

**PRELIMINARY INFORMATION ON SEROLOGIC RESPONSES
TO INFLUENZA VIRUS VACCINES**

**PREPARED FOR
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
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**DATA FROM
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
BETHESDA, MARYLAND**

CURRENT TO FEBRUARY 7, 2004

TABLE OF CONTENTS

SERUM PANELS	3
ANTIGENS	4
H1N1 ADULT AND ELDERLY.....	5-6
H3N2 ADULT AND ELDERLY	7-8
B ADULT AND ELDERLY	9-10
2001 VACCINE STUDY FOR B SEROLOGIES	11
PEDIATRIC SEROLOGIES	12
ACKNOWLEDGEMENTS.....	13

SERUM PANELS USED FOR STUDIES

SERUM SUPPLIED BY		VACCINE COMPONENTS
1. ALAN HAMPSON WHO, MELBOURNE, AUSTRALIA	ADULTS ELDERLY	A/NEW CALEDONIA/20/99-LIKE (H1N1) A/PANAMA/2007/99 (H3N2) B/SHANGDONG/07/97
2. JOHN WOOD, PH.D NIBSC, LONDON, ENGLAND	ADULTS ELDERLY	A/NEW CALEDONIA/20/99 (H1N1) A/PANAMA/2007/99 (H3N2) B/SHANGDONG/7/97
3. TAKATO ODIGARI, PH.D. TOKYO, JAPAN	ADULTS ELDERLY	A/NEW CALEDONIA/20/99-LIKE (H1N1) A/PANAMA/2007/99-LIKE (H3N2) B/HONG KONG/330/01-LIKE
4. STEFAN GRAVENSTEIN, M.D. EASTERN VIRGINIA MEDICAL SCHOOL	ADULTS ELDERLY PEDIATRIC	A/NEW CALEDONIA/20/99-LIKE (H1N1) A/PANAMA/2007/99-LIKE (H3N2) B/HONG KONG/330/01-LIKE
5. STEFAN GRAVENSTEIN, M.D. EASTERN VIRGINIA MEDICAL SCHOOL (VACCINE USED IN 2001-02)	ADULTS ELDERLY	A/NEW CALEDONIA/20/99-LIKE (H1N1) A/PANAMA/2007/99-LIKE (H3N2) B/VICTORIA/504/2000

ANTIGENS FOR SEROLOGIES

H1N1

A/New Caledonia/20/99 IVR116*	E9
A/Belem/84066/03 (H1N2)	E5
A/Virginia/20/03	X2C2E1

H3N2

A/Panama/2007/99 RESVIR17*	E6
A/Texas/40/03	SpfCK4E4
A/Chile/8266e/2003	SpfCK4E4
A/Fiujian/445/03	E6
A/Victoria/584/03	E4
A/Texas/141/03	E4
A/Kumamoto/102/02	X4E6
A/Wyoming/03/03	SpfCK2E3
A/Hong Kong/1186/03	SpfCK3E4

B

B/Shandong/07/97* **	E8
B/Hong Kong/1434/02* **	E5
B/Sichuan/259/03**	C2E3
B/Jilin/20/03**	E5

* = REPRESENTATIVE OF VACCINE STRAINS

** = ETHER TREATED

E = EGG PASSED VIRUS

X = UNKNOWN

C = TISSUE CULTURE

SpfCK = SPECIFIC PATHOGEN FREE CHICK EMBRYO KIDNEY

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA A (H1N1) VIRUSES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		% \geq 32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
AUSTRALIA ADULTS (2/2004)	CBER	24	A/New Caledonia/20/99*	<8	68	17	88	83
			A/Belem/84066/03 (H1N2)	<8	117	21	92	88
			A/Virginia/20/03	<8	52	5	83	88
EUROPE ADULTS (2/2004)		24	A/New Caledonia/20/99*	<8	25	4	58	58
			A/Belem/84066/03 (H1N2)	<8	27	4	54	67
			A/Virginia/20/03	<8	18	0	50	58
JAPAN ADULTS (2/2004)		25	A/New Caledonia/20/99*	<8	16	16	32	48
			A/Belem/84066/03 (H1N2)	<8	16	16	44	36
			A/Virginia/20/03	<8	12	0	20	28
USA ADULTS (2/2004)		20	A/New Caledonia/20/99*	11	39	20	75	40
			A/Belem/84066/03 (H1N2)	9	45	20	75	50
			A/Virginia/20/03	9	44	20	70	50
			* Vaccine Strain					

