

(Revised 10/18/2002)

<b>Product Name:</b>	<b>Semi AFP-Test</b>	<b>KGST111</b>	<b>Max Reading Time</b>	<b>10'</b>
	DIMDI Reg.-Nr.: DE/CA22/1116-146-IVD			
<b>Product Format:</b>	Dipstrip ( )	Cassette ( x )	Midstream ( )	Other ( )
<b>Specimen:</b>	Urine ( )	Serum ( x )	Whole Blood ( x )	Other ( )
<b>Negative Control Lot:</b>	10061101-8		<b>Sensitivity:</b>	25ng/ml
<b>Positive Control Lot:</b>	A0221		<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: 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	- Serum	- WITHIN 10'	+ AT 1'24"	+ AT 1'45"	3'
2	- Serum	- WITHIN 10'	+ AT 1'26"	+ AT 1'43"	3'
3	< 25 ng/ml	- WITHIN 10'	+ AT 1'24"	+ AT 1'45"	3'
4	< 25 ng/ml	- WITHIN 10'	+ AT 1'26"	+ AT 1'43"	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	= 25 ng/ml	+ AT 4'27" Color=R	+ AT 1'09"	+ AT 1'29"	3'
6	= 25 ng/ml	+ AT 4'29" Color=R	+ AT 1'11"	+ AT 1'31"	3'
7	> 25 ng/ml	+ AT 2'02" Color>R	+ AT 1'29"	+ AT 1'30"	3'
8	> 25 ng/ml	+ AT 2'04" Color>R	+ AT 1'31"	+ AT 1'32"	3'

Conclusion: Pass x Not Pass \_\_\_\_\_

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

**Lot Number: 201103108**

**Exp Date :2013-08**



QM-Manager  
 Günter Keul

2011-04-12  
 Date

**09SM02005**