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Certificate of Analysis

(Revised 10/18/2002)

Product Name:	Rota-Adeno-Combo	KGST195	Max Reading Time	10'
Product Format:	Cassette		Specimen:	Human Stool
Lot Number:	20081101		Exp Date:	2011-04
			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: ___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.

Detailed visual test results using negative control:

		positive control							
ITEM	Sensitivity	1		2		3		4	
		C	T	C	T	C	T	C	T
Adeno	+Human Sample	37"	3'16"	39"	3'18"	37"	3'16"	39"	3'18"
Rota	+Human Sample	27"	1'51'	29"	1'53"	27"	1'51"	29"	1'53"
		negative control							
ITEM	negative control	5		6		7		8	
		C	T	C	T	C	T	C	T
Adeno	-Human Stool	39"	-	41"	-	39"	-	41"	-
Rota	-Human Stool	29"	-	31"	-	29"	-	31"	-

Conclusion: Pass ___x___ Not Pass _____

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

QM-Manager
 Günter Keul

2008-11-30

Date

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