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA A (H1N1) VIRUSES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		% \geq 32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
AUSTRALIA ELDERLY (2/2004)	CBER	24	A/New Caledonia/20/99*	10	24	13	58	38
			A/Belem/84066/03 (H1N2)	20	35	54	75	33
			A/Virginia/20/03	13	39	38	83	42
EUROPE ELDERLY (2/2004)		24	A/New Caledonia/20/99*	<8	9	4	17	25
			A/Belem/84066/03 (H1N2)	<8	13	0	33	38
			A/Virginia/20/03	<8	10	4	17	29
JAPAN ELDERLY (2/2004)		30	A/New Caledonia/20/99*	<8	<8	7	27	23
			A/Belem/84066/03 (H1N2)	<8	9	13	30	23
			A/Virginia/20/03	<8	<8	10	27	30
USA ELDERLY (2/2004)		17	A/New Caledonia/20/99*	<8	18	12	41	29
			A/Belem/84066/03 (H1N2)	<8	20	12	35	47
			A/Virginia/20/03	<8	28	24	47	35
			* Vaccine Strain					

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA A (H3N2) VIRUSES

TRIAL	TEST SITE	# SERA	VIRUS STRAIN	GMT		% \geq 32or40		4 FOLD
				PRE	POST	PRE	POST	
AUSTRALIA ADULTS (2/2004)	CBER	24	A/Panama/2007/99	<16	64	25	92	63
			A/Texas/40/03	<16	39	21	88	54
			A/Chile/8266/03	21	88	54	88	46
			A/Fiujian/445/03	18	72	33	88	46
			A/Victoria/584/03	17	78	38	96	63
			A/Texas/141/03	<16	24	33	38	25
EUROPE ADULTS (2/2004)		24	A/Panama/2007/99	<16	18	4	42	50
			A/Texas/40/03	<16	<16	0	42	50
			A/Chile/8266/03	<16	28	8	58	58
			A/Fiujian/445/03	<16	27	0	54	54
			A/Victoria/584/03	<16	28	4	46	33
			A/Texas/141/03	<16	<16	8	29	21
JAPAN ADULTS (2/2004)		25	A/Panama/2007/99	<16	17	16	40	20
			A/Texas/40/03	<16	<16	8	16	4
			A/Chile/8266/03	<16	23	28	56	20
			A/Fiujian/445/03	<16	<16	16	36	12
			A/Victoria/584/03	<16	17	12	40	28
			A/Texas/141/03	<16	18	20	40	16
USA ADULTS (2/2004)		21	A/Panama/2007/99	27	64	67	81	38
			A/Texas/40/03	<16	43	38	81	29
			A/Chile/8266/03	29	129	57	95	52
			A/Fiujian/445/03	20	75	43	81	57
			A/Victoria/584/03	24	92	48	85	52
			A/Texas/141/03	17	27	38	53	19
			*Vaccine Strain					

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA A (H3N2) VIRUSES

TRIAL	TEST SITE	# SERA	VIRUS STRAIN	GMT		%≥32or40		4 FOLD
				PRE	POST	PRE	POST	
AUSTRALIA ELDERLY (2/2004)	CBER	24	A/Panama/2007/99 RESVIR17*	18	38	42	67	17
			A/Texas/40/03	<16	28	33	58	25
			A/Chile/8266/03	21	59	46	71	33
			A/Fiujian/445/03	20	48	38	63	25
			A/Victoria/584/03	20	44	38	58	25
			A/Texas/141/03	<16	30	33	67	29
JAPAN ELDERLY (2/2004)		30	A/Panama/2007/99 RESVIR17*	<16	<16	43	63	23
			A/Texas/40/03	<16	<16	37	40	20
			A/Chile/8266/03	<16	18	60	83	23
			A/Fiujian/445/03	<16	<16	37	37	3
			A/Victoria/584/03	<16	<16	43	50	3
			A/Texas/141/03	<16	<16	17	20	3
USA ELDERLY (2/2004)		21	A/Panama/2007/99 RESVIR17*	28	48	67	95	19
			A/Texas/40/03	20	29	48	71	14
			A/Chile/8266/03	37	83	67	100	33
			A/Fiujian/445/03	24	56	38	81	43
			A/Victoria/584/03	31	65	48	86	38
			A/Texas/141/03	17	24	29	52	5
			*Vaccine Strain					

