number and expiration date.



QM-Manager
 Günter Keul

2010-11-21
 Date

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