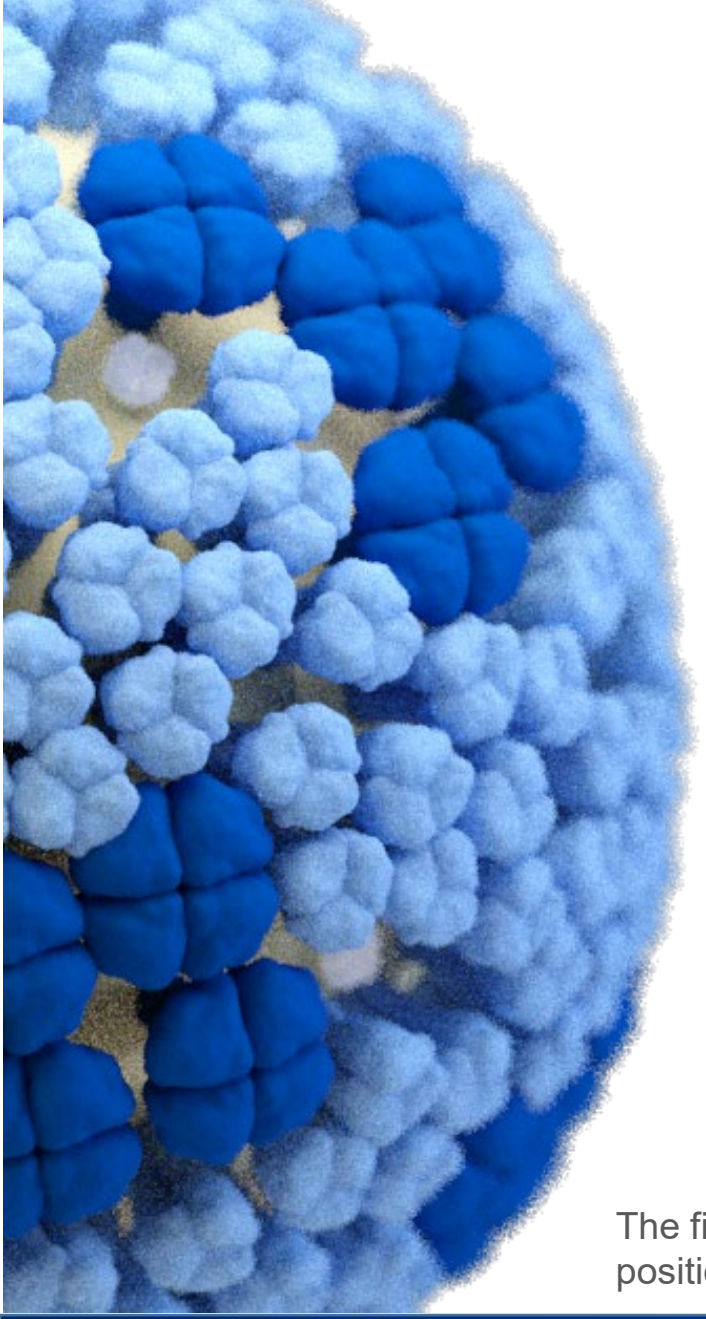

Information For The Vaccine And Related Biological Products Advisory Committee CBER, FDA

Global Influenza Virus Surveillance and Characterization October 9th, 2025

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National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA 30333

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Global vaccine recommendations for the 2026 southern hemisphere

It is recommended that vaccines for use in the 2026 southern hemisphere influenza season contain the following:

Trivalent: Egg-based Vaccines
- **an A/Missouri/11/2025 (H1N1)pdm09-like virus*;**
- **an A/Singapore/GP20238/2024 (H3N2)-like virus*; and**
- **a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.**

Trivalent: Cell-, recombinant protein- or nucleic acid-based Vaccines
- **an A/Missouri/11/2025 (H1N1)pdm09-like virus*;**
- **an A/Sydney/1359/2024 (H3N2)-like virus*; and**
- **a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.**

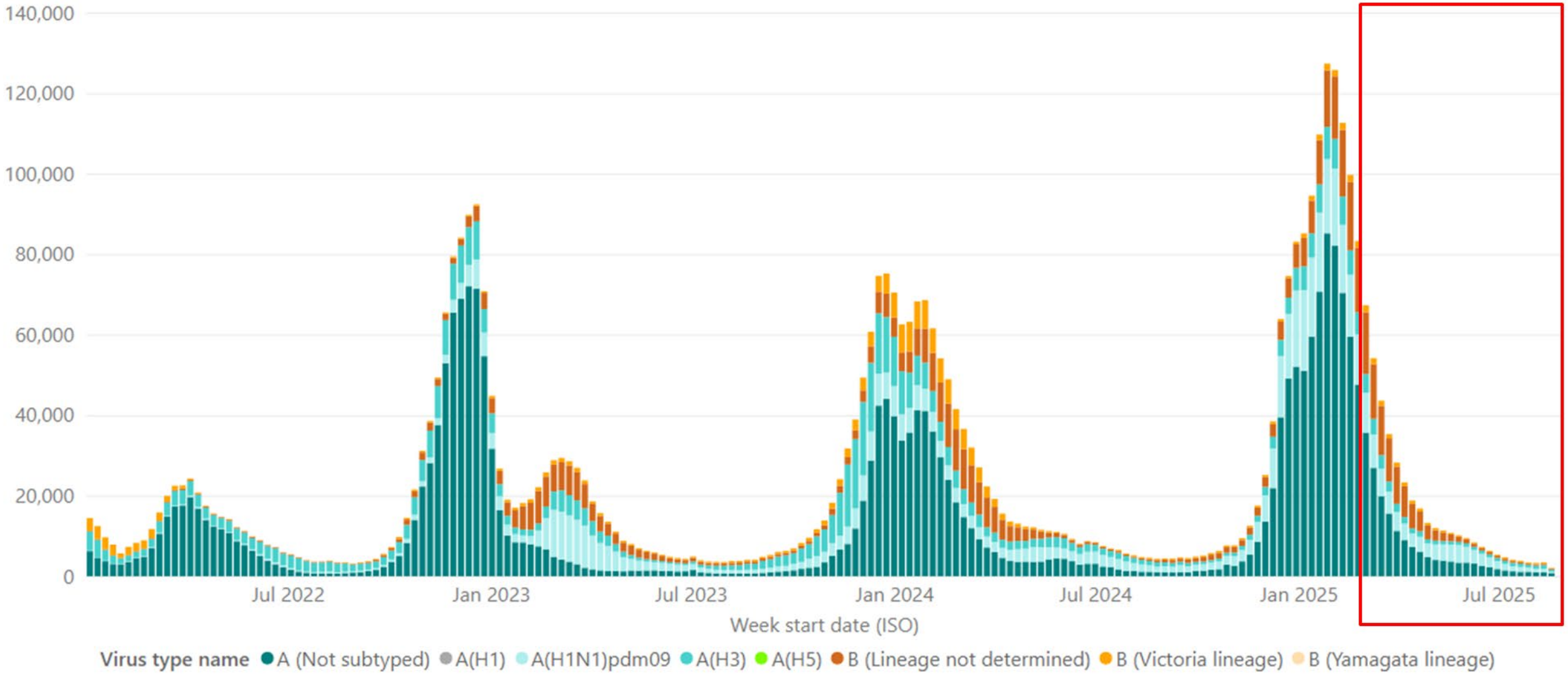
*** Different from that recommended for the 2025 southern hemisphere and 2025-2026 northern hemisphere seasons**

Recommendation and technical reports available at: https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations

Candidate vaccine viruses & publications

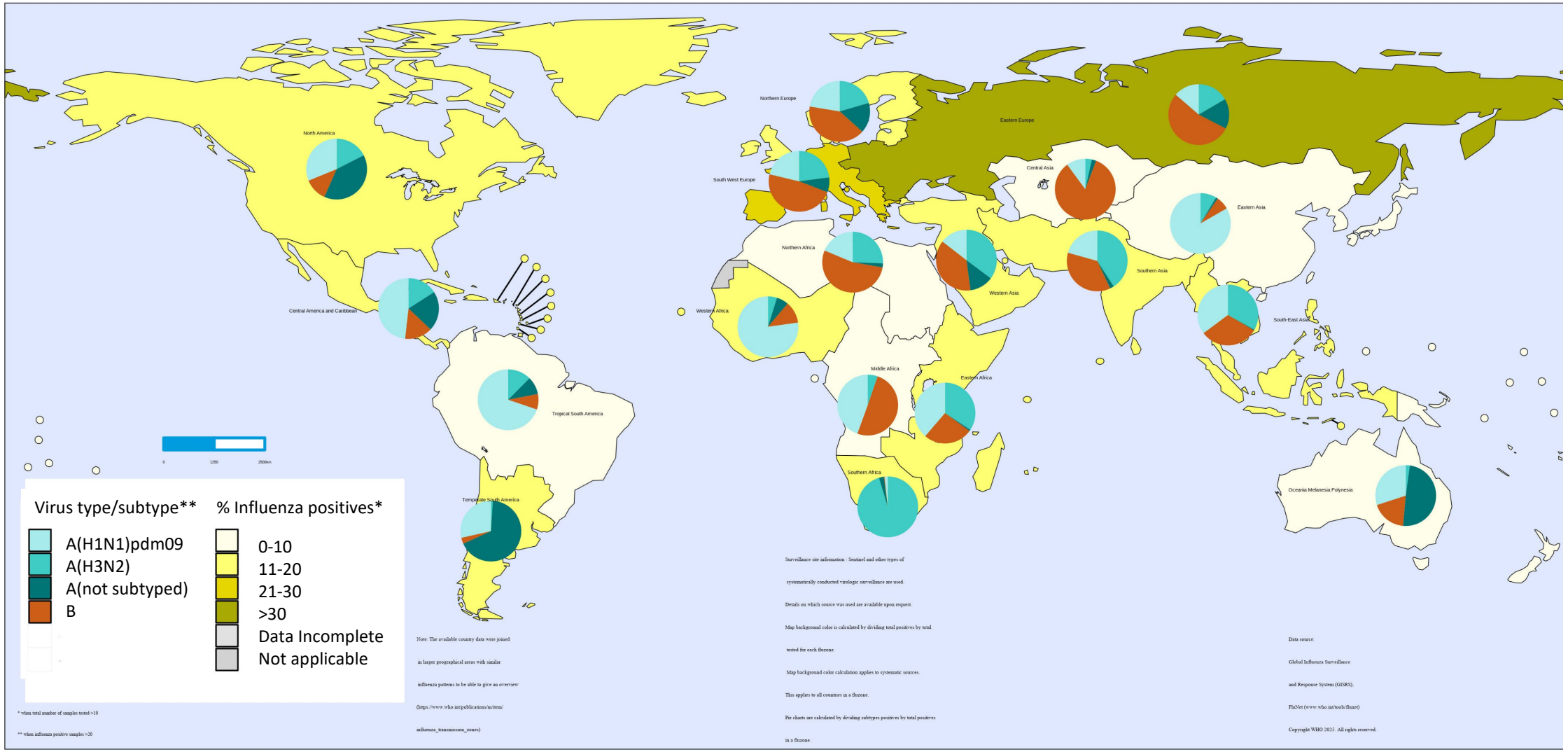
- The recommended composition of influenza virus vaccines for SH 2026 and FAQ;
  - https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2026-southern-hemisphere-influenza-season
- Summary of genetic and antigenic characteristics of zoonotic influenza A viruses and development of candidate vaccine viruses for pandemic preparedness
  - https://cdn.who.int/media/docs/default-source/influenza/who-influenza-recommendations/vcm-sh-2025
- Candidate vaccine viruses and reagents
  - Seasonal: https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/candidate-vaccine-viruses
  - Zoonotic: https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/zoonotic-influenza-viruses-and-candidate-vaccine-viruses
- Guidance to tropical and subtropical countries: which formulation (northern hemisphere vs. southern hemisphere) and when to start vaccination:
  - https://www.who.int/teams/global-influenza-programme/vaccines/vaccine-in-tropics-and-subtropics

Global Circulation of Influenza Viruses Since 2022



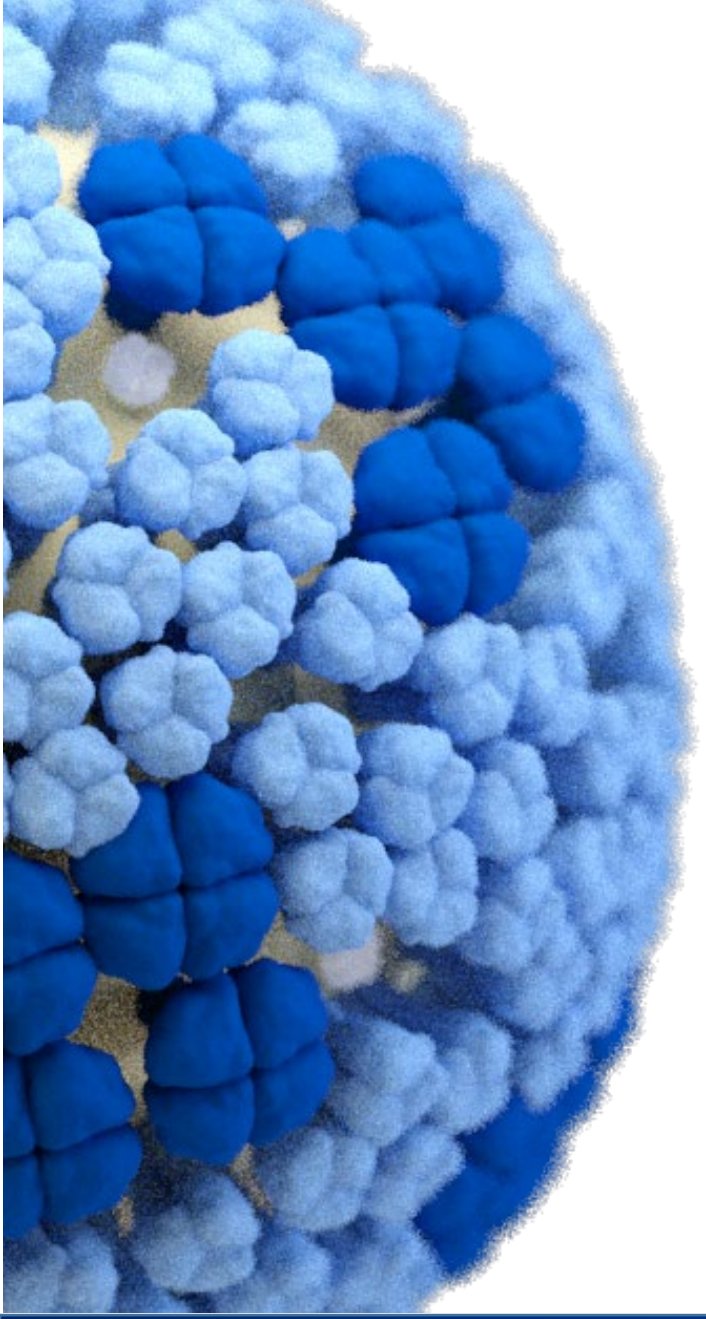
VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Influenza activity and global distribution of type/subtype



