K960702

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SUMMARY OF SAFETY AND EFFECTIVENESS

CRP-LATEX "SEIKEN" XR on the Cobas Mira Chemistry Analyzer

Below summarizes and compares the performance of CRP-LATEX "SEIKEN" XR 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. This summary shows that the two reagent systems are substantially equivalent.

INTENDED USE

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

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METHOD	CRP-LATEX "SEIKEN" XR	**quantex CRP plus** BIOKIT USA, Inc. 113 Hartwell Avenue Lexington, MA 02173
Product Code	600554	3000-2092
Min. Detectable Conc.	0.1 mg/dl	0.3 mg/dl
Precision (Between-run)	1.03 mg/dl 1.94% 5.03 mg/dl 2.24% 9.99 mg/dl 1.58%	less than 10%
Linearity	0.1 - 20.0 mg/dl	0.3 - 10.0 mg/dl
Correlation	y = 0.005 + 1.126X y = CRP-LATEX "SEIKEN" XR x = quantex CRP plus n = 122 r = 0.9976	

The CRP-LATEX "SEIKEN" XR and the quantex CRP plus are similar in that both:

* Are reagent systems for the quantitation of the concentration of CRP in human serum.
* Are based on the agglutination of CRP in serum with latex particles coated with anti-CRP.
* Employ the absorbance change observed as the basis for quantitation.
* Are intended for use with the Cobas Mira chemistry analyzer.

The CRP-LATEX "SEIKEN" XR and the quantex CRP plus are different in that:

* The CRP-LATEX "SEIKEN" uses a multistandard calibration curve and the quantex CRP plus a single point calibrator as the basis for calculating the concentration of CRP.
* The minimal detectable concentration for the CRP-LATEX "SEIKEN" XR is 0.1 mg/dl; that for the quantex CRP plus is 0.3 mg/dl.
* The maximum quantifiable concentration for the CRP-LATEX "SEIKEN" XR is 20.0 mg/dl; that for the Biokit system is 10.0 mg/dl

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

CRP	**CRP-LATEX "SEIKEN" XR**	**quantex CRP plus**
S.VOL (ul)	4	3
REAGENT VOL (R1) (ul)	150	350
START R1 VOL (R2) (ul)	85	80
START R2 VOL (R2) (ul)	--	80
CALC.STEP	RATE	ENDPOINT
STD	MULTI (0,1,5,10,15,20)	1 POINT
UNIT	mg/dl	mg/dl
WAVELENGTH	550 nm	550 nm

PROTOCOL AND DATA SUMMARY

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

ACCURACY

One hundred and twenty two serum samples with values spanning the reportable range for the assay were obtained and tested in parallel using the CRP-LATEX "SEIKEN" XR and the quantex CRP 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

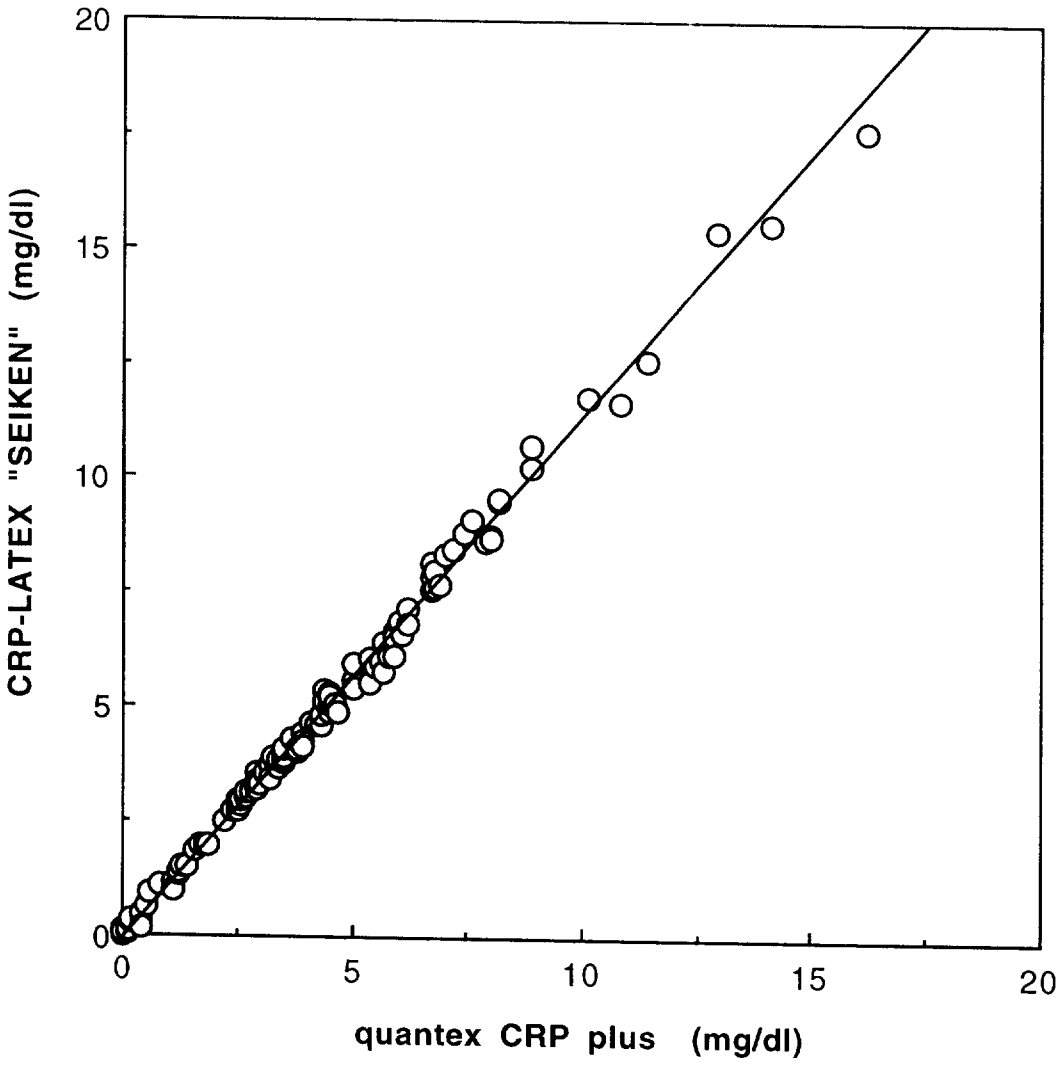
Linearity was determined by analyzing a series of twelve calibrators, covering the reportable range of the assay, with three separate lot numbers of reagents.