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA B VIRUSES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		% ≥32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
AUSTRALIA ADULTS (2/2004)	CBER	24	B/Shandong/07/97*	<8	64	17	92	79
			B/Hong Kong/1434/02	<8	87	8	92	88
			B/Sichuan/259/03	<8	49	8	79	75
			B/Jilin/20/03	19	64	46	75	50
EUROPE ADULTS (2/2004)		24	B/Shandong/07/97*	<8	17	0	46	46
			B/Hong Kong/1434/02	<8	18	0	46	54
			B/Sichuan/259/03	<8	19	0	46	54
			B/Jilin/20/03	<8	<8	8	38	38
JAPAN ADULTS (2/2004)		25	B/Shandong/07/97*	<8	<8	32	52	12
			B/Hong Kong/1434/02*	<8	18	36	52	32
			B/Sichuan/259/03	<8	19	33	56	24
			B/Jilin/20/03	18	28	48	60	16
USA ADULTS (2/2004)		21	B/Shandong/07/97	<8	42	5	71	71
			B/Hong Kong/1434/02*	<8	71	5	86	86
			B/Sichuan/259/03	<8	57	5	81	76
			B/Jilin/20/03	18	71	43	85	43
			*Vaccine Strain					

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA B VIRUSES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		% \geq 32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
AUSTRALIA ELDERLY (2/2004)	CBER	24	B/Shandong/07/97*	\leq 8	30	8	67	67
			B/Hong Kong/1434/02	\leq 8	43	8	97	79
			B/Sichuan/259/03	\leq 8	21	8	58	58
			B/Jilin/20/03	\leq 8	51	29	79	46
EUROPE ELDERLY (2/2004)		24	B/Shandong/07/97*	\leq 8	11	4	26	38
			B/Hong Kong/1434/02	\leq 8	12	4	33	42
			B/Sichuan/259/03	\leq 8	14	4	38	46
			B/Jilin/20/03	\leq 8	11	21	33	21
JAPAN ELDERLY (2/2004)		30	B/Shandong/07/97*	\leq 8	9	30	37	10
			B/Hong Kong/1434/02*	\leq 8	10	43	50	3
			B/Sichuan/259/03	\leq 8	9	43	37	7
			B/Jilin/20/03	\leq 8	\leq 8	23	23	3
USA ELDERLY (2/2004)		21	B/Shandong/07/97	\leq 8	56	5	62	62
			B/Hong Kong/1434/02*	\leq 8	51	10	48	76
			B/Sichuan/259/03	\leq 8	45	10	48	57
			B/Jilin/20/03	23	58	33	62	29
			*Vaccine Strain					

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS: 2001-2002 VACCINES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		% \geq 32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
USA ADULTS (2/2004)	CBER	16	B/Victoria/504/00*	64	157	75	93	13
			B/Sichuan/259/03	<8	16	31	50	31
			B/Jilin/20/03	30	76	50	88	31
USA ELDERLY (2/2004)		15	B/Victoria/504/00*	18	31	47	60	20
			B/Sichuan/259/03	<8	12	13	27	20
			B/Jilin/20/03	21	24	47	53	0
			*Vaccine Strain					

PEDIATRIC HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA VIRUSES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		% \geq 32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
PEDIATRIC	CBER	30	A/New Caledonia/20/99*	\leq 8	25	10	50	80
			A/Belem/84066/03 (H1N2)	\leq 8	39	10	63	83
			A/Virginia/20/03	\leq 8	34	10	77	93
PEDIATRIC (2/2004)		31	A/Panama/2007/99*	\leq 8	40	10	58	87
			A/Kumamoto/102/02	\leq 8	31	13	61	74
			A/Wyoming/03/03	\leq 8	13	10	16	39
			A/Hong Kong/1186/03	\leq 8	11	10	13	32
PEDIATRIC		30	B/Shandong/07/97*	\leq 8	21	3	57	77
			B/Hong Kong/1434/02*	\leq 8	31	0	75	83
			B/Sichuan/259/03	\leq 8	26	0	67	80
			B/Jilin/20/03	\leq 8	\leq 8	0	3	7
		Range 8-38 (Months) Mean 21	*Vaccine Strain					

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