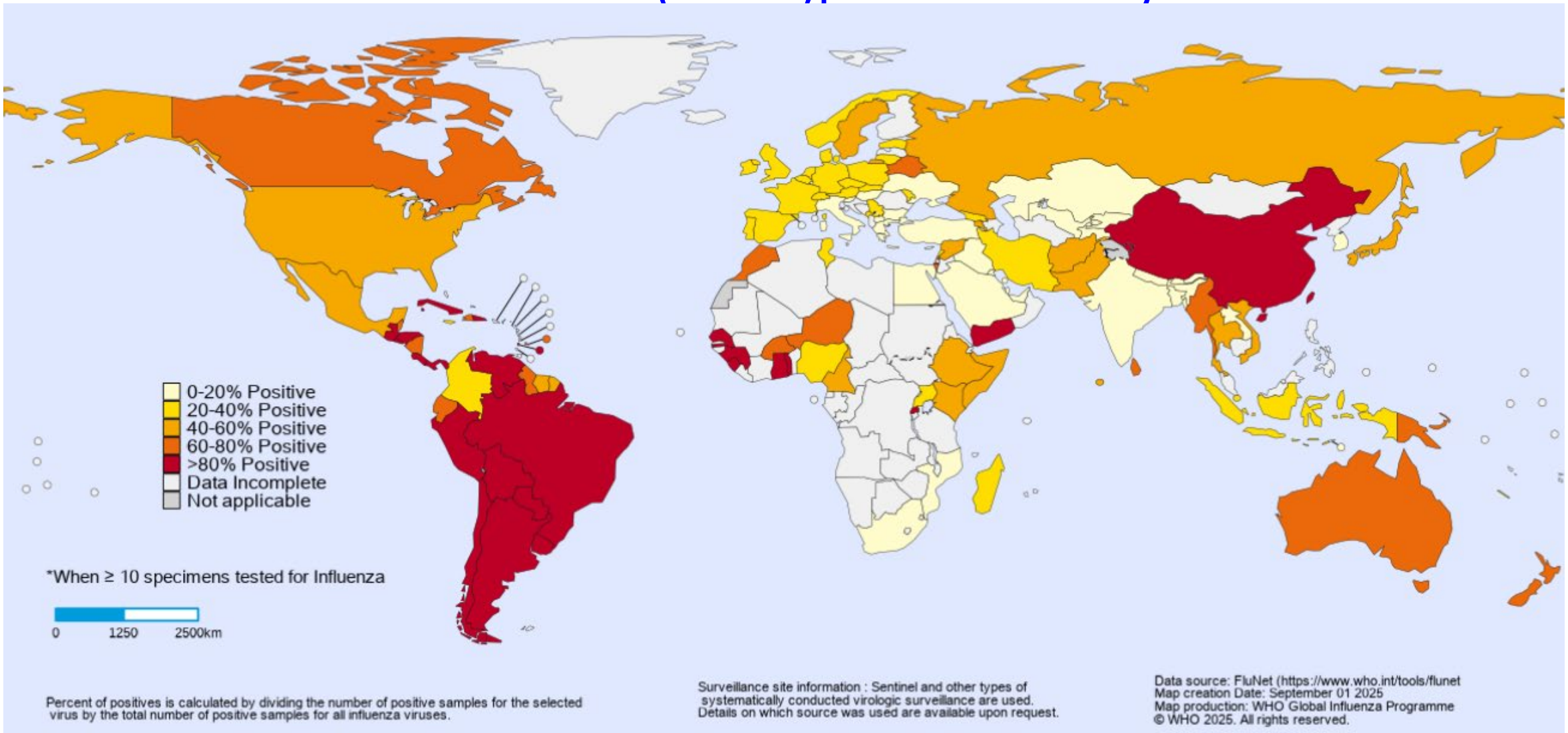
World Health Organization

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ



A(H1N1)pdm09 Viruses

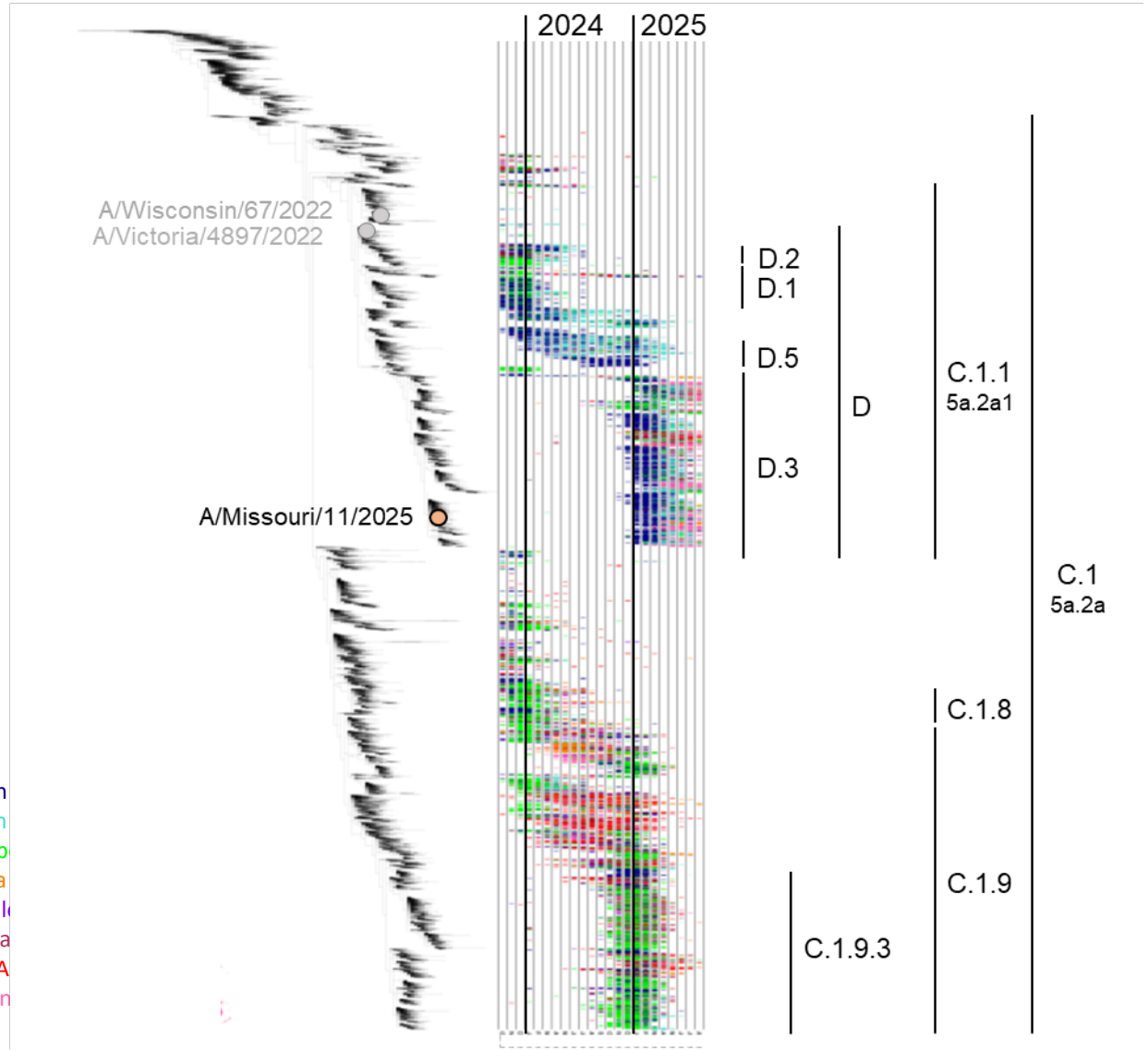
Influenza A(H1N1)pdm09 activity

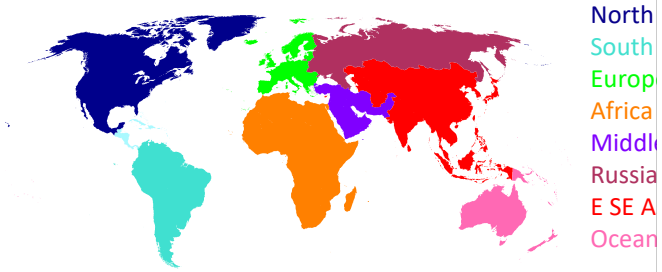


Data source: FluNet, (https://www.who.int/tools/flunet), Global Influenza Surveillance and Response System (1 September 2025)

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

A(H1N1)pdm09 HA phylogeography



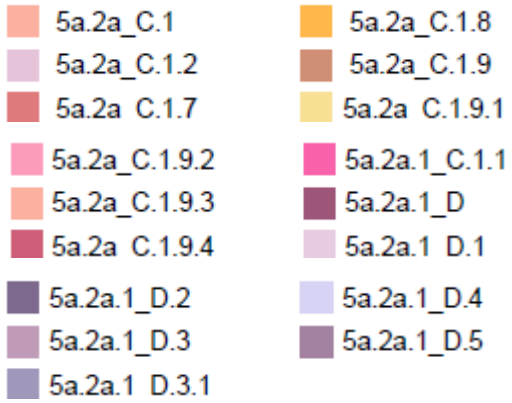


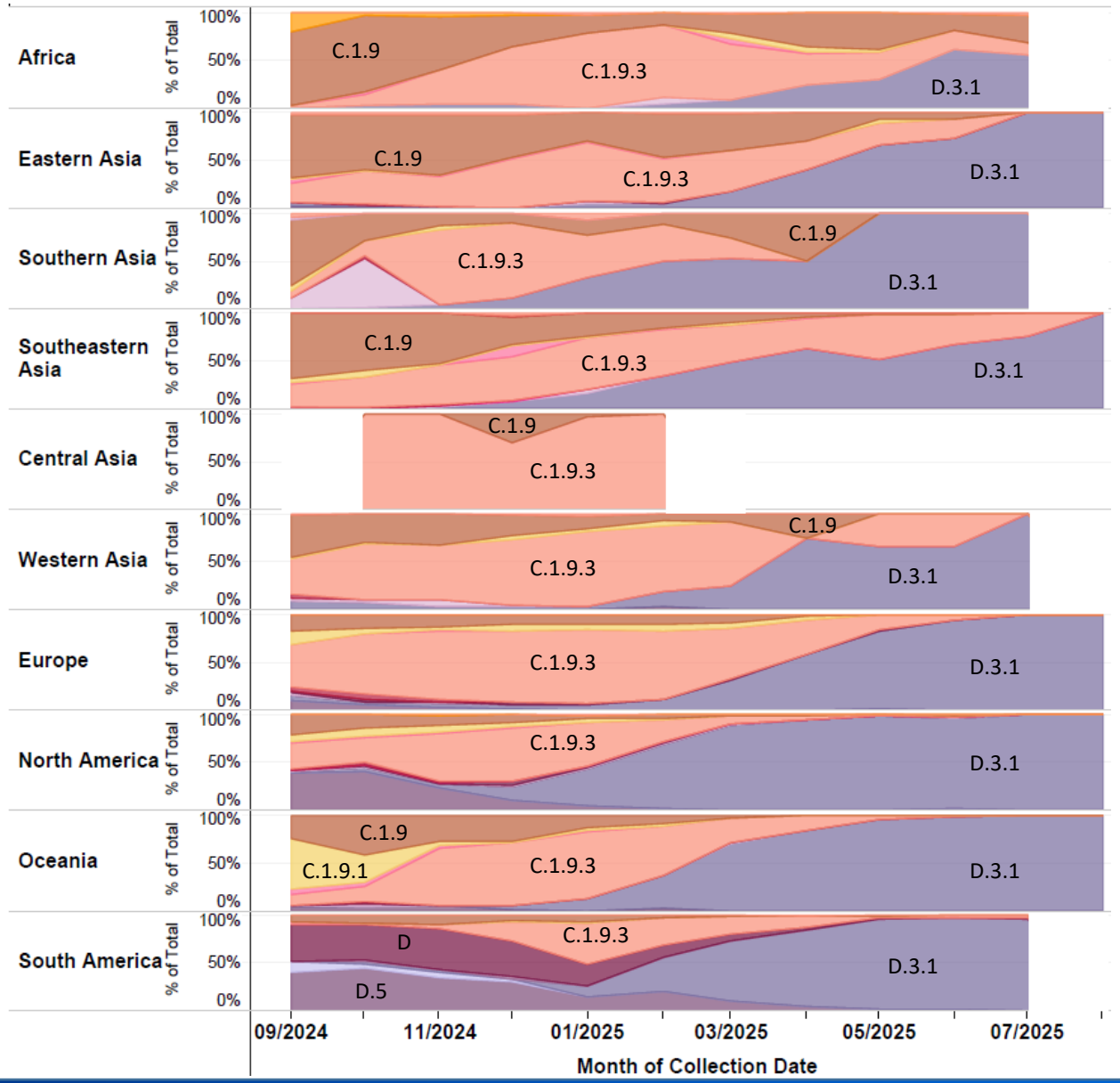
Source:
University of Cambridge

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

A(H1N1)pdm09 Extended Diversity Plot by Geographic Region

Sep. 1, 2024 - Present

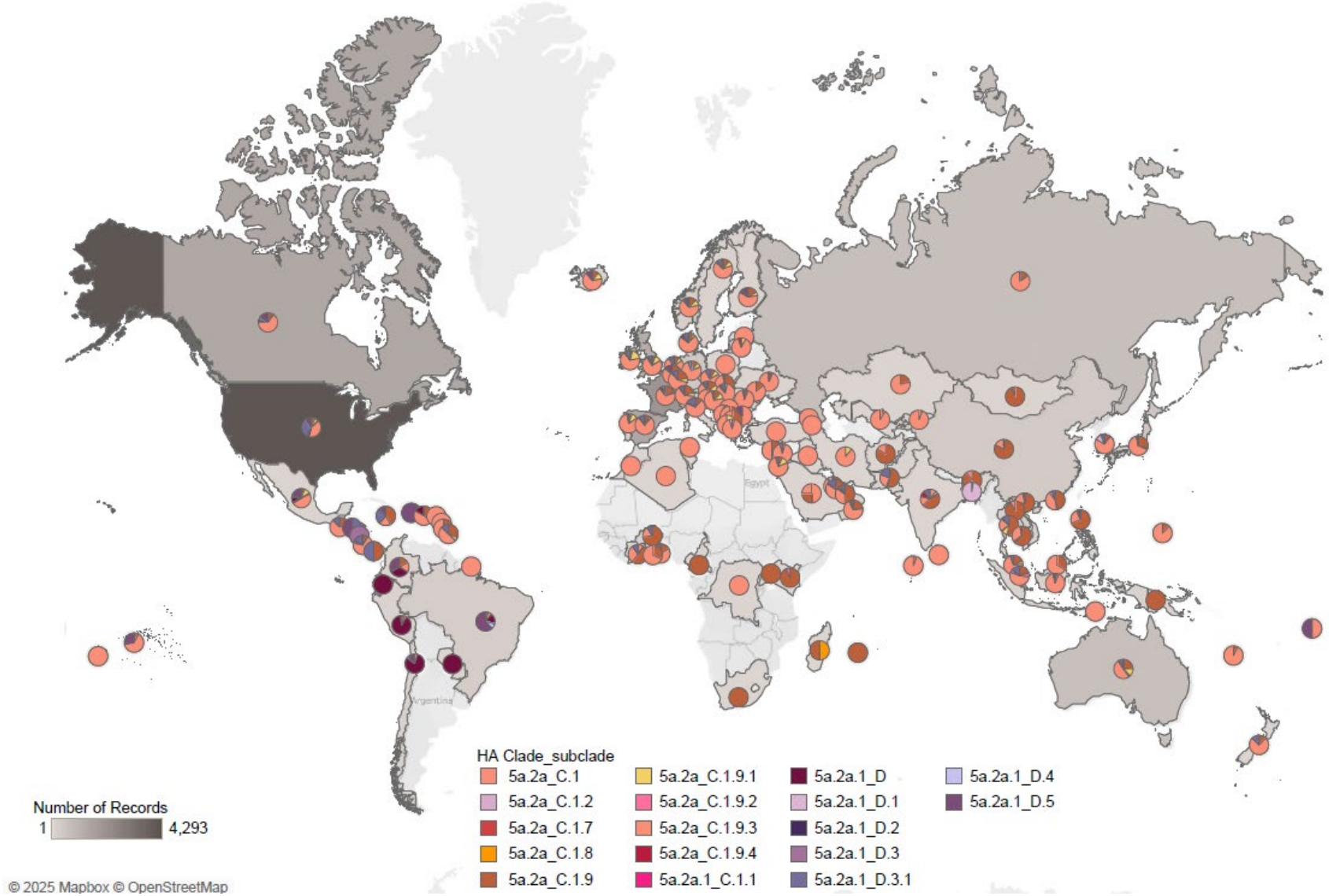




https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™

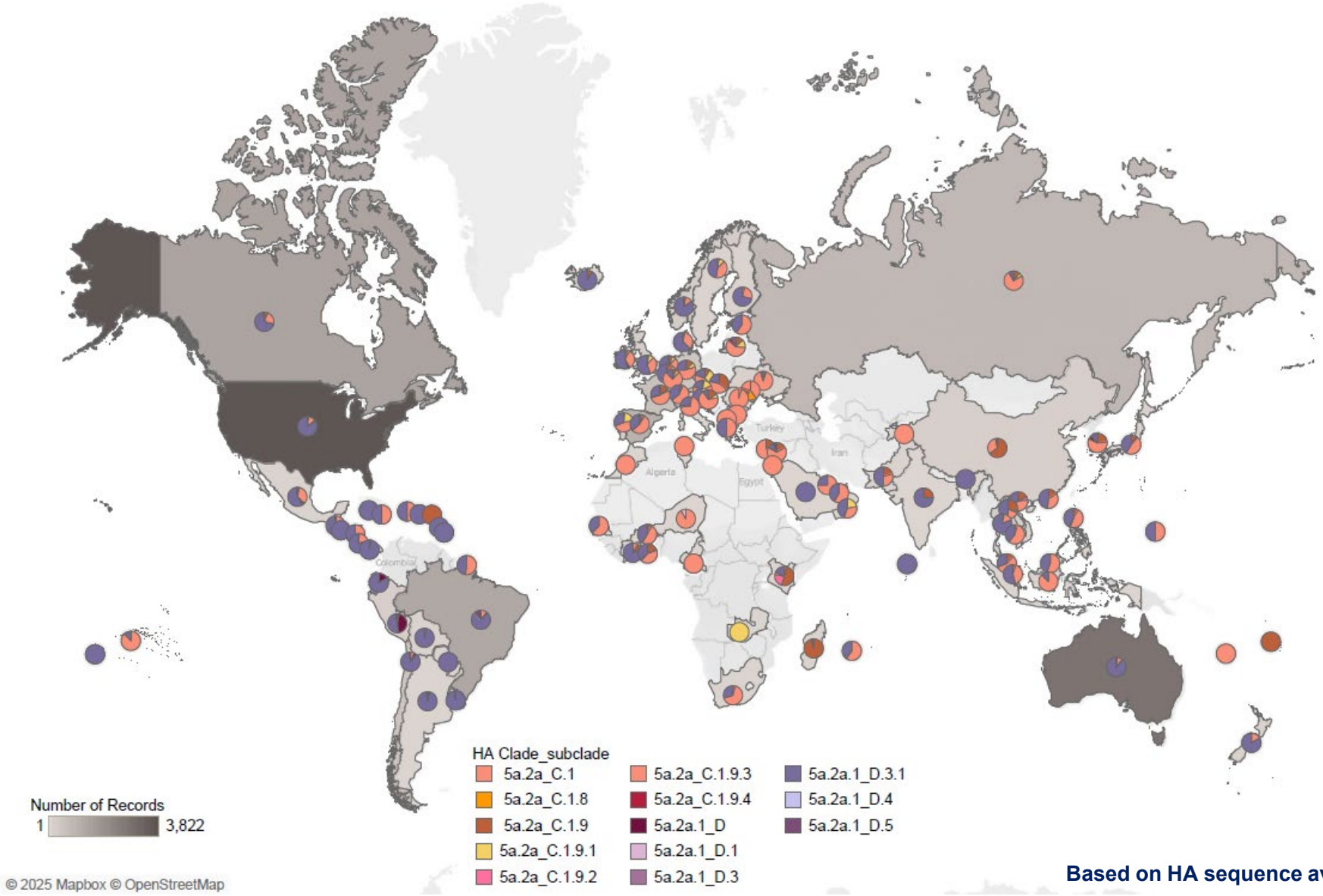
Global A(H1N1)pdm09 HA clade diversity: Sep 2024 to Jan 2025



