

(Revised 10/18/2002)

Product Name: Semi CEA-Test	KGST186	Max Reading Time 15'
DIMDI Reg.-Nr.: DE/CA22/1116-145-IVD		
Product Format: Dipstrip ()	Cassette (x)	Midstream () Other ()
Specimen: Urine ()	Serum (x)	Whole Blood (x) Other ()
Negative Control Lot: 569418506	Sensitivity: 5ng/ml	
Positive Control Lot: 1601	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: 3 colored lines visible in the result window within the maximum reading time.
 Negative: 2 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	"Control Line" Observed at	"Reference Line" Observed at	Background Clearance Observed at
1	< 5ng/ml	- WITHIN 15'	+ AT 2'05"	+ AT 2'41"	3'
2	< 5ng/ml	- WITHIN 15'	+ AT 2'07"	+ AT 2'43"	3'
3	< 5ng/ml	- WITHIN 15'	+ AT 2'05"	+ AT 2'41"	3'
4	< 5ng/ml	- WITHIN 15'	+ AT 2'07"	+ AT 2'43"	3'

b. Detailed visual rest results using positive control:

Sample No.	Positive Control or Specimen	"Test Line" Observed at	"Control Line" Observed at	"Reference Line" Observed at	Background Clearance Observed at
5	= 5 ng/ml	+ AT 15'' Color=R	+ AT 1'50"	+ AT 2'26"	3'
6	= 5 ng/ml	+ AT 15'' Color=R	+ AT 1'52"	+ AT 2'28"	3'
7	> 5 ng/ml	+ AT 15'' Color>R	+ AT 1'55"	+ AT 2'15"	3'
8	> 5 ng/ml	+ AT 15'' Color>R	+ AT 1'57"	+ AT 2'17"	3'

Conclusion: Pass x Not Pass

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

Lot Number: 201111106

Exp Date :2014-04



QM-Manager
 Günter Keul

2011-04-12
 Date

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