

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

**PREPARED FOR
THE VACCINES AND RELATED BIOLOGICAL
PRODUCTS ADVISORY COMMITTEE**

**DATA FROM
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
BETHESDA, MARYLAND**

CURRENT TO JANUARY 28, 2002

SERUM PANELS USED FOR STUDIES

	SERUM SUPPLIED BY		VACCINE COMPONENTS
1.	ALAN HAMPSON WHO, MELBOURNE	ADULTS ELDERLY	A/NEW CALEDONIA/20/99 (H1N1) A/PANAMA/2007/99 (H3N2) B/JOHANNESBURG/5/99
2.	JOHN WOOD, PH.D NIBSC, LONDON	ADULTS ELDERLY	A/NEW CALEDONIA/20/99 (H1N1) A/PANAMA/2007/99 (H3N2) B/GUANGDONG/120/2000
3.	STEFAN GRAVENSTEIN, M.D. EASTERN VIRGINIA MEDICAL SCHOOL	ADULTS ELDERLY	A/NEW CALEDONIA/20/99 (H1N1) A/PANAMA/2007/99 (H3N2) B/VICTORIA/504/2000

ANTIGENS FOR SEROLOGIES

H1N1

A/NEW CALEDONIA/20/99 (IVR-116) *	E8
A/HUBEI/288/2001	E5
A/BANGKOK/255/2001	E6
A/HAWAII/15/2001	TC4
A/WISCONSIN/12/2001	TC3
A/FUJIAN/156/2000	E6
A/AUCKLAND/65/2001	E3
A/CHRISTCHURCH/4/2001	E6

H3N2

A/PANAMA/2007/99 (RESVIR-17)*	E5
A/ARGENTINA/3759/2001	E6
A/PHILIPPINES/78890/2001	X/TC3
A/SINGAPORE/26/2001	E3
A/DARWIN/3/2000	E9
A/FUJIAN/140/2000	E6
A/CHILE/6416/2001	E5

B

B/JOHANNESBURG/5/99 * **	E6
B/GUANGDONG/120/2000 * **	E6
B/VICTORIA/504/2000* **	CEK1/E12
B/SHIZUOKA/15/2001**	E8
B/TEXAS/22/2001**	TC3/E2
B/HONG KONG/692/2001**	TC3/E2
B/SICHUAN/317/2001**	E5
B/SINGAPORE/1/2001 **	E4
B/BRAZIL/952/2001 **	EXE2
B/SHIZUOKA/480/2000 **	E7
B/HAWAII/10/2001 **	E4
B/HONG KONG/330/2001**	E4

* = REPRESENTATIVE OF VACCINE STRAINS
 ** = ETHER TREATED
 E = EGG PASSED VIRUS
 CEK = CHICK EMBRYO KIDNEY
 TC = OTHER TISSUE CULTURE
 X = UNKNOWN

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA A (H1N1) VIRUSES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		% ≥32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
AUSTRALIA ADULTS Age=27 YR	CBER 1/2002	24	A/NEW CALEDONIA/20/99 IVR116*	<10	329	0	100	100
			A/HUBEI/288/2001	<10	359	0	100	76
			A/BANGKOK/255/2001	<10	196	0	96	84
			A/HAWAII/15/2001	<10	60	0	67	63
			A/WISCONSIN/12/2001	<10	98	0	92	56
EUROPE ADULTS Age=24 YR		24	A/NEW CALEDONIA/20/99 IVR116*	<10	73	0	71	67
			A/HUBEI/288/2001	<10	53	0	50	67
			A/BANGKOK/255/2001	<10	42	0	50	67
			A/HAWAII/15/2001	<10	21	0	42	38
			A/WISCONSIN/12/2001	<10	60	0	71	83
USA ADULTS Age=39 YR		24	A/NEW CALEDONIA/20/99 IVR116*	20	59	42	75	42
			A/HUBEI/288/2001	24	78	33	75	54
			A/BANGKOK/255/2001	20	48	33	71	42
			A/HAWAII/15/2001	<10	22	25	58	42
			A/WISCONSIN/12/2001	11	31	25	63	42

* = 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 ADULTS	CBER 9/2001	24	A/NEW CALEDONIA/20/99 IVR116*	<10	35	0	54	54
			A/AUCKLAND/65/01	<10	13	0	29	29
			A/CHRISTCHURCH/4/01	<10	29	0	50	50
			A/FUJIAN/156/2000	<10	38	0	54	54
EUROPE ADULTS		24	A/NEW CALEDONIA/20/99 IVR116*	<10	30	0	50	54
			A/AUCKLAND/65/01	<10	36	0	54	63
			A/CHRISTCHURCH/4/01	<10	45	0	58	67
			A/FUJIAN/156/2000	<10	42	0	54	71