https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™

Global A(H1N1)pdm09 HA clade diversity: Feb 2025 to Aug 2025



https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™

Antigenic analysis of A(H1N1)pdm09 viruses in HI assays

Antisera to southern hemisphere 2025 vaccine virus antigens

C.1.1 (5a.2a.1)			D (5a.2a.1)		
WHO CC	A/Wisconsin/67/2022-like Cell	Low (≥ 8 fold)	WHO CC	A/Victoria/4897/2022-like Egg	Low (≥ 8 fold)
CDC	1041 (100%)	3 (0%)	CDC	1033 (100%)	3 (0%)
CNIC	1515 (99%)	9 (1%)	CNIC	1506 (99%)	18 (1%)
FCI	260 (96%)	12 (4%)	FCI	267 (98%)	5 (2%)
NIID	65 (90%)	7 (10%)	NIID	66 (92%)	6 (8%)
VIDRL	2689 (100%)	11 (0%)	VIDRL	2679 (99%)	21 (1%)
TOTAL	5570 (99%)	42 (1%)	TOTAL	5551 (99%)	53 (1%)

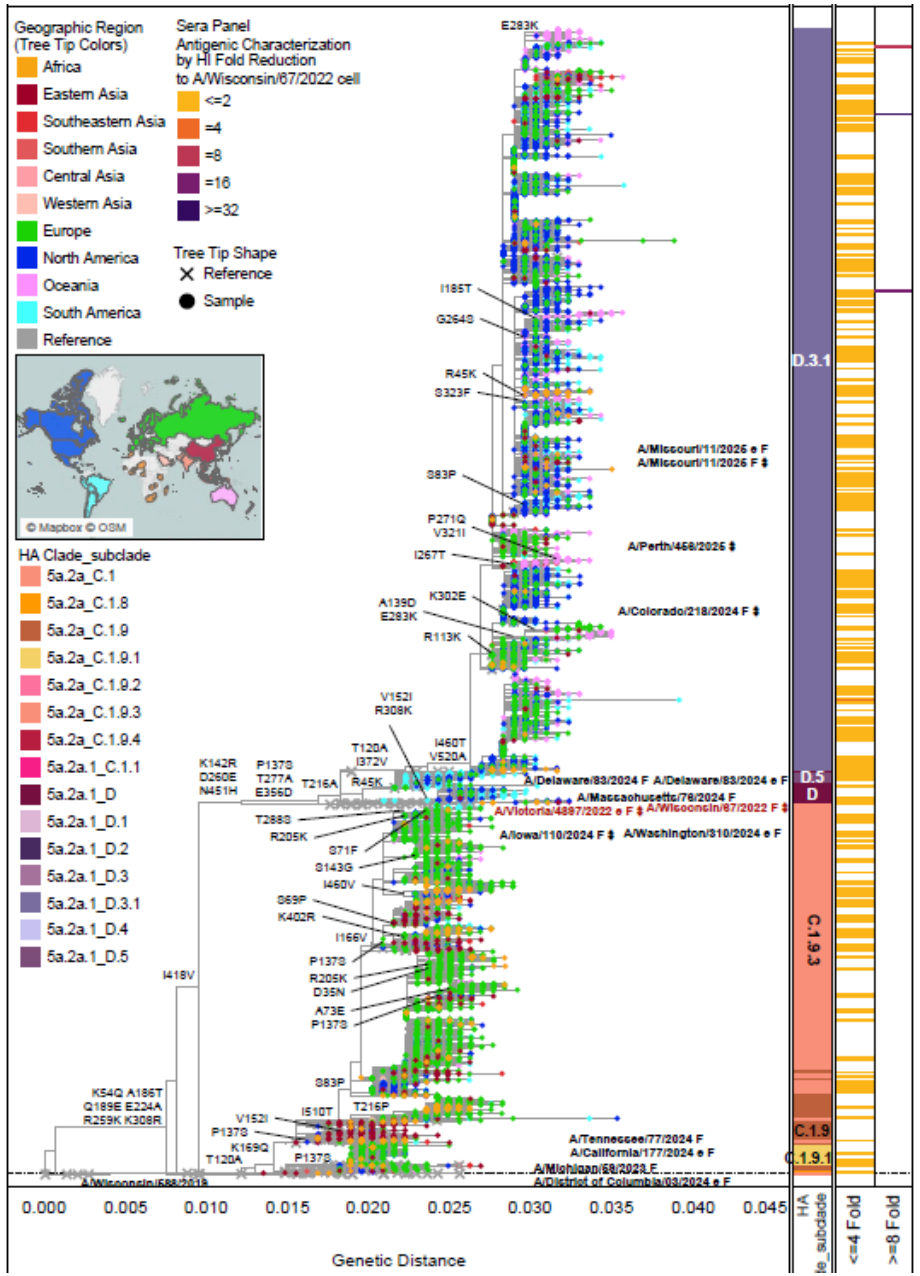
“Low” reactor represented titers ≥ 8-fold lower than vaccine strain homologous titer by HI

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

A(H1N1)pdm09 Integrated Genotype and Phenotype Analysis

Antigenic Characterization by HI using Ferret Antisera Fold Reduction into A/Wisconsin/67/2022 cell

- <=2
- =4
- =8
- =16
- >=32



5a.2a.1
(D, D.3.1, D.5)

5a.2a
(C.1.9, C.1.9.1, C.1.9.3)

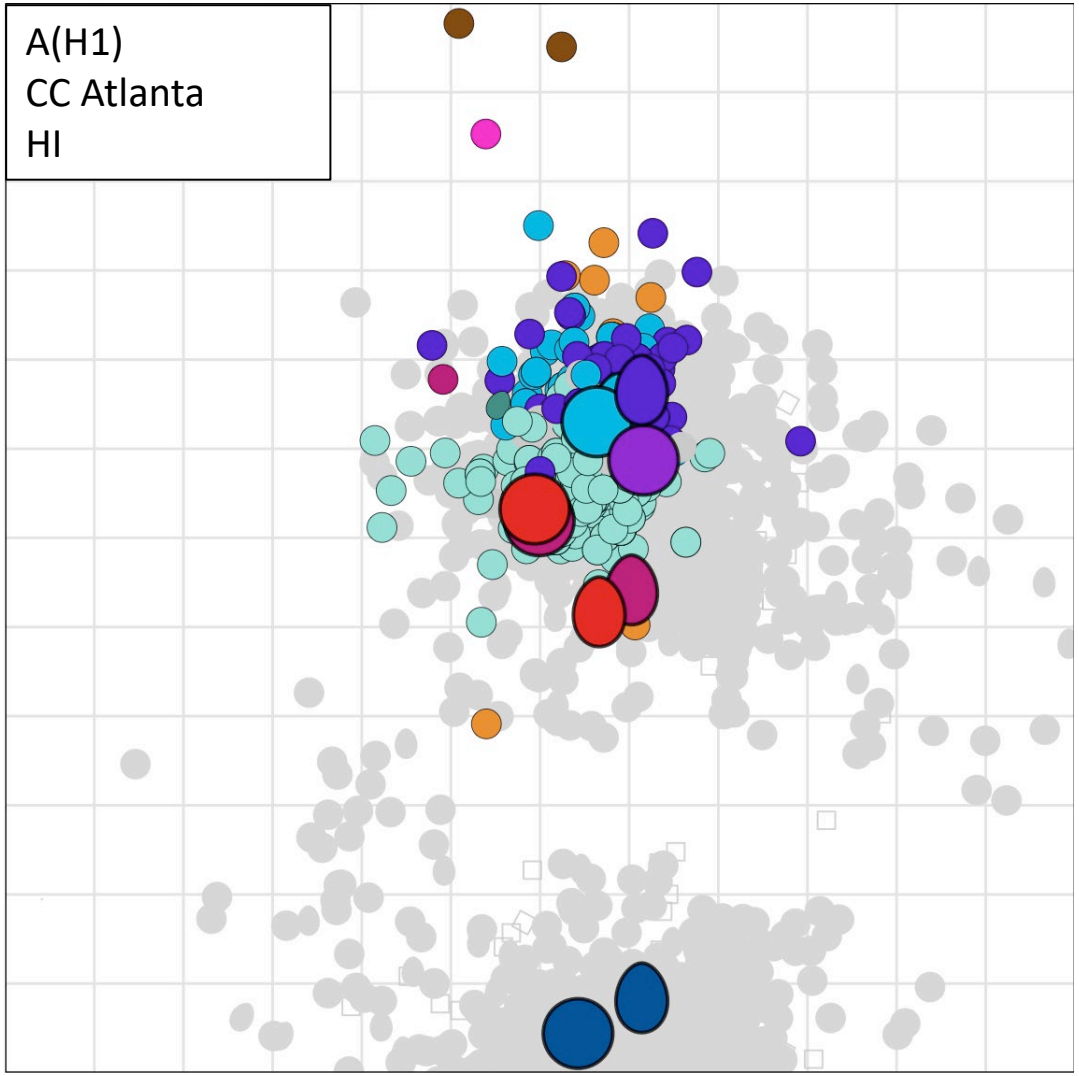
Based on HA sequence availability from GISAID EpiFlu™

A(H1N1)pdm09 HI Table

		REFERENCE FERRET ANTISERA				
		5a.2a		5a.2a.1		
		C.1.9	C.1.9.3	C.1.1	D	D.3.1
	HA subclade	A/MICHIGAN/59/2023 SIAT	A/IOWA/110/2024 SIAT	A/WISCONSIN/67/2022 SIAT	A/VICTORIA/4897/2022 EGG	A/MISSOURI/11/2025 SIAT
REFERENCE VIRUSES						
A/MICHIGAN/59/2023	C.1.9	**5120**	2560	5120	2560	2560
A/IOWA/110/2024	C.1.9.3	5120	**5120**	5120	5120	5120
A/WISCONSIN/67/2022	C.1.1	5120	2560	**5120**	5120	5120
A/VICTORIA/4897/2022	D	2560	2560	5120	**5120**	5120
A/MISSOURI/11/2025	D.3.1	2560	1280	5120	5120	**5120**
TEST VIRUSES						
A/MADAGASCAR/1730/2025	C.1.9	5120	5120	5120	5120	5120
A/MADAGASCAR/1765/2025	C.1.9	5120	1280	5120	2560	5120
A/BELGIUM/0013/2025	C.1.9.1	5120	2560	5120	2560	5120
A/BELGIUM/0026/2025	C.1.9.3	2560	1280	5120	2560	2560
A/BELGIUM/0036/2025	C.1.9.3	5120	2560	5120	2560	5120
A/BURKINA FASO/4217/2025	C.1.9.3	5120	5120	5120	2560	5120
A/GHANA/3606/2025	C.1.9.3	5120	2560	5120	2560	2560
A/GHANA/3798/2025	D.1	2560	2560	5120	5120	5120
A/MINNESOTA/85/2025	D.1	2560	2560	5120	5120	5120
A/BELGIUM/0040/2025	D.3.1	640	640	1280	1280	1280
A/URUGUAY/365/2025	D.3.1	1280	1280	5120	2560	5120
A/BELGIUM/0057/2025	D.3.1	1280	1280	5120	2560	2560
A/URUGUAY/584/2025	D.3.1	2560	2560	5120	2560	5120
A/URUGUAY/645/2025	D.3.1	160	80	640	320	640
A/RONDONIA/358426625-IAL/2025	D.3.1	640	640	2560	2560	5120
A/SAO PAULO/358388305-IAL/2025	D.3.1	2560	2560	5120	5120	5120
A/SAO PAULO/358397628-IAL/2025	D.3.1	640	640	2560	2560	2560
A/MICHIGAN/103/2025	D.3.1	2560	1280	5120	5120	5120
A/COTE D'IVOIRE/1954/2025	D.3.1	5120	2560	5120	5120	5120
A/PENNSYLVANIA/508/2025	D.3.1	2560	1280	5120	2560	5120
A/PENNSYLVANIA/509/2025	D.3.1	2560	2560	5120	5120	5120
A/WISCONSIN/115/2025	D.3.1	2560	1280	5120	5120	5120
A/MISSOURI/63/2025	D.3.1	2560	1280	5120	5120	5120
A/MISSOURI/64/2025	D.3.1	2560	2560	5120	5120	5120
A/BURKINA FASO/5575/2025	D.3.1	5120	2560	5120	5120	5120
A/NEW YORK/127/2025	D.3.1	1280	1280	5120	5120	5120
A/SAO PAULO/358378577-IAL/2025	D.5	2560	1280	5120	5120	5120

four-fold or greater reduction compared to the homologus virus titre

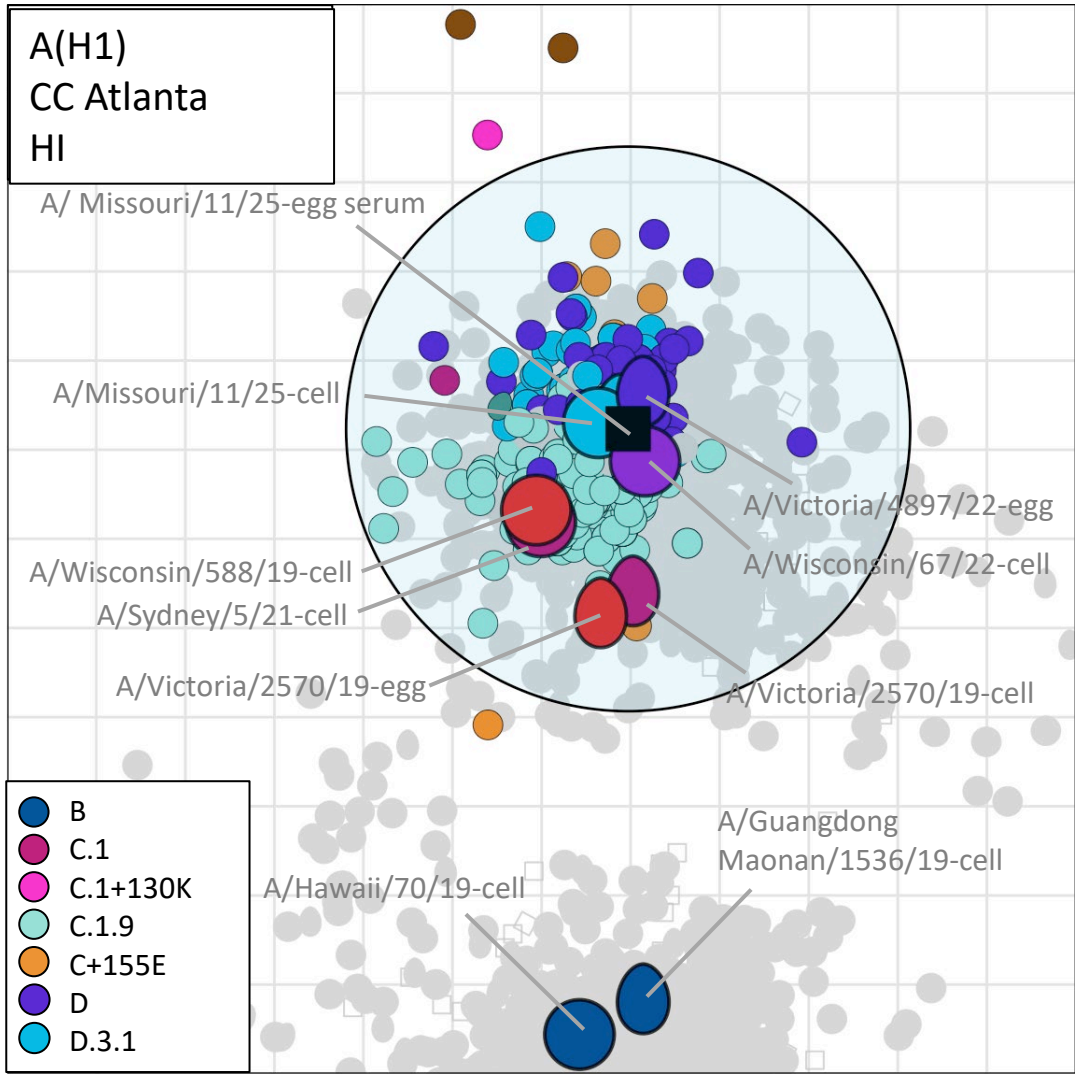
A(H1N1)pdm09 antigenic cartography



Source: University of Cambridge

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

A(H1N1)pdm09 antigenic cartography



Serum circles (within 8-fold of homologous titers)

