

K960703

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## SUMMARY OF SAFETY AND EFFECTIVENESS

### RF -LATEX "SEIKEN" on the Cobas Mira Chemistry Analyzer

Below summarizes and compares the performance of RF LATEX "SEIKEN" and a similar device previously given FDA clearance for marketing in the US. The information contained in this summary was obtained from data prepared at and which is on file at Denka Seiken, Co. Inc. The summary shows that the two reagent systems are substantially equivalent.

#### INTENDED USE

This *in vitro* diagnostic procedure is intended to quantitatively measure RF in human serum on the Cobas Mira chemistry analyzer. Such measurements are used in the diagnosis and treatment of rheumatoid arthritis.

METHOD	RF-LATEX "SEIKEN"	quantex RF plus BIOKIT USA, Inc. 113 Hartwell Avenue Lexington, MA 02173
Product Code	602534	3000-2095
Min. Detectable Conc.	3 IU/ml	5 IU/ml
Precision (Between-run)	20.3 IU/ml 5.23% 40.2 IU/ml 3.14% 59.2 IU/ml 1.26%	less than 10%
Linearity	3 - 120 IU/ml	5 - 100 IU/ml
Correlation	$y = -0.947 + 1.053x$ $y = \text{RF-LATEX "SEIKEN"}$ $x = \text{quantex RF plus}$ $r = 0.984$ $n = 92$	

**The RF-LATEX "SEIKEN" and the quantex RF plus are similar in that both :**

- \* Are reagent systems for the quantitation of the concentration of rheumatoid factor (RF) in human serum.
- \* Are based on the agglutination of RF in serum with latex particles coated with anti-RF (human IgG).
- \* Employ the absorbance change observed as the basis for quantitation.
- \* Calculate the amount of RF by interpolation from a calibration curve prepared from calibrators of known concentration.
- \* Are intended for use with the Cobas Mira chemistry analyzer (or other suitable analyzer).

**The RF-LATEX "SEIKEN" and the quantex RF plus are different in that:**

- \* The minimal detectable concentration for the RF-LATEX "SEIKEN" is 3 IU/ml; that for the quantex RF plus is 5 IU/ml.
- \* The maximum quantifiable concentration for the RF-LATEX "SEIKEN" system is 120 IU/ml; that for the quantex RF plus is 100 IU/ml.

**The following further summarizes similarities and differences between the two reagent systems.**

RF	RF-LATEX "SEIKEN"	quantex RF plus
S.VOL (ul)	6	6
REAGENT VOL (R1) (ul)	180	350
START R1 VOL (R2) (ul)	60	50
CALC. STEP	ENDPOINT	ENDPOINT
STD	MULTI (5)	MULTI (4)
UNIT	IU/ml	IU/ml
WAVELENGTH	550 nm	550 nm

## PROTOCOL AND DATA SUMMARY

This section provides data generated by Denka Seiken Co., Ltd. characterizing the performance of the RF-LATEX "SEIKEN" Reagent System. The protocols used for data generation are given below, and the results are attached.

### ACCURACY

Ninety two serum samples with values spanning the reportable range for the assay were obtained and tested in parallel using the RF-LATEX "SEIKEN" and the quantex RF plus Reagent System.

### PRECISION

Within run precision was determined by analyzing ten replicates each of five levels of commercial control serum. Between run precision was determined by analyzing three levels of commercial control serum once per day for ten days.