* = vaccine strain

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA A (H1N1) VIRUSES

TRIAL	TEST SITE	NO. OF SERA	VIRUS STRAIN	GMT		%≥32or40		% 4 FOLD RISE
				PRE	POST	PRE	POST	
AUSTRALIA ELDERLY Age= 71 YR	CBER 1/2002	24	A/NEW CALEDONIA/20/99 IVR116*	10	52	21	75	72
			A/HUBEI/288/2001	12	65	29	83	76
			A/BANGKOK/255/2001	<10	53	17	83	84
			A/HAWAII/15/2001	10	36	8	67	63
			A/WISCONSIN/12/2001	15	53	38	75	56
EUROPE ELDERLY Age= 68 YR		24	A/NEW CALEDONIA/20/99 IVR116*	<10	49	13	63	67
			A/HUBEI/288/2001	<10	38	8	58	67
			A/BANGKOK/255/2001	<10	31	8	50	67
			A/HAWAII/15/2001	<10	14	0	29	38
			A/WISCONSIN/12/2001	<10	52	8	54	83
USA ELDERLY Age=73 YR		24	A/NEW CALEDONIA/20/99 IVR116*	<10	16	17	42	25
			A/HUBEI/288/2001	13	24	25	46	33
			A/BANGKOK/255/2001	<10	17	17	33	38
			A/HAWAII/15/2001	<10	<10	13	13	21
			A/WISCONSIN/12/2001	11	16	33	50	29

* = 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	
EUROPE ELDERLY	CBER 9/2001	24	A/NEW CALEDONIA/20/99 IVR116*	<10	26	8	50	63
			A/AUCKLAND/65/01	<10	21	13	50	54
			A/CHRISTCHURCH/4/01	<10	27	8	54	63
			A/FUJIAN/156/2000	<10	26	8	58	54

* = 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 Age=27 YR	CBER 1/2002	24	A/PANAMA/2007/99 RESVIR17* A/ARGENTINA/3759/2001 A/PHILIPPINES/78890/2001	12	220	17	100	100
				10	247	25	92	95
				13	53	21	88	59
EUROPE ADULTS Age=24 YR		24	A/PANAMA/2007/99 RESVIR17* A/ARGENTINA/3759/2001 A/PHILIPPINES/78890/2001	<10	104	4	92	92
				<10	65	4	75	75
				<10	25	0	46	79
USA ADULTS Age=39 YR		24	A/PANAMA/2007/99 RESVIR17* A/ARGENTINA/3759/2001 A/PHILIPPINES/78890/2001	34	78	63	88	42
				34	117	63	100	58
				20	30	50	63	13

• = 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	CBER 9/2001	24	A/PANAMA/2007/99 RESVIR17*	<10	67	0	67	67
			A/SINGAPORE/26/2001	<10	52	0	63	63
			A/DARWIN/3/2000	<10	<10	0	13	13
			A/FUJIAN/140/2000	<10	69	0	71	71
			A/CHILE/6416/2001	<10	29	0	46	46
EUROPE ADULTS		24	A/PANAMA/2007/99 RESVIR17*	<10	101	0	88	92
			A/SINGAPORE/26/2001	<10	62	0	88	92
			A/DARWIN/3/2000	<10	22	4	50	54
			A/FUJIAN/140/2000	<10	53	4	67	83
			A/CHILE/6416/2001	<10	39	0	63	79

* = 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 ELDERLY Age= 71 YR	CBER 1/2002	24	A/PANAMA/2007/99 RESVIR17* A/ARGENTINA/3759/2001 A/PHILIPPINES/78890/2001	10	90	25	100	76
				<10	86	4	92	68
				25	58	63	88	36
EUROPE ELDERLY Age= 68 YR		24	A/PANAMA/2007/99 RESVIR17* A/ARGENTINA/3759/2001 A/PHILIPPINES/78890/2001	<10	55	13	58	71
				<10	62	8	58	71
				<10	18	4	33	50
USA ELDERLY Age=73 YR		24	A/PANAMA/2007/99 RESVIR17* A/ARGENTINA/3759/2001 A/PHILIPPINES/78890/2001	13	39	29	71	46
				14	68	29	88	58
				13	19	46	42	33

* = 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 ELDERLY	CBER 9/2001	24	A/PANAMA/2007/99 RESVIR17*	<10	21	0	38	38
			A/SINGAPORE/26/2001	<10	14	0	29	29
			A/DARWIN/3/2000	<10	<10	0	8	8
			A/FUJIAN/140/2000	<10	14	0	29	29
			A/CHILE/6416/2001	<10	<10	0	13	13
EUROPE ELDERLY		24	A/PANAMA/2007/99 RESVIR17*	<10	59	17	75	75
			A/SINGAPORE/26/2001	<10	35	0	58	71
			A/DARWIN/3/2000	<10	19	0	33	54
			A/FUJIAN/140/2000	<10	33	8	63	63
			A/CHILE/6416/2001	<10	20	0	46	50