Source: University of Cambridge

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Human post-vaccination serum analysis of A(H1N1)pdm09 viruses

				C.1.1 (5a.2a.1) - WI/67 - CELL						D (5a.2a.1) - VIC/4897 - CELL	D.3.1 (5a.2a.1) - MO/11-LIKE* - MO/11 CELL		- TAS/318 CELL		TOKYO/EIS10-554 CELL	+R113K - CO/218-LIKE - CO/218 CELL		BHR/2522 0003050 CELL	+R113K +A139D +E283K - DAR/1015 - CELL		+R113K +K156N +Q193K - TOKYO/EIS11-980 - CELL		C.1.9 (5a.2a) - NW/SWL1231 - CELL	+G155E - KOBE/24357 - CELL	+I166V - NOR/07606 - CELL	+S69P +P137S +I166V - HD/SWL1105-LIKE - HD/SWL1105 CELL	TOKYO/EIS11-294 CELL	+T120A +I166V +K169Q - IA/110 - CELL	+P137S +G155E +I166V - VIC/42 - CELL		+S190T +E283Q - LL/SWL1278 - CELL
				CDC HI	CBER HI	MHRA HI	NIID HI	VIDRL HI	VIDRL MN	CNIC HI	CDC HI	CBER HI	VIDRL HI	VIDRL MN	NIID HI	CDC HI	CBER HI	MHRA HI	VIDRL HI	VIDRL MN	MHRA HI	NIID HI	CNIC HI	MHRA HI	MHRA HI	CNIC HI	NIID HI	CDC HI	VIDRL HI	VIDRL MN	CNIC HI
A/WISCONSIN/67/2022-LIKE CELL	Adult	ccIIV4 (cell)	Australia	249	320	378	411	147	589	128	√	191	√	√	√	√	√	211	√	√	249	256	41	156	169	√	√	√	85	82	√
		IIV4 (egg)	Australia	229	271	557	348	160	311	147	√	121	√	√	√	√	√	320	√	√	√	√	68	286	√	√	√	√	√	√	189	√
		IIV3 (egg)	Peru	133							√					√												√				
			South Africa	149							√					√												√				
	Elderly	aIIV4 (egg-adjuvant)	Australia	39	55	95	75	32	59	19	X	25	X	√	√	X	43	51	X	√	√	√	X	61	59	X	√	X	X	35	X
											0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	3 (100.0)	0 (0.0)	0 (0.0)	1 (33.3)	1 (33.3)	2 (66.7)	3 (100.0)	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	3 (100.0)	0 (0.0)

Statistically non-inferior = √

Statistically non-inferior but reference virus GMT < 40 = X

GMT Ratio Lower-Bound (90% CI)

0.000 — 1.000

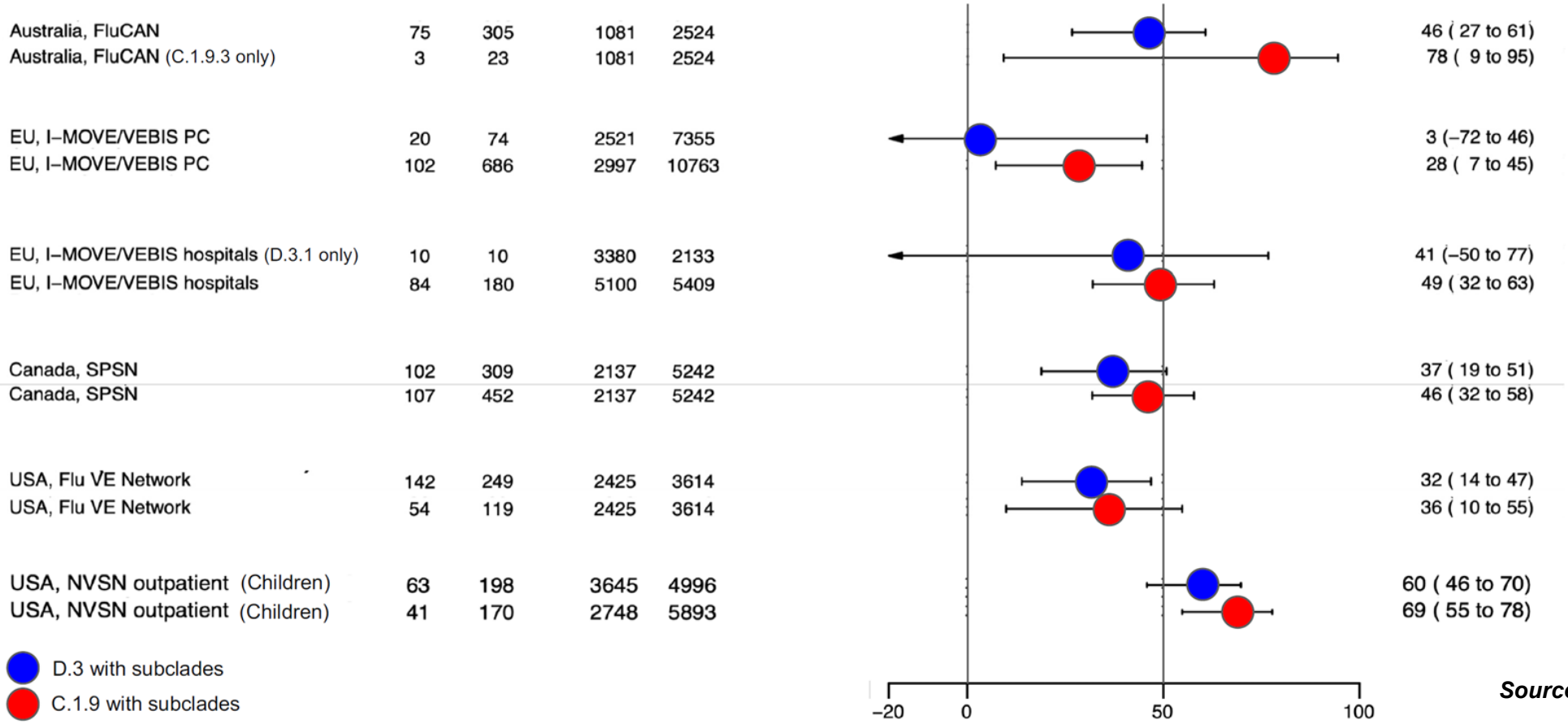
Geometric Mean Titer (GMT) ratios between reference and test antigens are calculated with 90% (CI) confidence intervals for each cohort and panel location. Unadjusted model results are shown. If the CI lower bound is greater than 50%, it is statistically non-inferior (95% confidence level); otherwise, it is *possibly* inferior. Heat map cells are colored using the GMT ratio lower bound. Blue indicates statistical non-inferiority and orange denotes *possible* inferiority. Numbers shown are post-vaccination GMTs for the unadjusted model. They are shown for reference antigens and possibly inferior test antigens. Marks, √ or X, denote statistically significant non-inferiority when the reference virus GMT is ≥40 or <40, respectively.

Strains abbreviated: A/COLORADO/218/2024 (CO/218); A/IOWA/110/2024 (IA/110); A/MISSOURI/11/2025 (MO/11); A/PERTH/456/2025 (PERTH/456); A/VICTORIA/4897/2022 (VIC/4897); A/WISCONSIN/67/2022 (WI/67).

Vaccine Effectiveness (VE)

VE against A(H1N1)pdm09 by subclade – all ages (inpatients and outpatients)

Network	Positive V	Positive UV	Negative V	Negative UV	VE [95% CL]
Australia, FluCAN	75	305	1081	2524	46 (27 to 61)
Australia, FluCAN (C.1.9.3 only)	3	23	1081	2524	78 (9 to 95)
EU, I–MOVE/VEBIS PC	20	74	2521	7355	3 (–72 to 46)
EU, I–MOVE/VEBIS PC	102	686	2997	10763	28 (7 to 45)
EU, I–MOVE/VEBIS hospitals (D.3.1 only)	10	10	3380	2133	41 (–50 to 77)
EU, I–MOVE/VEBIS hospitals	84	180	5100	5409	49 (32 to 63)
Canada, SPSN	102	309	2137	5242	37 (19 to 51)
Canada, SPSN	107	452	2137	5242	46 (32 to 58)
USA, Flu VE Network	142	249	2425	3614	32 (14 to 47)
USA, Flu VE Network	54	119	2425	3614	36 (10 to 55)
USA, NVSN outpatient (Children)	63	198	3645	4996	60 (46 to 70)
USA, NVSN outpatient (Children)	41	170	2748	5893	69 (55 to 78)



Source: GIVE Consortium

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Influenza A(H1N1)pdm09: antiviral susceptibility

Neuraminidase inhibitors

- Of 3,988 A(H1N1)pdm09 virus clinical samples and isolates examined by genetic and/or phenotypic analyses, 96 viruses showed evidence of reduced susceptibility to neuraminidase inhibitors (NAIs):
  - 88 had an H275Y NA substitution and two had a Q136K substitution.
  - The remaining six viruses had H275Y and S247N, H275H/Y and S247N, S247R, I223K, I223R or N295S substitutions.

Endonuclease inhibitors

- Of 3,326 A(H1N1)pdm09 viruses examined by genetic and/or phenotypic analyses, four viruses showed evidence of reduced susceptibility to the endonuclease inhibitor baloxavir marboxil:
  - Three had an E199G PA substitution, and one had an I38T substitution.

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Influenza A(H1N1)pdm09 summary (1)

Phylogenetics of A(H1N1)pdm09 HA genes

- A(H1N1)pdm09 viruses circulated globally and predominated in most regions.
- The HA genes of viruses that were genetically characterized belonged to the clade 5a.2a subclade C.1.9 and C.1.9.3 or clade 5a.2a.1 subclade D.3 and D.3.1.
- 5a.2a.1 viruses from subclade D.3.1 have now largely displaced 5a.2a viruses and other subclades of 5a.2a.1 viruses in all regions.

Influenza A(H1N1)pdm09 summary (2)

Antigenic characteristics of A(H1N1)pdm09 viruses

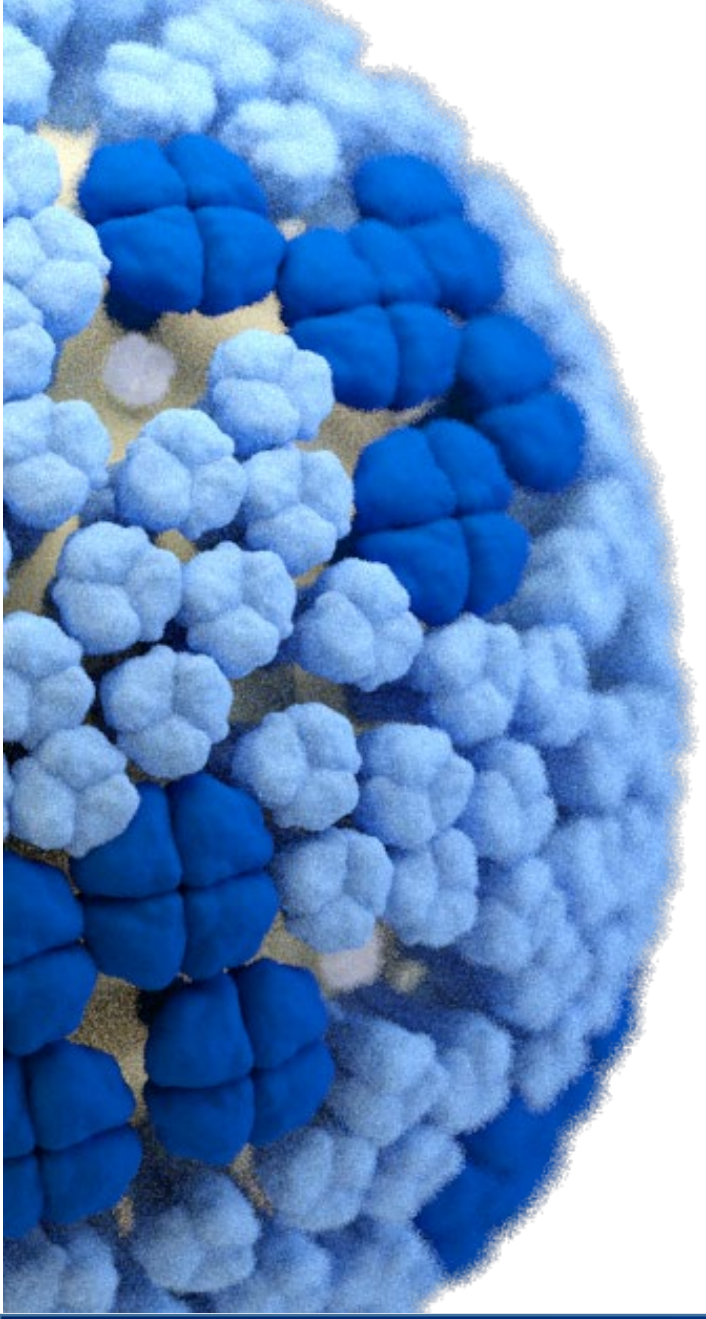
- Post-infection ferret antisera raised against the SH 2025 and NH 2025-2026 A(H1N1)pdm09 vaccine viruses (cell culture-propagated A/Wisconsin/67/2022 and egg-propagated A/Victoria/4897/2022) from the 5a.2a.1 clade recognized 5a.2a and 5a.2a.1 viruses well.
- Post-infection ferret antisera raised against viruses from HA subclade D.3.1 (e.g., A/Missouri/11/2025) better recognized recently circulating viruses from both 5a.2a and 5a.2a.1 clades compared to post-infection ferret antisera raised against recent viruses from HA subclades C.1.9 and C.1.9.3.

