



**BGT**  
**BioGenTechnologies**  
**GmbH**  
 Von-Langen-Weg 10  
 48565 Steinfurt  
 e-mail: info@biogentechnologies.de  
 web: www.biogentechnologies.de

## Certificate of Analysis

(Revised 10/18/2002)

<b>Product Name:</b>	<b>Semi-Ferritin-Test</b>	<b>KGST171</b>	<b>Max Reading Time</b>	<b>15'</b>
<b>Product Format:</b>	Dipstrip ( )	Cassette ( x )	Midstream ( )	Other ( )
<b>Specimen:</b>	Urine ( )	Serum ( x )	Whole Blood ( x )	Other ( )
<b>Negative Control Lot:</b>	N/A		<b>Sensitivity:</b>	50ng/ml
<b>Positive Control Lot:</b>	<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:   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	< 10ng/ml	- WITHIN 15'	+ AT 1'19"	+ AT 1'41"	3'
2	< 10ng/ml	- WITHIN 15'	+ AT 1'21"	+ AT 1'43"	3'
3	< 10ng/ml	- WITHIN 15'	+ AT 1'19"	+ AT 1'41"	3'
4	< 10ng/ml	- WITHIN 15'	+ AT 1'21"	+ 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	=50ng/ml	+AT5' Color=R	+ AT 1'22"	+ AT 1'07"	3'
6	=50ng/ml	+AT5'02" Color=R	+ AT 1'24"	+ AT 1'09"	3'
7	> 50ng/ml	+AT3'10" Color > R	+ AT 1'20"	+ AT 1'09"	3'
8	> 50ng/ml	+AT3'12" Color > R	+ AT 1'22"	+ AT 1'11"	3'

Conclusion: Pass   x   Not Pass           

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

**Lot Number:20080701**

**Exp Date :2010-12**

QM-Manager  
Günter Keul

2008-05-08  
Date

**09SM02005**