

(Revised 10/18/2002)

Product Name:	Rota-Adeno-Combo DIMDI Reg.-Nr.: DE/CA22/1116-190-IVD	KGST195	Max Reading Time	10'
Product Format:	Cassette		Specimen:	Human Stool
Lot Number:	201111107		Exp Date:	2014-04
			Quantity:	

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.

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

2011-12-17
 Date

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