Influenza A(H1N1)pdm09 summary (3)

Human serology studies

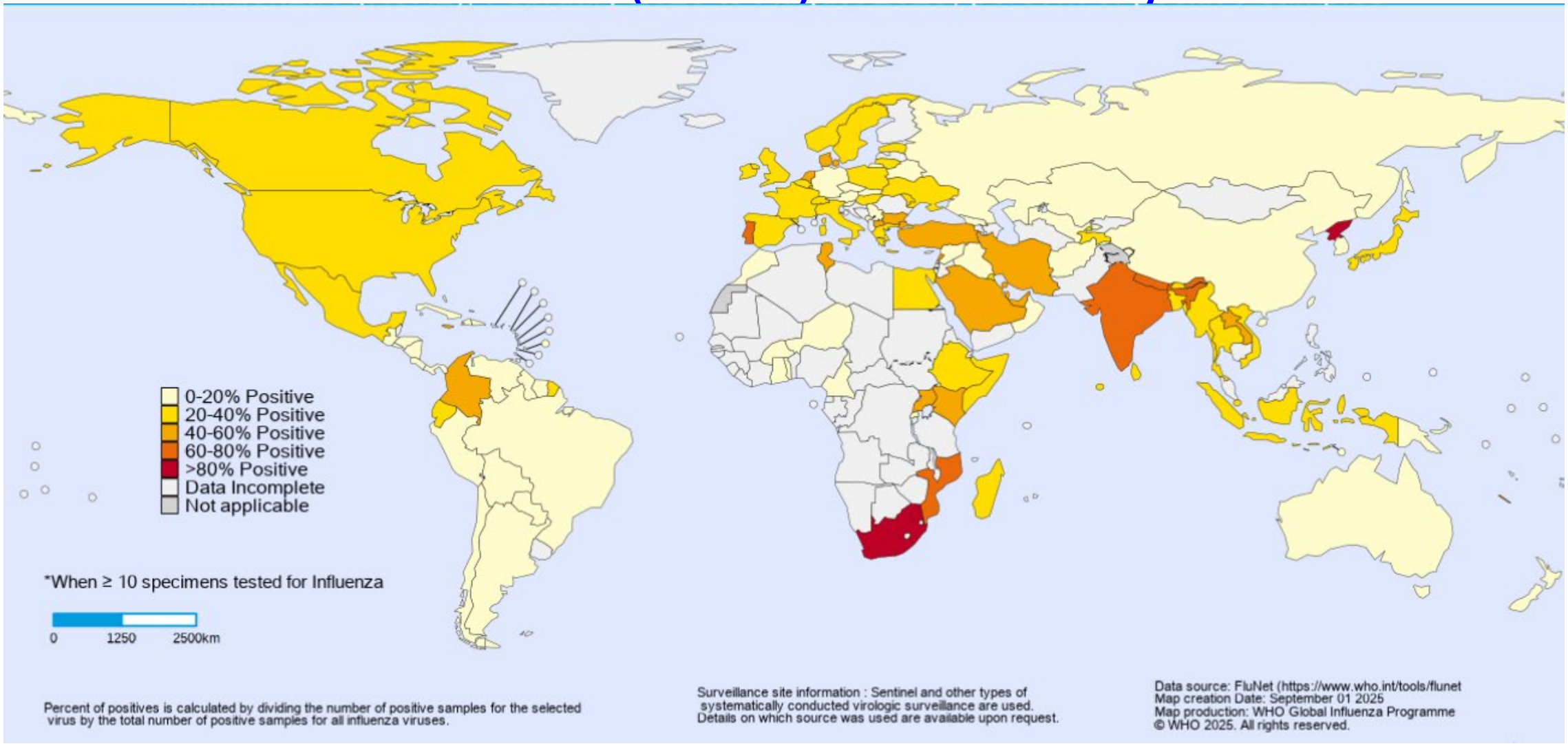
- Human serology studies were conducted using the SH 2025 or NH 2024-2025 influenza vaccine formulation vaccinated serum panels by HI assays with recent circulating A(H1N1)pdm09 viruses with HA genes from 5a.2a subclades C.1.9 and C.1.9.3 and 5a.2a1 subclades D.3 and D.3.1.
- When compared to the responses to cell culture-propagated A/Wisconsin/67/2022 (H1N1)pdm09-like vaccine reference viruses, post-vaccination geometric mean titers (GMTs) were significantly reduced for some recently circulating viruses from across the genetic diversity.

The data supported recommending A/Missouri/11/2025 (H1N1)pdm09-like (D.3.1) viruses as the A(H1N1)pdm09 vaccine antigens for the 2026 southern hemisphere.



A(H3N2) Viruses

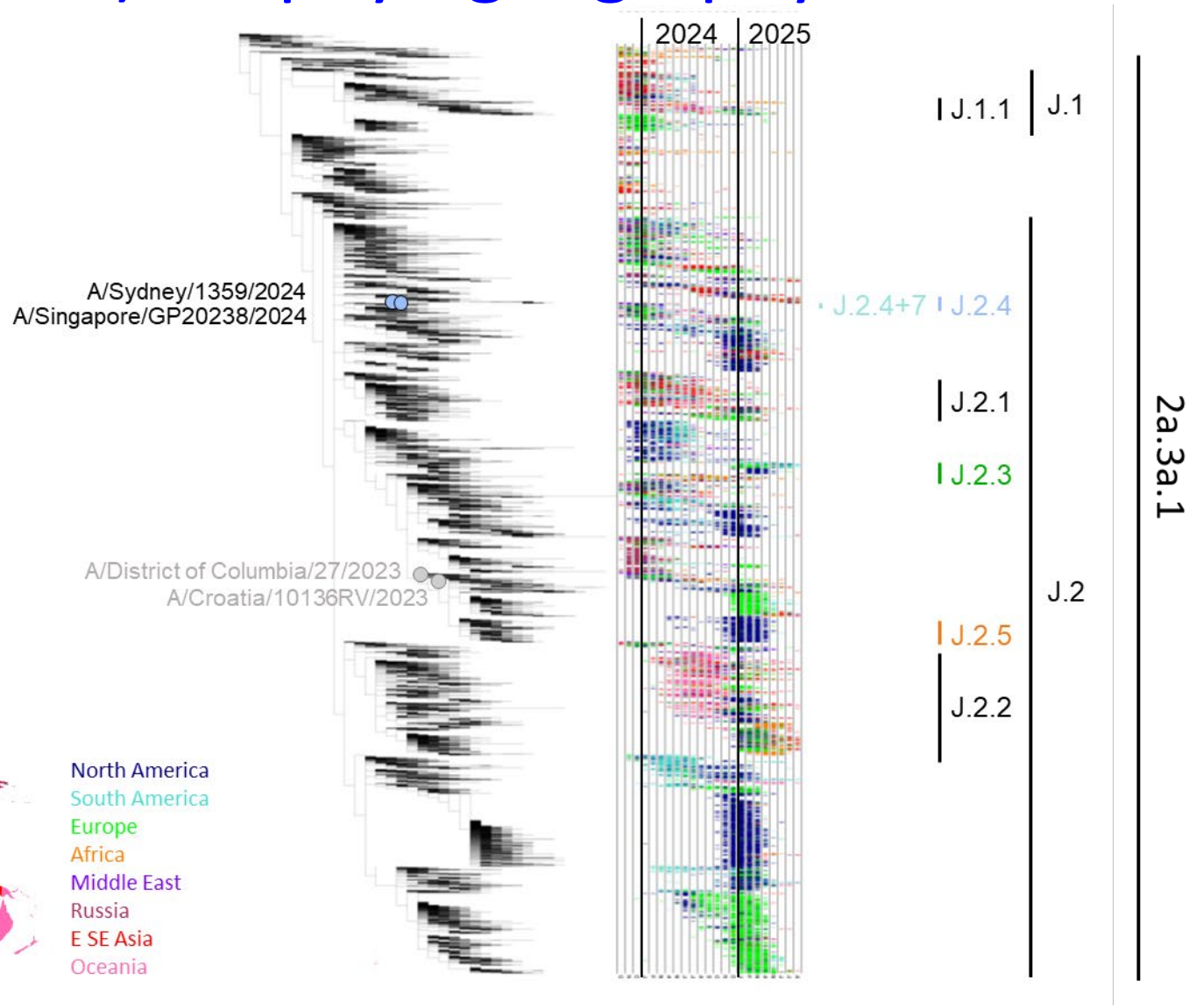
Influenza A(H3N2) virus activity



Data source: FluNet, (https://www.who.int/tools/flunet), Global Influenza Surveillance and Response System (1 September 2025)

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

A(H3N2) HA phylogeography



Source: University of Cambridge, UK

https://clades.nextstrain.org/

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

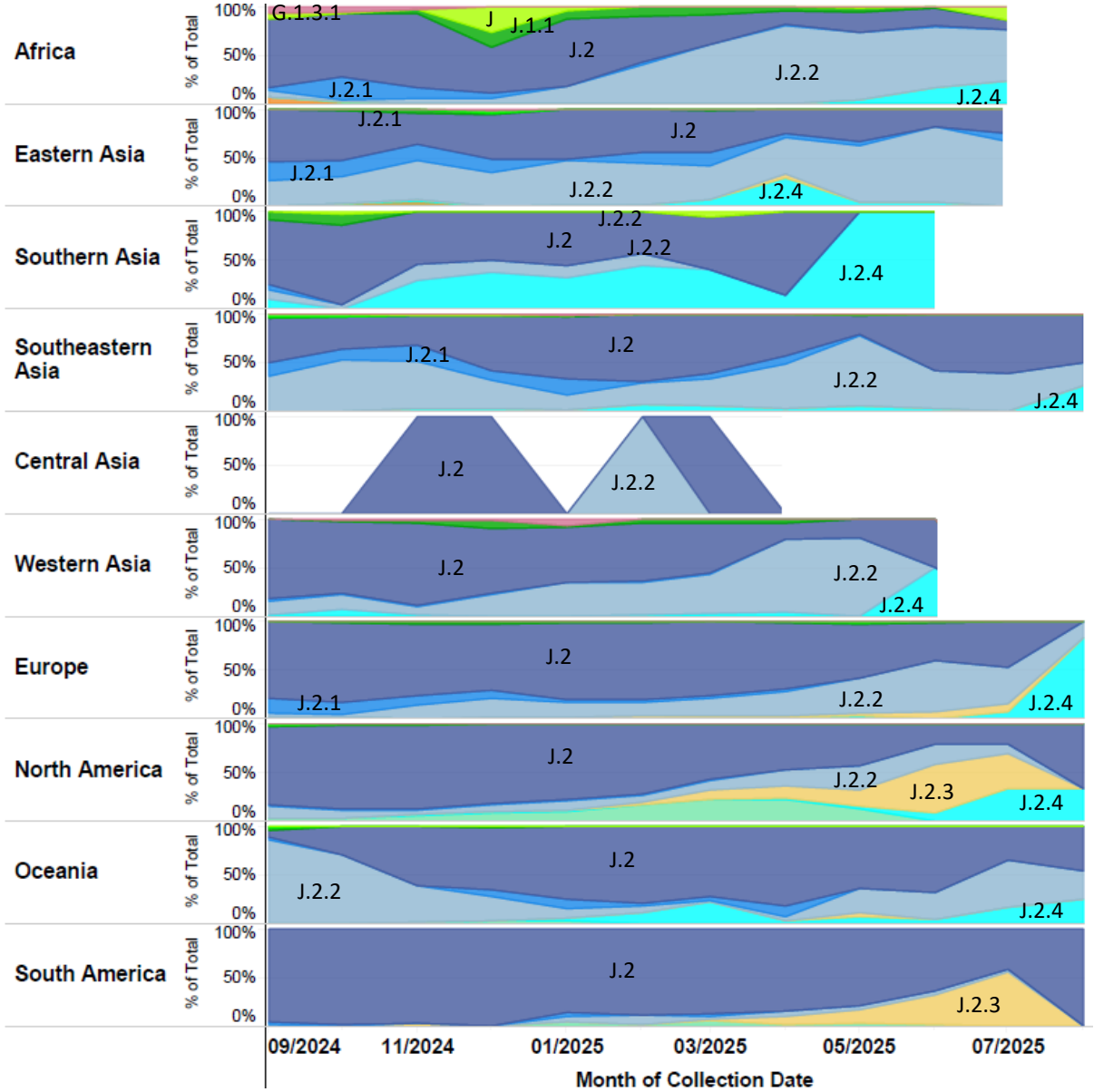
A(H3N2) Extended Diversity Plot by Geographic Region

Sep. 1, 2024 - Present

HA Clade_subclade

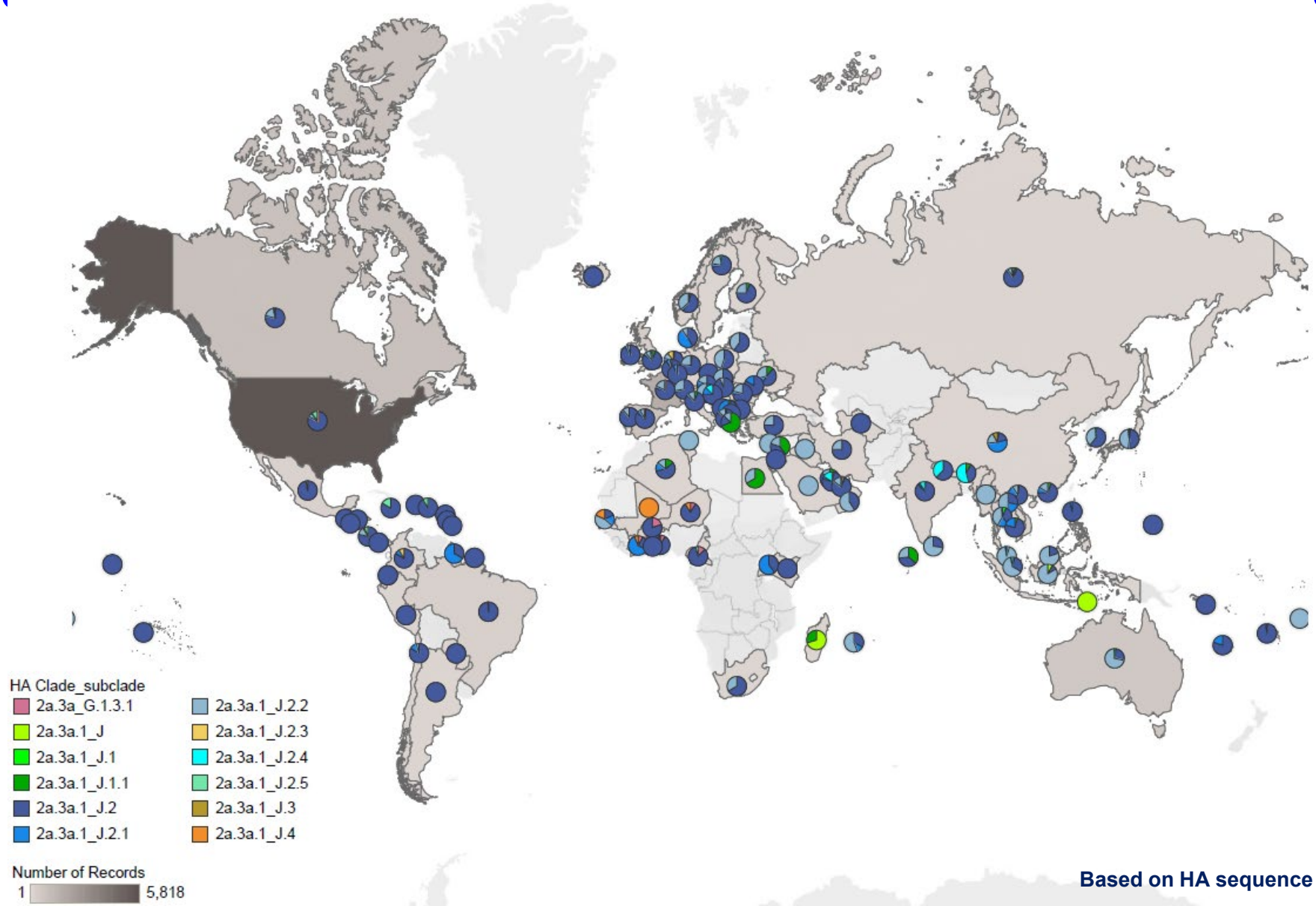
2a.3a_G.1.3.1
2a.3a.1_J.1
2a.3a.1_J.2
2a.3a.1_J
2a.3a.1_J.1.1
2a.3a.1_J.2.1
2a.3a.1_J.2.2
2a.3a.1_J.2.4
2a.3a.1_J.3
2a.3a.1_J.2.3
2a.3a.1_J.2.5
2a.3a.1_J.4

https://clades.nextstrain.org/



Based on HA sequence availability from GISAID EpiFlu™

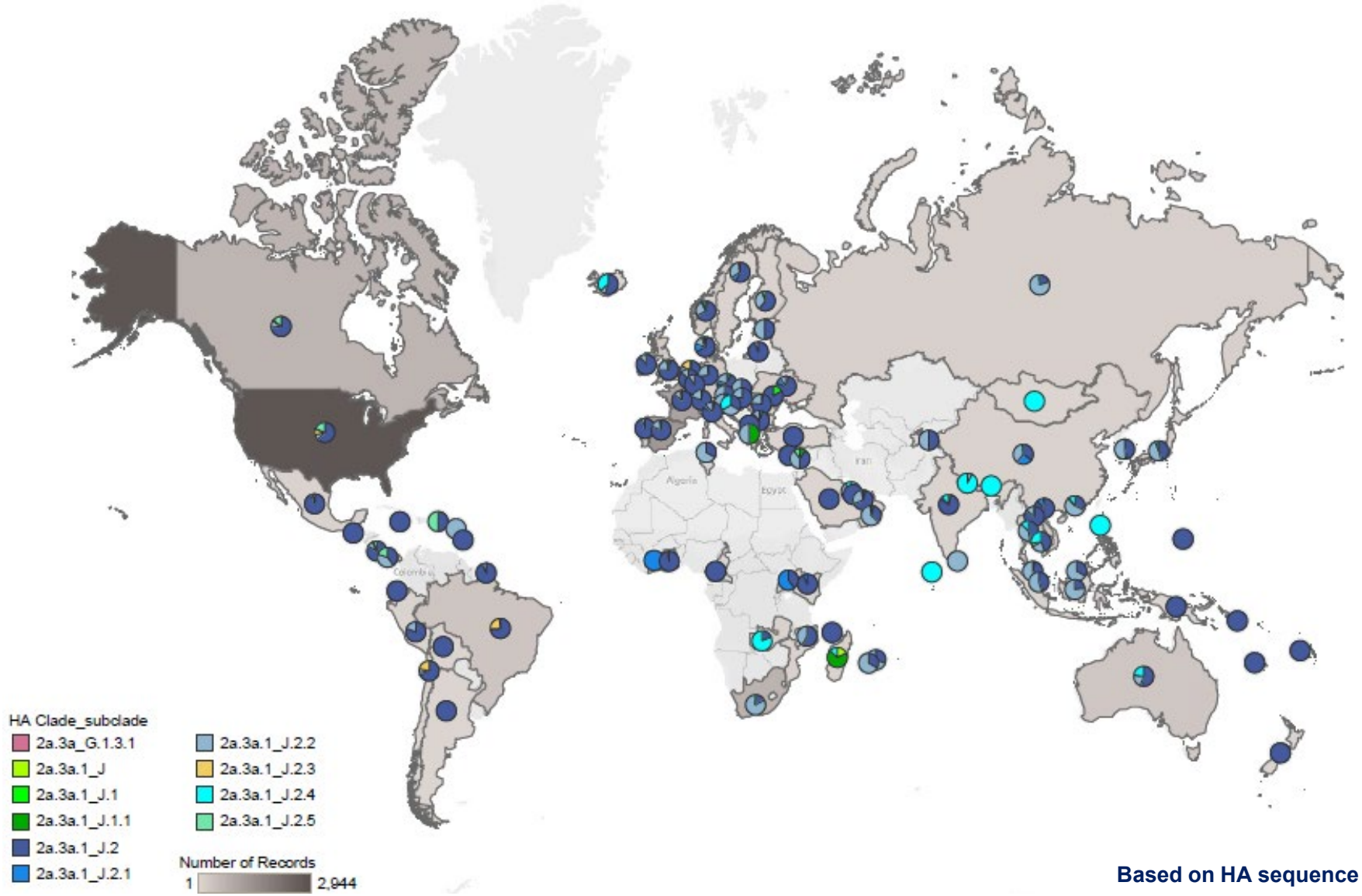
Global A(H3N2) HA clade diversity: Sep 2024 to Jan 2025



https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™

Global A(H3N2) HA clade diversity: Feb 2025 to Aug 2025



https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™

Antigenic analysis of A(H3N2) viruses in **HI** assays

HI Assay

Antisera to **southern hemisphere 2025 antigens** (J.2)

