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## Certificate of Analysis

(Revised 10/18/2002)

<b>Product Name:</b>	<b>Hämoglobin-Haptoglobin Combo-Test</b>	<b>KGST173</b>	<b>Max Reading Time</b>	<b>10'</b>
<b>Product Format:</b>	Cassette		<b>Specimen:</b>	Human Stool
<b>Lot Number:</b>	20080504		<b>Exp Date:</b>	2010-10
			<b>Quantity:</b>	

### 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

		<b>positive control</b>							
ITEM	Sensitivity	1		2		3		4	
		C	T	C	T	C	T	C	T
Hb	25 ng/ml	46"	3'14"	48"	3'16"	46"	3'14"	48"	3'16"
Hb/Hp	25 ng/ml	1'06"	1'39"	1'08"	1'41"	1'06"	1'39"	1'08"	1'41"
		<b>negative control</b>							
ITEM	negative control	5		6		7		8	
		C	T	C	T	C	T	C	T
Hb	-Human Stool	49"	-	51"	-	49"	-	51"	-
Hb/Hp	-Human Stool	51"	-	53"	-	51"	-	53"	-

Conclusion: Pass   x   Not Pass                   

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

QM-Manager  
 Günter Keul

2008-06-07  
 Date

09SM02005