### LINEARITY

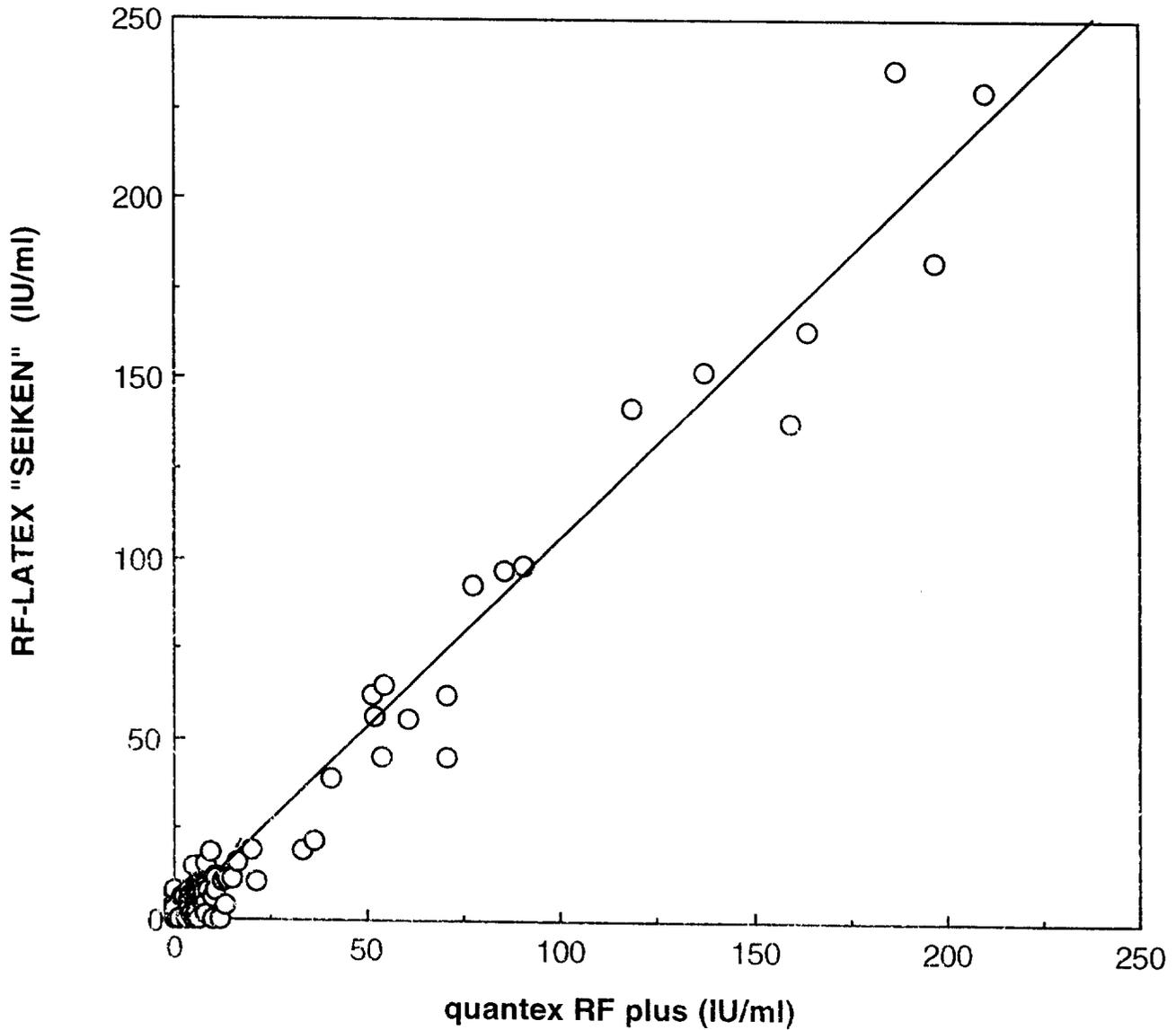
Linearity was determined by analyzing a series of six calibrators, covering the reportable range of the assay, with 3 separate lot numbers of reagents.

### STABILITY

Stability was determined by analyzing three levels of commercial control serum at three month intervals over the shelf life of two lot numbers of reagents.

# CORRELATION

quantex RF Plus / RF-LATEX "SEIKEN"



Correlation quantex RF plus / RF-LATEX "SEIKEN"

NUMBER OF CASES : 92  
INTERCEPT (a) = -0.94678  
 $r = 0.9840$

REGRESSION EQUATION:  $y = a + bX$   
SLOPE (b) = 1.0532006  
 $r^2 = 0.9683$

## RF-LATEX "SEIKEN"

### PRECISION (WITHIN-RUN)

NO. OF CUPS SELECTED THAT WERE RUN = 10  
RUN PRECISION ON CONC. DATA IN IU/ML

SAMPLE NO.	MEAN	SD	C.V. %
1	10.29	0.30	2.95
2	19.85	0.18	0.91
3	29.51	0.33	1.11
4	39.00	0.55	1.41
5	48.37	0.69	1.43

### PRECISION (BETWEEN-RUN )

DAY	IU/ml		
	Sample 1	Sample 2	Sample 3
1	10.5	19.6	38.0
2	10.6	20.1	37.6
3	10.6	19.8	37.2
4	10.2	19.7	37.8
5	10.4	20.1	37.8
6	10.5	19.5	37.0
7	10.8	20.4	39.2
8	10.5	19.9	37.6
9	10.5	19.9	37.2
10	10.3	19.6	37.8
Average	10.49	19.86	37.72
SD	0.17	0.28	0.61
C.V. %	1.59	1.41	1.62

**LINEARITY**

IU/ml	IU/ml			
	Lot. 1	Lot. 2	Lot.3	Average
20.0	10.4	10.0	9.3	9.9
40.0	19.3	21.2	19.0	19.8
60.0	28.1	28.2	28.4	28.2
80.0	39.1	38.6	38.7	38.8
100.0	47.6	49.0	49.7	48.8
120.0	59.3	60.0	58.4	59.2
A =	-0.07	0.12	-0.87	-0.29
B =	0.973	0.982	0.994	0.983
r =	0.9989	0.9996	0.9996	0.9995
$y = A + Bx$				

**STABILITY** Stored at 4 °C

MONTH	Lot. 1 (IU/ml)			Lot.2 (IU/ml)		
	Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3
0	10.2	19.4	39.5	11.8	18.4	39.7
3	10.4	19.3	39.3	9.3	18.4	38.6
6	10.4	19.9	37.7	9.7	18.2	39.3
12	10.7	19.2	37.4	9.8	17.8	37.6
15	10.0	19.0	36.3	9.5	17.6	38.1