WHO CC	A/District of Columbia/27/2023-like Cell 2a.3a.1 (J2)	Low (≥ 8 fold)	WHO CC	A/Croatia/10136RV/2023 -Like Egg 2a.3a.1 (J2)	Low (≥ 8 fold)
CDC	444 (91%)	45 (9%)	CDC	273 (56%)	216 (44%)
CNIC	210 (90%)	24 (10%)	CNIC	151 (65%)	83 (35%)
FCI	268 (97%)	9 (3%)	FCI	219 (79%)	58 (21%)
NIID	90 (95%)	5 (5%)	NIID	41 (43%)	54 (57%)
VIDRL	377 (94%)	22 (6%)	VIDRL	199 (50%)	200 (50%)
Total	1389 (93%)	105 (7%)	Total	883 (59%)	611 (41%)

"Low" represented titers ≥ 8-fold lower than vaccine strain homologous titer

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Antigenic analysis of A(H3N2) viruses in **VN** assays

VN Assay

Antisera to **southern hemisphere 2025 antigens** (J.2)

WHO CC	A/District of Columbia/27/2023 -like Cell 2a.3a.1 (J.2)	Low (≥ 8 fold)
CDC	238 (92%)	21 (8%)
FCI	98 (95%)	5 (5%)
VIDRL	42 (95%)	2 (5%)
Total	378 (93%)	28 (7%)

WHO CC	A/Croatia/10136RV/2023 -like Egg 2a.3a.1 (J.2)	Low (≥ 8 fold)
FCI	91 (88%)	12 (12%)
VIDRL	21 (48%)	23 (52%)
Total	112 (76%)	35 (24%)

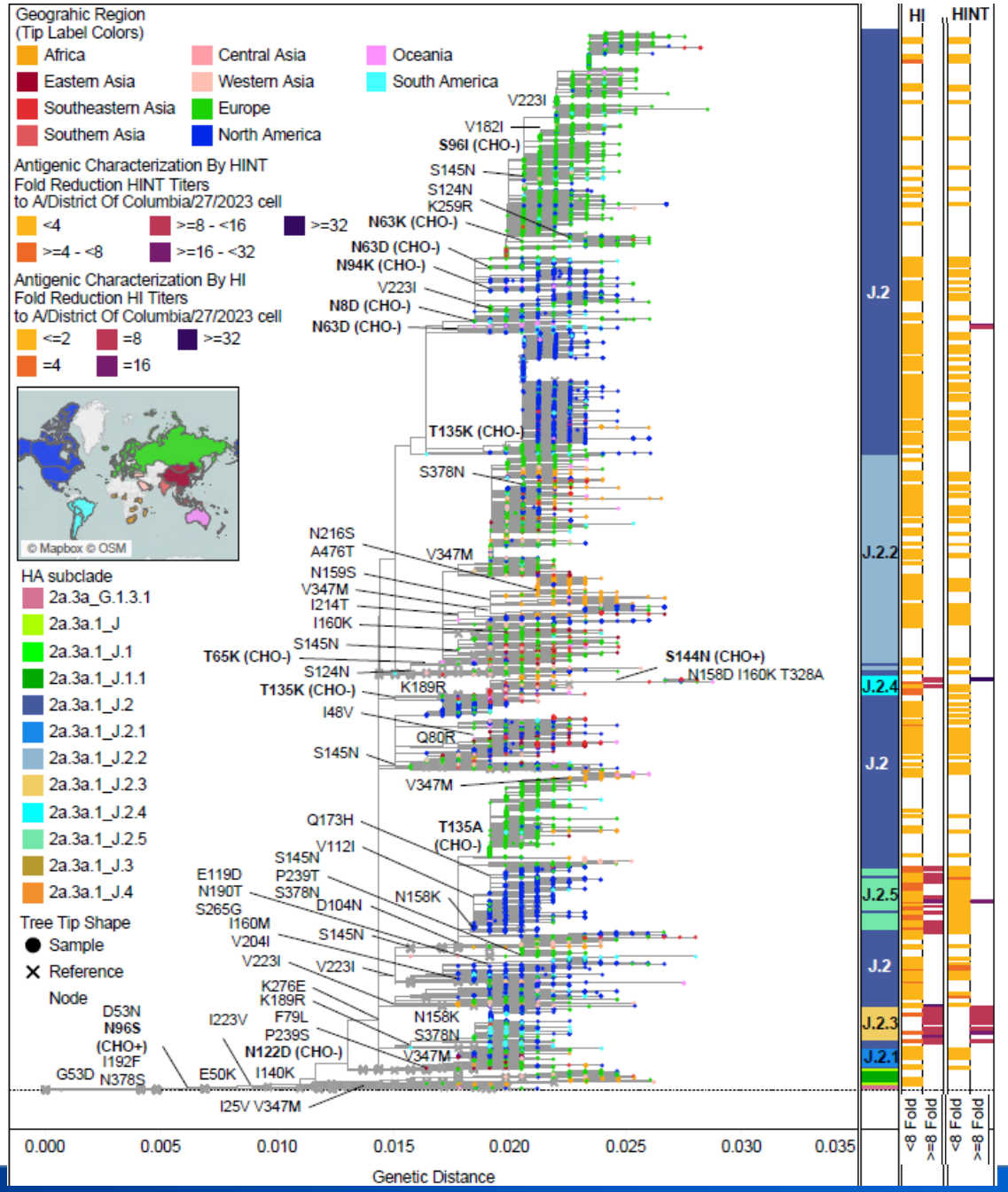
"Low" represented titers ≥ 8-fold lower than vaccine strain homologous titer

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

A(H3N2) Integrated Genotype and Phenotype Analysis

Clade	Subclade	HA AA changes vs. A/District Of Columbia/27/2023
2a.3a	G.1.3.1	D122N(CHO+), K140I, N145S, V223I, E276K
2a.3a.1	G.1.3.1.1	D122N(CHO+), N145S, E276K
	J	D122N(CHO+), N145S, E276K
	J.1	I25V, D122N(CHO+), N145S, E276K, V347M
	J.1.1	I25V, D122N(CHO+), E276K, V347M
	J.2	N145S
	J.2.1	F79L, N145S, P239S

Clade	Subclade	HA AA changes vs. A/District Of Columbia/27/2023
2a.3a.1	J.2.2	S124N, N145S
	J.2.3	N145S, N158K, K189R, S378N
	J.2.4	T135K(CHO-), N145S, K189R
	J.2.5	D104N, N158K
	J.3	D122N(CHO+), N145S, E276K, V505I
	J.4	D122N(CHO+), N145S, Q173R

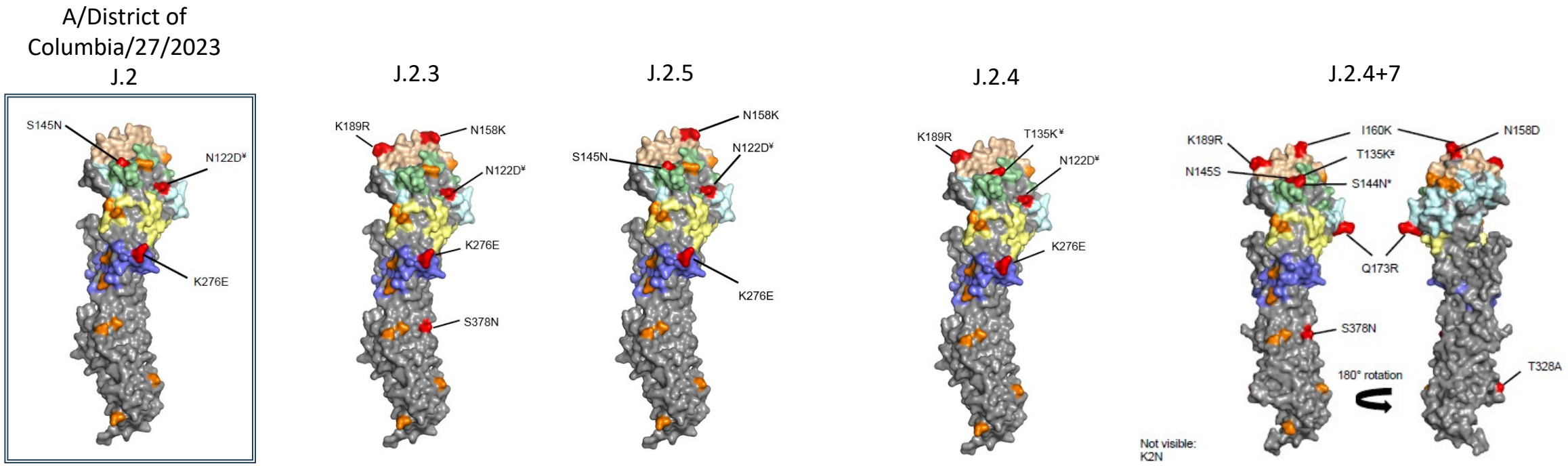


https://clades.nextstrain.org/

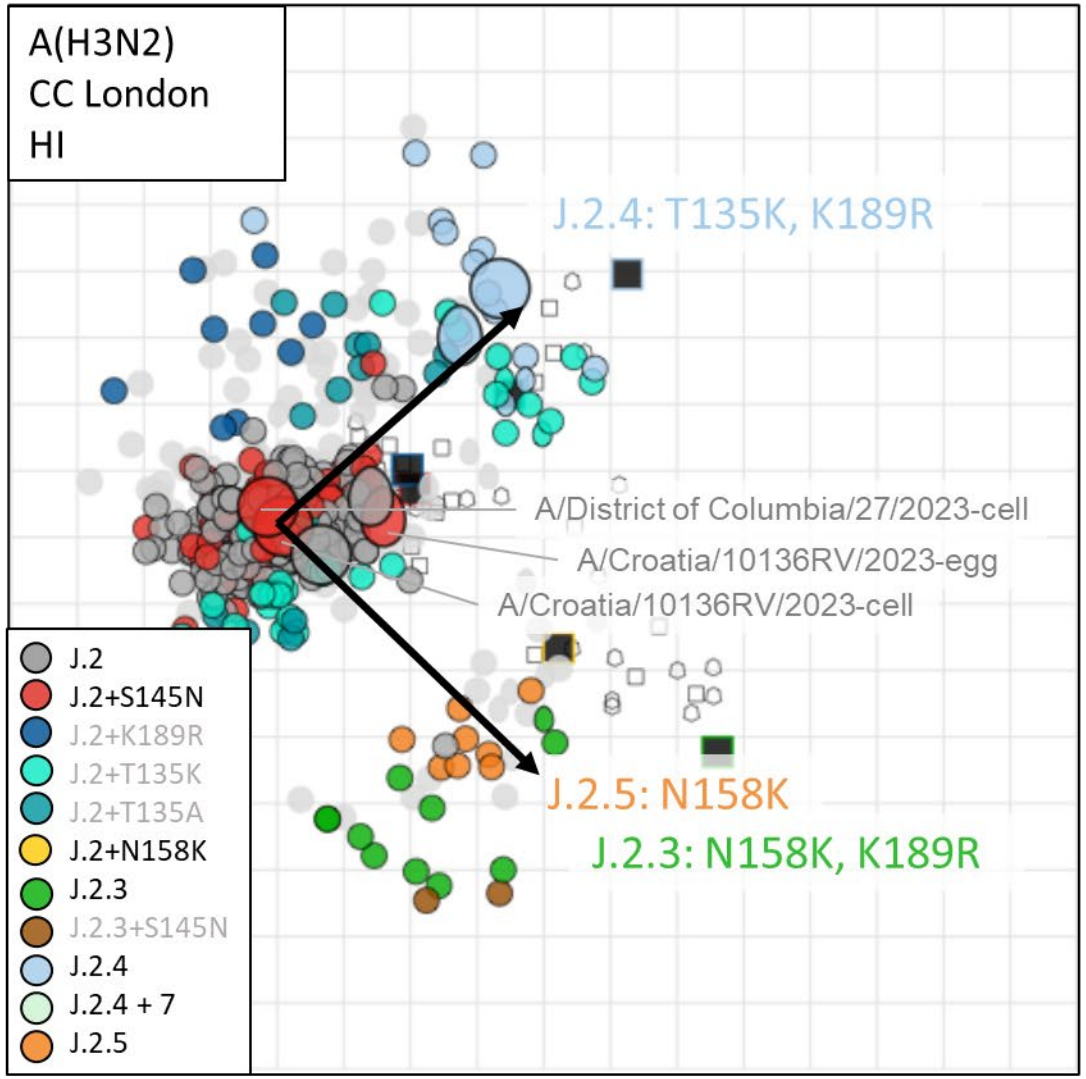
Based on HA sequence availability from GISAID EpiFlu™

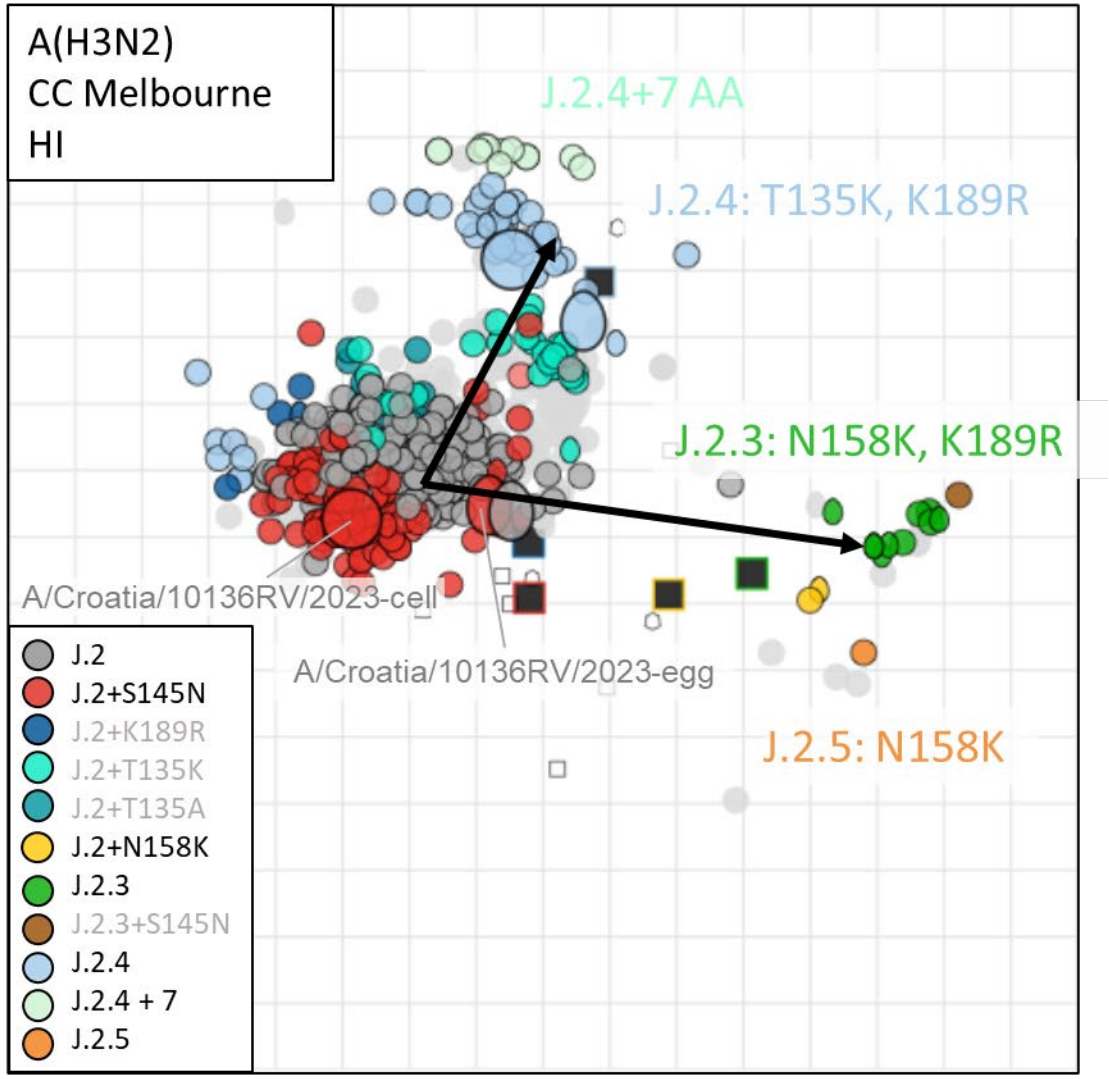
A(H3N2) Integrated Genotype and Phenotype Analysis

