

(Revised 10/18/2002)

Product Name:	Combi-Cardiac-Test	KGST125	Max Reading Time	15'
	DIMDI-Reg.-Nr.:			
	DE/CA22/1116-167-IVD			
Product Format:	Dipstrip ()	Cassette (x)	Midstream ()	Other ()
Specimen:	Urine ()	Serum (x)	Whole Blood (x)	Other ()
Negative Control Lot:	10102704		Sensitivity:	1 ng/ml 50 ng/ml 5 ng/ml
Positive Control Lot:	29743		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: ___2-4___ 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.

a. Detailed visual test results using negative control:

Sample No.	Negative Control or Specimen	"Test Line" Observed at	"Test Line" Observed at	"Test Line" Observed at	"Control Line" Observed at	Background Clearance Observed at
1	- Whole Blood	- WITHIN 15'	- WITHIN 15'	- WITHIN 15'	+ AT 2'46"	3'
2	- Whole Blood	- WITHIN 15'	- WITHIN 15'	- WITHIN 15'	+ AT 2'50"	3'
3	- Whole Blood	- WITHIN 15'	- WITHIN 15'	- WITHIN 15'	+ AT 2'46"	3'
4	- Whole Blood	- WITHIN 15'	- WITHIN 15'	- WITHIN 15'	+ AT 2'50"	3'

b. Detailed visual test results using positive control:

Sample No.	Positive Control or Specimen	"Test Line3" Observed at	"Test Line2" Observed at	"Test Line1" Observed at	"Control Line" Observed at	Background Clearance Observed at
5	+ Whole Blood	+ AT 5'12"	+ AT 3'14"	+ AT 2'09"	+ AT 2'39"	3'
6	+ Whole Blood	+ AT 5'15"	+ AT 3'15"	+ AT 2'10"	+ AT 2'40"	3'
7	+ Whole Blood	+ AT 5'12"	+ AT 3'14"	+ AT 2'09"	+ AT 2'39"	3'
8	+ Whole Blood	+ AT 5'15"	+ AT 3'15"	+ AT 2'10"	+ AT 2'40"	3'

Conclusion: Pass ___x___ Not Pass _____

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

Lot Number:201012106
Exp Date :2013-05


 QM-Manager
 Günter Keul

20010-12-24
 Date

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