* = vaccine strain

HEMAGGLUTINATION INHIBITION ANTIBODY TITERS TO INFLUENZA B VIRUSES

TRIAL	TEST SITE	# SERA	VIRUS STRAIN	GMT		% \geq 32or40		4 FOLD
				PRE	POST	PRE	POST	
AUSTRALIA ADULTS Age=27 YR	CBER 1/2002	24	B/VICTORIA/504/2000	15	718	46	100	100
			B/GUANGDONG/120/2000	16	320	42	100	100
			B/SHIZUOKA/15/2001	<10	311	21	96	95
			B/TEXAS/22/2001	13	302	38	92	91
			B/HONG KONG/692/2001	10	293	29	92	91
			B/SICHUAN/317/2001	11	185	17	88	86
			B/HONG KONG/330/2001	<10	13	8	38	27
			vaccine strain = B/Joburg/5/99					
EUROPE ADULTS Age=24 YR		24	B/VICTORIA/504/2000	<10	266	8	88	83
			B/GUANGDONG/120/2000*	<10	185	4	83	79
			B/SHIZUOKA/15/2001	<10	220	4	88	83
			B/TEXAS/22/2001	<10	202	4	88	83
			B/HONG KONG/692/2001	<10	174	4	88	83
			B/SICHUAN/317/2001	<10	143	4	88	83
			B/HONG KONG/330/2001	<10	22	0	46	50
			* = vaccine strain					
USA ADULTS Age=39 YR		24	B/VICTORIA/504/2000*	60	176	67	88	42
			B/GUANGDONG/120/2000	33	88	54	79	42
			B/SHIZUOKA/15/2001	32	99	54	79	46
			B/TEXAS/22/2001	32	93	54	79	42
			B/HONG KONG/692/2001	29	78	54	79	42
			B/SICHUAN/317/2001	23	58	50	79	29
			B/HONG KONG/330/2001	11	38	29	38	8
			* = 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	CBER 9/2001	24	B/JOBURG/5/99*	<10	85	4	79	79
			B/GUANGDONG/120/00	<10	85	8	75	79
			B/SINGAPORE/1/01	<10	73	0	71	71
			B/SHIZUOKA/480/2000	<10	98	13	83	83
			B/BRAZIL/952/01	<10	123	8	83	83
			B/HAWAII/10/01	<10	<10	0	0	0
EUROPE ADULTS)		24	B/JOBURG/5/99	<10	109	4	88	88
			B/GUANGDONG/120/00*	<10	117	4	88	83
			B/SINGAPORE/1/01	<10	110	4	83	88
			B/SHIZUOKA/480/2000	<10	123	4	88	83
			B/BRAZIL/952/01	<10	123	4	88	88
			B/HAWAII/10/01	<10	16	0	46	50

* = 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 Age= 71 YR	CBER 1/2002	24	B/VICTORIA/504/2000	13	147	33	83	68
			B/GUANGDONG/120/2000	12	100	21	75	68
			B/SHIZUOKA/15/2001	10	116	21	79	76
			B/TEXAS/22/2001	<10	76	21	79	71
			B/HONG KONG/692/2001	<10	71	13	71	68
			B/SICHUAN/317/2001	<10	71	17	71	64
			B/HONG KONG/330/2001	<10	<10	17	17	8
	Vaccine strain= B/Joburg/5/99							
EUROPE ELDERLY Age= 68 YR		24	B/VICTORIA/504/2000	<10	110	13	71	79
			B/GUANGDONG/120/2000*	<10	63	13	54	63
			B/SHIZUOKA/15/2001	<10	104	13	71	83
			B/TEXAS/22/2001	<10	64	13	58	75
			B/HONG KONG/692/2001	<10	60	13	54	67
			B/SICHUAN/317/2001	<10	44	13	50	58
			B/HONG KONG/330/2001	<10	13	4	29	25
	* = vaccine strain							
USA ELDERLY Age=73 YR		24	B/VICTORIA/504/2000*	30	59	63	75	25
			B/GUANGDONG/120/2000	25	43	54	67	21
			B/SHIZUOKA/15/2001	23	42	54	71	25
			B/TEXAS/22/2001	22	39	54	67	21
			B/HONG KONG/692/2001	26	39	54	67	13
			B/SICHUAN/317/2001	22	34	50	67	21
			B/HONG KONG/330/2001	18	25	38	50	21
	* = 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	CBER 9/2001	24	B/JOBURG/5/99*	<10	10	4	21	21
			B/GUANGDONG/120/00	<10	13	8	29	25
			B/SINGAPORE/1/01	<10	21	8	46	38
			B/SHIZUOKA/480/2000	<10	11	8	25	25
			B/BRAZIL/952/01	<10	12	8	29	29
			B/HAWAII/10/01	<10	<10	0	13	13
EUROPE ELDERLY		24	B/JOBURG/5/99	<10	41	13	63	63
			B/GUANGDONG/120/00*	<10	37	13	58	58
			B/SINGAPORE/1/01	<10	33	13	58	54
			B/SHIZUOKA/480/2000	<10	36	13	54	58
			B/BRAZIL/952/01	<10	30	8	54	58
			B/HAWAII/10/01	<10	<10	4	29	21

* = vaccine strain

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