- Multiple subclades with additional HA substitutions co-circulated
- Ferret antisera to A/District of Columbia/27/2023 viruses show reduced to poor reactivity with viruses from J.2.3, J.2.4 and J.2.5 HA subclades



A(H3N2) antigenic cartography

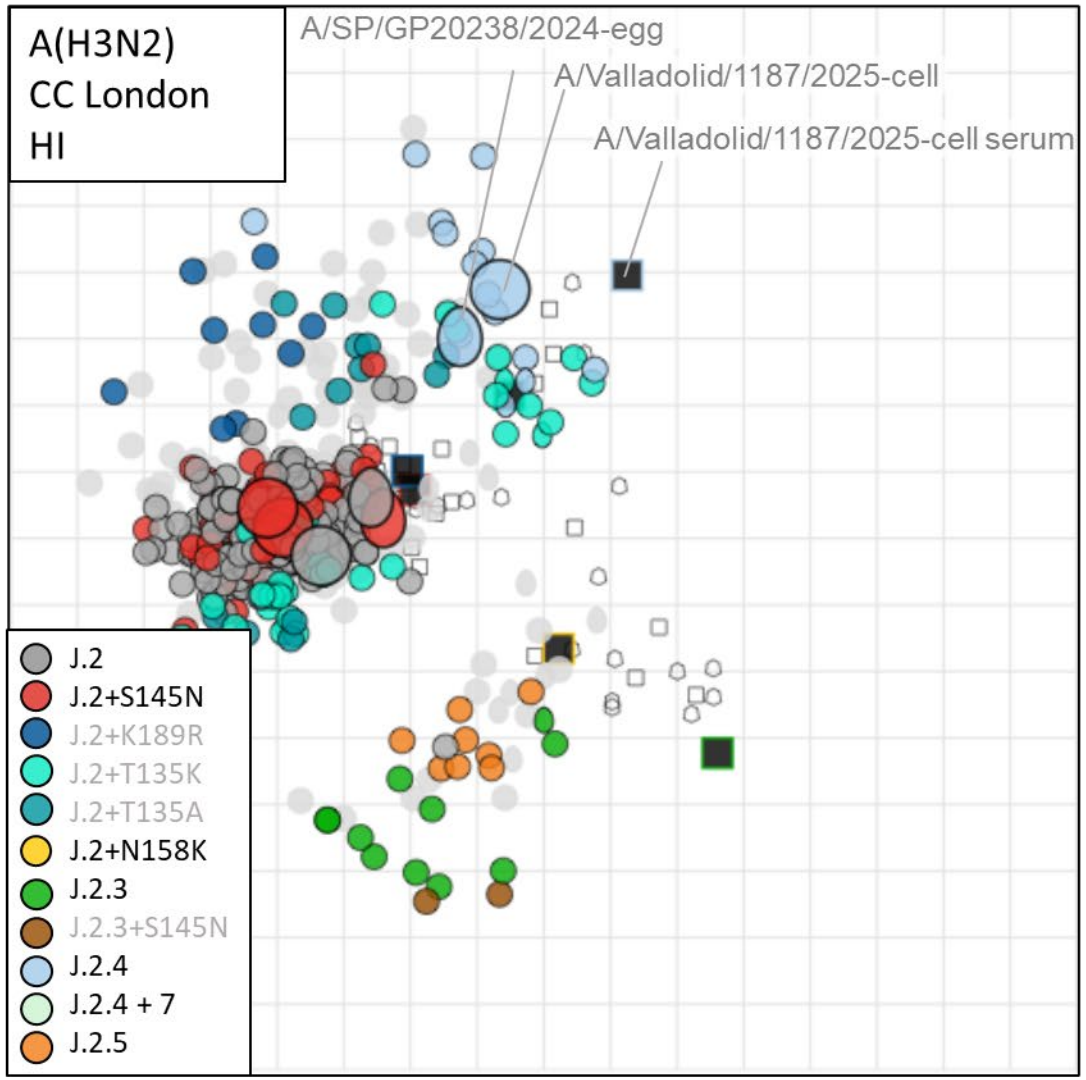


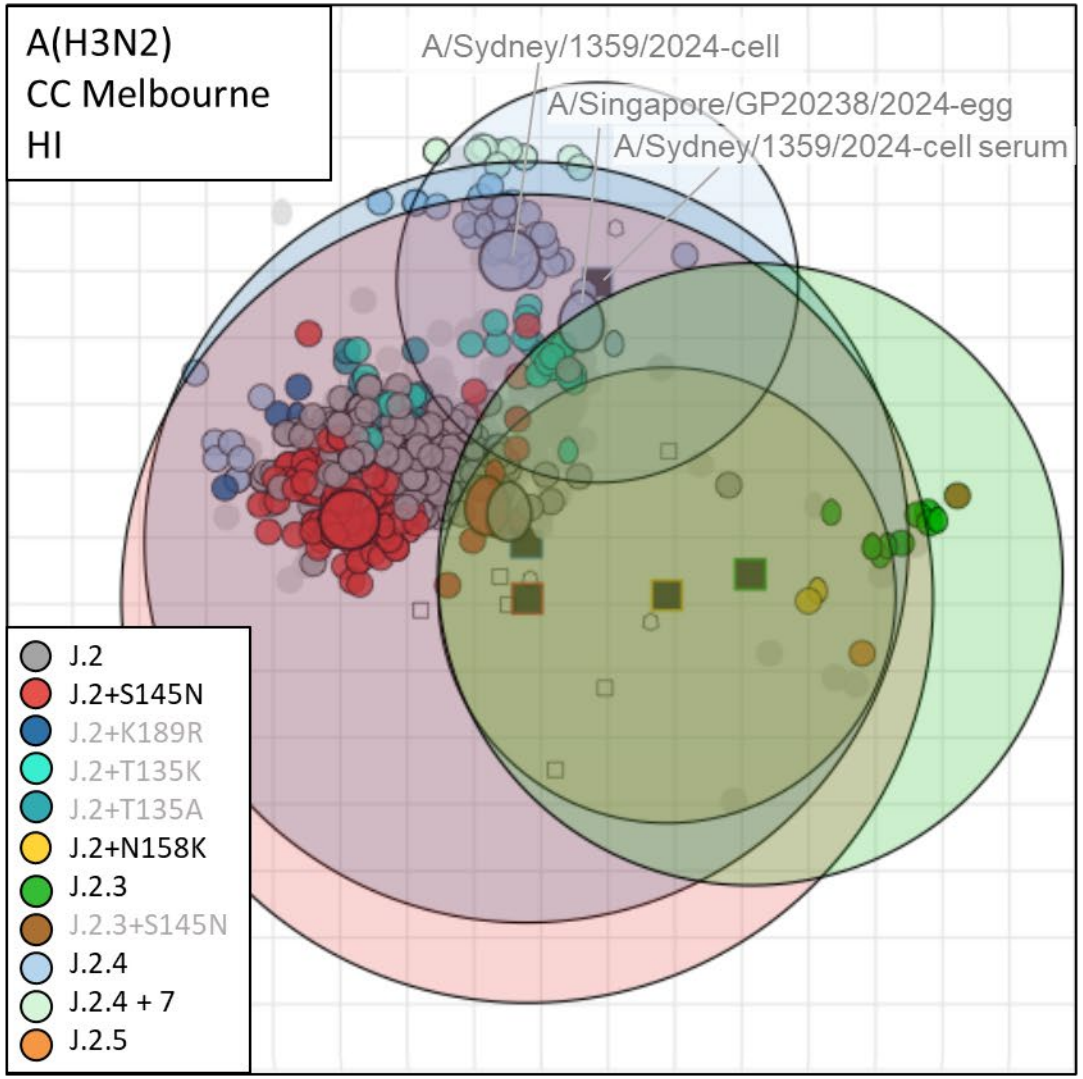


Source: University of Cambridge

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

A(H3N2) antigenic cartography





Serum circles (within 8-fold of homologous titers)

Source: University of Cambridge

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Human post-vaccination serum analysis of A(H3N2) viruses

WHO Collaborating Center (CC): Human Serological Panels
A(H3N2) -- HI & MN Protocol [CELL]

				J.2												J.2.1				J.2.2								J.2.3										J.2.4								J.2.5	
				-							+T135K (CHO-) +N145S							+T135A (CHO-)	+N145S +V223I +V347M			+N63K +F79L +K189R +P239S	+V102L +N145S +I160M +V347M	+T65K (CHO-) +S124N		+T65K (CHO-) +S124N +N145S	+T65K (CHO-) +S124N +N145S +I160K	+T65K (CHO-) +S124N +N145S +V347M										+N145S +N158K +K189R										+T135K (CHO-) +N145S +K189R				+T135K (CHO-) +N145S +K189R +V347M	+T135K (CHO-) +N145S +K189R +I374V		+N158K	
				DC/27-LIKE							WI/154-LIKE							ZAF/4109	FP/31-LIKE			CHE/ 47775	JN/1204	MN/97		PA/234-LIKE	KAN/IC2405		XC/1952-LIKE										VIC/769-LIKE										MS/37-LIKE				FY/11201	VAL/1187		KY/29	
				DC/27							WI/154	CAT/NSV H1024237 23	GN/1639	SYD/16	TOKYO/ EIS11-171	-	FP/31	TAS/557	-	-			PA/234	TAS/627	-			XC/1952	ZAF/ R05190									VIC/769						AK/08		TOKYO/ EIS13-029	MS/37		KAN/ AC2413	SYD/68	-	-	-	
				CELL							CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL
				CDC MN	CBER MN	CNIC HI	MHRA HI	NIID HI	VIDRL HI	CNIC HI	CDC MN	MHRA HI	GN/1639 CNIC HI	VIDRL HI	NIID HI	CDC MN	CNIC HI	VIDRL HI	CDC MN	MHRA HI	MHRA HI	VIDRL HI	CBER MN	NIID HI	CNIC HI	VIDRL HI	CDC MN	CBER MN	CNIC HI	MHRA HI	NIID HI	VIDRL HI	CDC MN	CBER MN	NIID HI	CDC MN	CBER MN	KAN/ AC2413 NIID HI	SYD/68 VIDRL HI	CNIC HI	MHRA HI	CDC MN	
A/DISTRICT OF COLUMBIA/27/2023 CELL	Adult	ccIIV4 (cell)	Australia	80	89	43	89	87	109	√	√	√	√	√	√	√	21	√	45	√	√	38	59	√	51	√	√	√	38	√	√	26	√	47	56	50	√	√	50	45	√	√	√	√
		IIV4 (egg)	Australia	112	100	56	151	112	135	√	√	√	√	76	√	√	24	√	53	√	√	61	78	√	39	√	√	√	23	√	24	29	57	43	39	43	√	78	47	50	68	23	68	√
		IIV3 (egg)	Peru	139							√							√				√												√			111						√	
			South Africa	86							√							√				√												√			√						√	
	Elderly	aIIV4 (egg-adjuvant)	Australia	139	130	55	117	83	121	√	√	√	√	√	√	√	23	√	72	√	√	48	√	√	46	√	√	√	44	√	√	49	√	61	80	√	√	√	√	√	√	√	√	83	
										0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	3 (100.0)	0 (0.0)	3 (100.0)	2 (66.7)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	1 (33.3)	3 (100.0)	1 (33.3)	3 (100.0)	3 (60.0)	2 (66.7)	0 (0.0)	2 (40.0)	2 (66.7)	2 (66.7)	1 (33.3)	1 (33.3)	1 (33.3)	1 (20.0)	

Geometric Mean Titer (GMT) ratios between reference and test antigens are calculated with 90% (CI) confidence intervals for each cohort and panel location. Unadjusted model results are shown. If the CI lower bound is greater than 50%, it is statistically non-inferior (95% confidence level); otherwise, it is *possibly* inferior. Heat map cells are colored using the GMT ratio lower bound. Blue indicates statistical non-inferiority and orange denotes *possible* inferiority. Numbers shown are post-vaccination GMTs for the unadjusted model. They are shown for ***reference antigens*** and possibly inferior test antigens (consolidated by passage-type). Marks, √ or X, denote statistically significant non-inferiority when the reference virus GMT is ≥40 or <40, respectively. **Number** and **percent** (in parentheses) of *possibly* inferior responses are summarized below the heat map.

Hemagglutination inhibition (HI) assay results reported by CNIC, MHRA, NIID, and VIDRL are indicated in addition to all microneutralization (MN) protocol trends.

Included Strains: A/ALASKA/08/2025 (AK/08); A/CATALONIA/NSVH102423723/2024 (CAT/NSVH102423723); A/DISTRICT OF COLUMBIA/27/2023 (DC/27); A/FUJIAN-PINGHE/31/2025 (FP/31); A/FUJIAN-YANPING/11201/2025 (FY/11201); A/GUANGXI-LONGZHOU/1484/2025 (GL/1484); A/GUIZHOU-NANMING/1639/2025 (GN/1639); A/JILIN-NINGJIANG/1204/2025 (JN/1204); A/KANAGAWA/AC2413/2025 (KAN/AC2413); A/KANAGAWA/IC2405/2024 (KAN/IC2405); A/KENTUCKY/29/2024 (KY/29); A/MINNESOTA/97/2024 (MN/97); A/MISSISSIPPI/37/2025 (MS/37); A/PENNSYLVANIA/234/2024 (PA/234); A/SOUTH AFRICA/4109/2025 (ZAF/4109); A/SOUTH AFRICA/R05190/2025 (ZAF/R05190); A/SWITZERLAND/47775/2024 (CHE/47775); A/SYDNEY/16/2025 (SYD/16); A/SYDNEY/68/2025 (SYD/68); A/TASMANIA/557/2025 (TAS/557); A/TASMANIA/627/2025 (TAS/627); A/TOKYO/EIS11-171/2024 (TOKYO/EIS11-171); A/TOKYO/EIS13-029/2025 (TOKYO/EIS13-029); A/VALLADOLID/1187/2025 (VAL/1187); A/VICTORIA/769/2025 (VIC/769); A/WISCONSIN/154/2024 (WI/154); A/XINJIANG-CHANGJI/1952/2025 (XC/1952).