STABILITY

Stabillity 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 CRP plus / CRP-LATEX "SEIKEN"



Correlation quantex CRP plus / CRP-LATEX "SEIKEN"

NUMBER OF CASES : 122
INTERCEPT (a) = 0.0054380
r = 0.9976

REGRESSION EQUATION : y = a + bX
SLOPE (b) = 1.1258245
r^2 = 0.9952

CRP-LATEX "SEIKEN" XR

PRECISION (WITHIN-RUN)

NO. OF CUPS SELECTED THAT WERE RUN = 10

RUN PRECISION ON CONC. DATA IN MG/DL

SAMPLE NO.	MEAN	SD	C.V. %
1	1.06	0.04	3.36
2	3.09	0.07	2.35
3	5.10	0.10	2.02
4	10.01	0.32	3.20
5	15.02	0.57	3.77

PRECISION (BETWEEN-RUN)

DAY	mg/dl		
	Sample 1	Sample 2	Sample 3
1	1.04	4.85	10.14
2	1.05	5.02	9.69
3	1.05	5.14	10.16
4	1.01	5.03	9.82
5	1.06	4.96	9.99
6	1.02	5.14	9.85
7	1.03	5.13	10.02
8	1.02	5.11	10.08
9	1.05	4.85	9.99
10	1.00	5.09	10.15
Average	1.03	5.03	9.99
SD	0.02	0.11	0.16
C.V. %	1.94	2.24	1.58

LINEARITY

mg/dl	mg/dl			
	Lot. 1	Lot. 2	Lot.3	Average
0.50	0.57	0.54	0.42	0.51
1.00	1.06	1.10	1.03	1.06
2.00	2.06	2.10	2.11	2.09
4.00	3.91	3.87	3.97	3.92
6.00	5.71	5.76	5.75	5.74
8.00	7.94	7.79	7.95	7.89
10.00	9.76	9.78	9.87	9.80
12.00	11.58	11.25	11.75	11.53
14.00	13.64	13.86	13.68	13.73
16.00	15.86	15.65	15.93	15.81
18.00	17.87	17.80	18.06	17.91
20.00	19.76	19.76	19.62	19.71
A =	-0.007	-0.009	-0.010	-0.009
B =	0.985	0.981	0.989	0.985
r =	0.9998	0.9996	0.9998	0.9998
$y = A + Bx$				

STABILITY Stored at 4 ℃.

MONTH	Lot. 1 (mg/dl)			Lot.2 (mg/dl)		
	Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3
0	1.07	5.21	10.31	1.08	4.93	9.72
3	1.07	4.83	10.02	0.96	5.17	10.59
6	0.99	5.33	10.30	0.99	5.04	10.06
12	0.93	5.10	9.98	1.03	4.94	9.90
15	1.02	5.16	10.45	1.05	5.05	9.77