

(Revised 10/18/2002)

Product Name:	BCM-Test	KGST205	Max ReadingTime	10'
Product Format:	Cassette		Secimen:	Human Urine
Lot Number:	201111108		Exp. Date:	2014-04
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	+Human urine	44"	9'	46"	9'	44"	9'	46"	9'
Bladder	+Human urine	1'02"	1'29"	1'04"	1'31"	1'02"	1'29"	1'04"	1'31"
		negative control							
ITEM	negative control	5		6		7		8	
		C	T	C	T	C	T	C	T
Hb	-Human urine	1'02"	-	1'04"	-	1'02"	-	1'04"	-
Bladder	-Human urine	1'10"	-	1'12"	-	1'10"	-	1'12"	-

 Conclusion: Pass x Not Pass

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



 QM-Manager
 Günter Keul

2011-12-17
 Date

09SM02005