

(Revised 10/18/2002)

<b>Product Name:</b>	<b>StrepA</b>	<b>KGST109</b>	<b>Max Reading Time</b>	<b>10'</b>
<b>Product Format:</b>	Dipstrip ( )	Cassette ( x )	Midstream ( )	Other ( )
<b>Specimen:</b>	Urine ( )	Serum ( )	Whole Blood ( )	Other ( x )
<b>Negative Control Lot:</b>	09021204		<b>Sensitivity:</b>	N/A
<b>Positive Control Lot:</b>	08020101		<b>Quantity:</b>	

**Raw materials:**

- All reagents and raw materials used in the manufacture of the one step tests are qualified for use by many different parameters.
- Only qualified materials are released to manufacturing for product preparation.
- 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.

## a. Detailed visual test results using negative control:

Sample No.	Negative Control or Specimen	"Test Line" Observed at	"Control Line" Observed at	Background Clearance Observed at
1	-HUMAN CELL	- WITHIN 10'	+ AT 27"	3'
2	-HUMAN CELL	- WITHIN 10'	+ AT 29"	3'
3	-HUMAN CELL	- WITHIN 10'	+ AT 27"	3'
4	-HUMAN CELL	- WITHIN 10'	+ AT 29"	3'

## b. Detailed visual rest results using positive control:

Sample No.	Positive Control or Specimen	"Test Line" Observed at	"Control Line" Observed at	Background Clearance Observed at
5	+HUMAN CELL	+ AT 33"	+ AT 23"	3'
6	+HUMAN CELL	+ AT 35"	+ AT 25"	3'
7	+HUMAN CELL	+ AT 33"	+ AT 23"	3'
8	+HUMAN CELL	+ AT 35"	+ AT 25"	3'

 Conclusion: Pass   x  

Not Pass \_\_\_\_\_

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

**Lot Number:20100405**
**Exp Date: 2012-09**


 QM-Manager  
 Günter Keul

2010-04-26

Date

**09SM02005**