



**QMLab GmbH**

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## Certificate of Analysis

RE-TYPED FROM THE ORIGINAL CERTIFICATE

Date: 2009-02-02

Product: Bladder Cancer Marker Test Cassette

PRODUCT CODE/ ART.-NO.	LOT NUMBER	EXPIRATION DATE	QUANTITY	PHYSICAL APPEARANCE
QML176	004A215-8128	2011-12	8500	conforms

### 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. 2. All the reagents are uniformly dissolved in the solution during the production process.

### Visual Result Description:

Positive: Two colored lines visible in the result window within the maximum reading time.  
Negative: One 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.

Detailed visual test results:									
		positive control							
ITEM	positive control	1		2		3		4	
		C	T	C	T	C	T	C	T
Hb	+ Human urine	48"	57"	50"	59"	48"	57"	50"	59"
Bladder	+ Human urine	27"	57"	29"	59"	27"	57"	29"	59"
		negative control							
ITEM	positive control	5		6		7		8	
		C	T	C	T	C	T	C	T
Hb	- Human urine	46"	-	48"	-	46"	--	48"	-
Bladder	- Human urine	26"	-	28"	-	26"	-	28"	-

Conclusion: Pass   x   Not Pass           

This batch of the product is assigned to the lot number and expiration day above.

### PRODUCT MANUFACTURING

The above listed product has been manufactured in accordance with the relevant standards (DIN EN ISO 13485:2003). No radioactive material of any kind is utilized in the product, or in the manufacturing of the product.

The above listed product does not contain any virus, reactive by-product of the same, or metabolic by-product of hepatitis A, B, C, or D or of the antibodies for the human acquired immune deficiency syndrome (AIDS).

If this product is shipped as bulk, QMLab GmbH assumes no responsibility for the packing and label claims.

QM-Management  
Günter Keul