WHO Collaborating Center (CC): Human Serological Panels
A(H3N2) -- HI & MN Protocol

				J.2																J.2.1		J.2.2								J.2.3																J.2.4										J.2.5	
				+D186A						-							+T135K (CHO-) +N145S					+T135A (CHO-)	+N145S +V223I +V347M		+N63K +F79L +K189R +P239S	+V102L +N145S +I160M +V347M	+T65K (CHO-) +S124N	+T65K (CHO-) +S124N +N145S	+T65K (CHO-) +S124N +N145S +I160K	+T65K (CHO-) +S124N +N145S +V347M										+N145S +N158K +K189R												+T135K (CHO-) +N145S +K189R					+T135K (CHO-) +N145S +K189R +F195Y	+T135K (CHO-) +N145S +K189R +V347M	+T135K (CHO-) +N145S +K189R +I374V		+N158K	
				CRO/10136RV							DC/27-LIKE							WI/154-LIKE				ZAF/4109	FP/31-LIKE		CHE/ 47775	JN/1204	MN/97		PA/234-LIKE	KAN/IC2405		XC/1952-LIKE										VIC/769-LIKE												MS/37-LIKE				SGP/ GP20238	FY/11201	VAL/ 1187		KY/29	
				-							DC/27					GL/1484		WI/154	CAT/NSV H1024237 23	GN/1639	SYD/16	TOKYO/ EIS11-171	-	FP/31	TAS/557	-	-			PA/234	TAS/627	-			XC/1952	ZAF/ R05190									VIC/769						AK/08		TOKYO/ EIS13-029	MS/37		KAN/ AC2413	SYD/68	-	-	-	
				EGG							CELL					CELL		CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL	CELL
				CDC MN	CBER MN	CNIC HI	MHRA HI	NIID HI	VIDRL HI	CDC MN	CBER MN	CNIC HI	MHRA HI	NIID HI	VIDRL HI	CNIC HI	CDC MN	MHRA HI	GN/1639 CNIC HI	VIDRL HI	NIID HI	CDC MN	CNIC HI	VIDRL HI	MHRA HI	CNIC HI	CDC MN	MHRA HI	MHRA HI	VIDRL HI	CBER MN	NIID HI	CNIC HI	VIDRL HI	CDC MN	CBER MN	MHRA HI	NIID HI	VIDRL HI	CDC MN	CBER MN	NIID HI	CDC MN	CBER MN	KAN/ AC2413 NIID HI	SYD/68 VIDRL HI	EGG VIDRL HI	CNIC HI	MHRA HI	CDC MN	
A/CROATIA/10136RV/2023 EGG	Adult	ccIIV4 (cell)	Australia	243	264	32	85	200	256	80	89	X	√	87	109	X	125	√	X	87	57	128	X	72	45	X	82	38	√	92	51	112	X	97	38	80	X	26	56	47	56	50	106	115	50	45	74	112	X	√	103	
		IIV4 (egg)	Australia	271	294	39	106	256	311	112	100	X	√	112	135	X	109	√	X	76	72	√	X	97	53	X	103	61	√	115	39	121	X	118	23	76	24	29	57	43	39	43	106	78	47	50	68	92	23	68	92	
		IIV3 (egg)	Peru	611						139							160					139					106													139			111								160	
			South Africa	251						86							126					83					92													70			86								77	
	Elderly	aIIV4 (egg-adjuvant)	Australia	453	469	32	117	204	288	139	130	X	√	83	121	X	219	√	X	95	51	166	X	75	72	X	109	48	√	121	46	113	X	126	44	144	X	49	55	61	80	95	113	197	98	48	113	121	X	√	83	
										5 (100.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)	3 (100.0)	0 (0.0)	5 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)	3 (100.0)	4 (80.0)	0 (0.0)	3 (100.0)	3 (100.0)	0 (0.0)	5 (100.0)	3 (100.0)	0 (0.0)	3 (100.0)	3 (100.0)	3 (100.0)	0 (0.0)	3 (100.0)	3 (100.0)	3 (100.0)	1 (33.3)	3 (100.0)	3 (100.0)	3 (100.0)	5 (100.0)	3 (100.0)	3 (100.0)	5 (100.0)	3 (100.0)	3 (100.0)	3 (100.0)	3 (100.0)	3 (100.0)	1 (33.3)	1 (33.3)	5 (100.0)	

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Statistically non-inferior = √
Statistically non-inferior but reference virus GMT < 40 = X

GMT Ratio Lower-Bound (90% CI)
0.000 — 1.000

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Influenza A(H3N2): antiviral susceptibility

Neuraminidase inhibitors

- Of 1,716 A(H3N2) viruses that were examined for neuraminidase inhibitor (NAI) susceptibility by genetic and/or phenotypic analyses, no viruses showed genetic or phenotypic evidence of reduced inhibition to neuraminidase inhibitors

Endonuclease inhibitors

- Of 1,735 A(H3N2) viruses examined by genetic and/or phenotypic analyses, no viruses showed evidence of reduced susceptibility to the endonuclease inhibitor baloxavir marboxil.

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Influenza A(H3N2) summary (1)

Phylogenetics of A(H3N2) HA genes

- Vast majority of viruses belonged to clade 2a.3a.1 HA genes diversified within clade 2a.3a.1 into subclades J.1-J.4,
- Viruses expressing HA N122D and K276E substitutions (J.2) predominated globally during this reporting period.
- Ongoing evolution in the HA gene of J.2 viruses observed globally necessitated the creation of J.2 subclades (J.2.1-J.2.5) to track the emerging viruses.
  - Viruses expressing HA from subclade J.2.1 (sharing substitutions F79L and P239S) were detected in very low numbers.
  - Viruses expressing HA subclade J.2.2 (sharing an S124N substitution) circulated globally and were detected in higher proportions in parts of Africa and Asia.
  - Small numbers of viruses expressing HA subclade J.2.3 (sharing substitutions N158K, K189R and S378N) circulated globally with higher proportions detected in South America.
  - Viruses expressing HA subclade J.2.4 (sharing T135K (potential loss of an N-glycosylation site) and K189R substitutions) continue to circulate, and a new group of J.2.4 viruses has emerged recently and expanded rapidly in nearly all regions.
  - Globally, small numbers of viruses expressing HA subclade J.2.5 (sharing substitutions D104N, S145N and N158K) circulated, with higher proportions observed in North America.

Influenza A(H3N2) summary (2)

Antigenic characteristics of A(H3N2) viruses

- Post-infection ferret antisera raised against cell culture-propagated A/District of Columbia/27/2023-like and egg-propagated A/Croatia/10136RV/2023-like (clade 2a.3a.1, subclade J.2) viruses, representing the A(H3N2) component for the SH 2025 and the NH 2025-26 influenza vaccines, recognized the majority of viruses well.
  - However, the ferret antisera recognized recent viruses in the J.2.3 (e.g., A/Netherlands/10685/2024), J.2.4 (e.g., A/Sydney/1359/2024) and J.2.5 (e.g., A/Kentucky/29/2024) HA subclades poorly.
- While ferret antisera raised against reference viruses from J.2.3 and J.2.5 HA subclades showed cross-recognition likely due to a shared HA substitution (N158K), ferret antisera raised against reference viruses from J.2.4 showed poor recognition of viruses from all other J.2 subclades apart from those with a shared HA substitution (T135K).
- Post-infection ferret antisera raised against cell culture-propagated A/Sydney/1359/2024-like and egg-propagated A/Singapore/GP20238/2024-like viruses from subclade J.2.4 recognized other J.2.4 viruses well including those with notable additional HA substitutions S144N (a potential addition of an N-glycosylation site), N158D, I160K and Q173R, which have recently emerged.

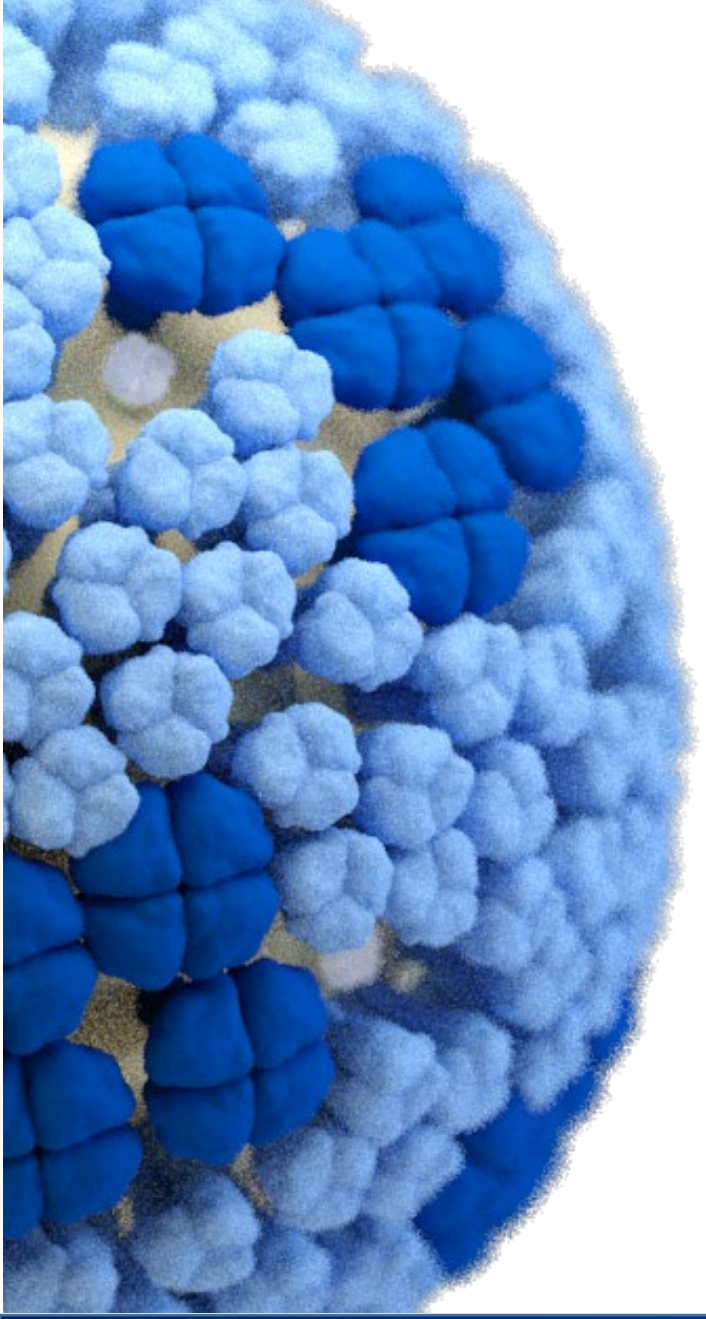
VCM Information meeting: https://www.youtube.com/@whowpro

Influenza A(H3N2) summary (3)

Human serology studies

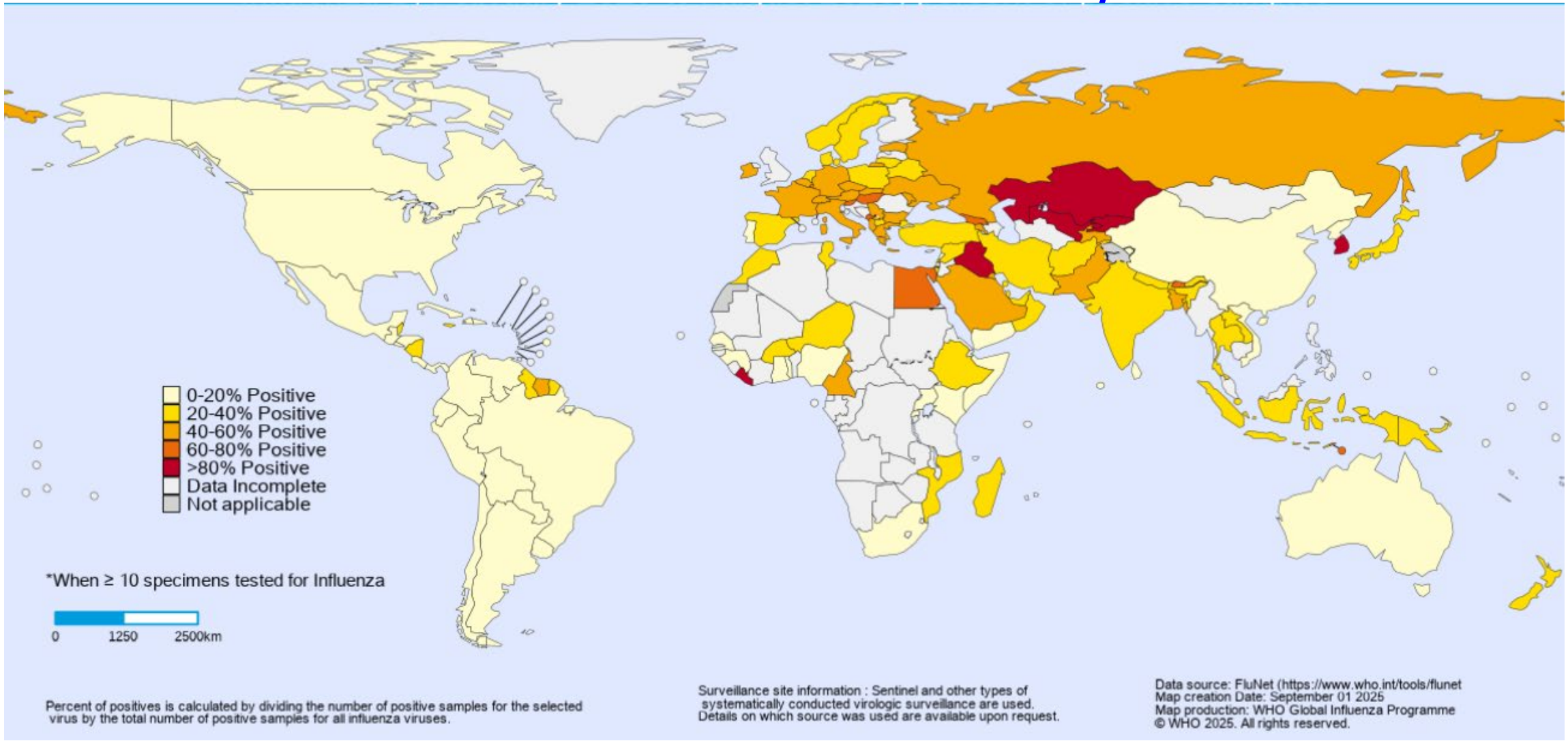
- Human serology studies were conducted using the SH 2025 serum panels as described above by HI and VN assays with recent circulating A(H3N2) viruses with HA genes from 2a.3a.1 subclades J.2, J.2.1, J.2.2, J.2.3, J.2.4 and J.2.5.
- When compared to titers against cell-propagated A/District of Columbia/27/2023-like vaccine reference viruses, post-vaccination HI GMTs or VN GMTs against many of the recent viruses in J.2.2, J.2.3, J.2.4 and J.2.5 subclades were significantly reduced.

The data supported recommending a cell-propagated A/Sydney/1359/2024 (H3N2)-like (J.2.4) virus and an egg-propagated A/Singapore/GP20238/2024 (H3N2)-like (J.2.4) virus as the A(H3N2) vaccine antigens for the 2026 southern hemisphere.



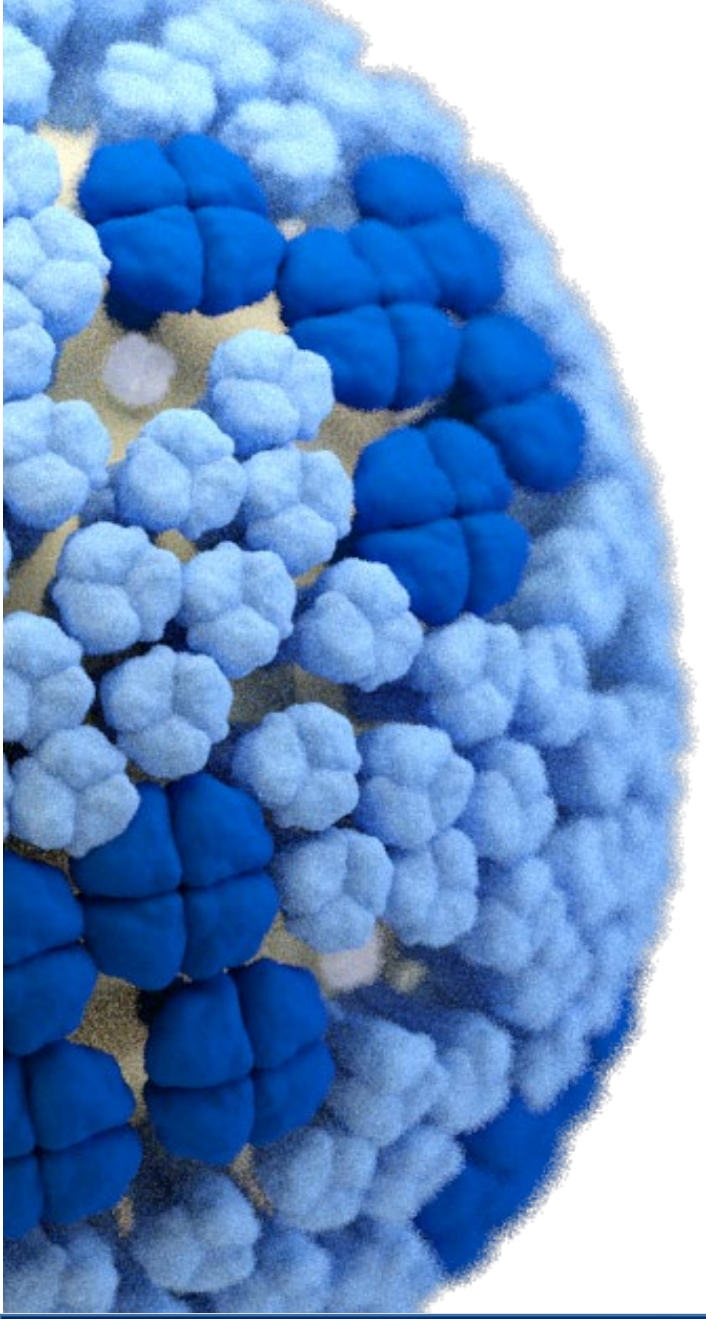
Influenza B Viruses

Influenza B virus activity



Data source: FluNet, (https://www.who.int/tools/flunet), Global Influenza Surveillance and Response System (1 September 2025)

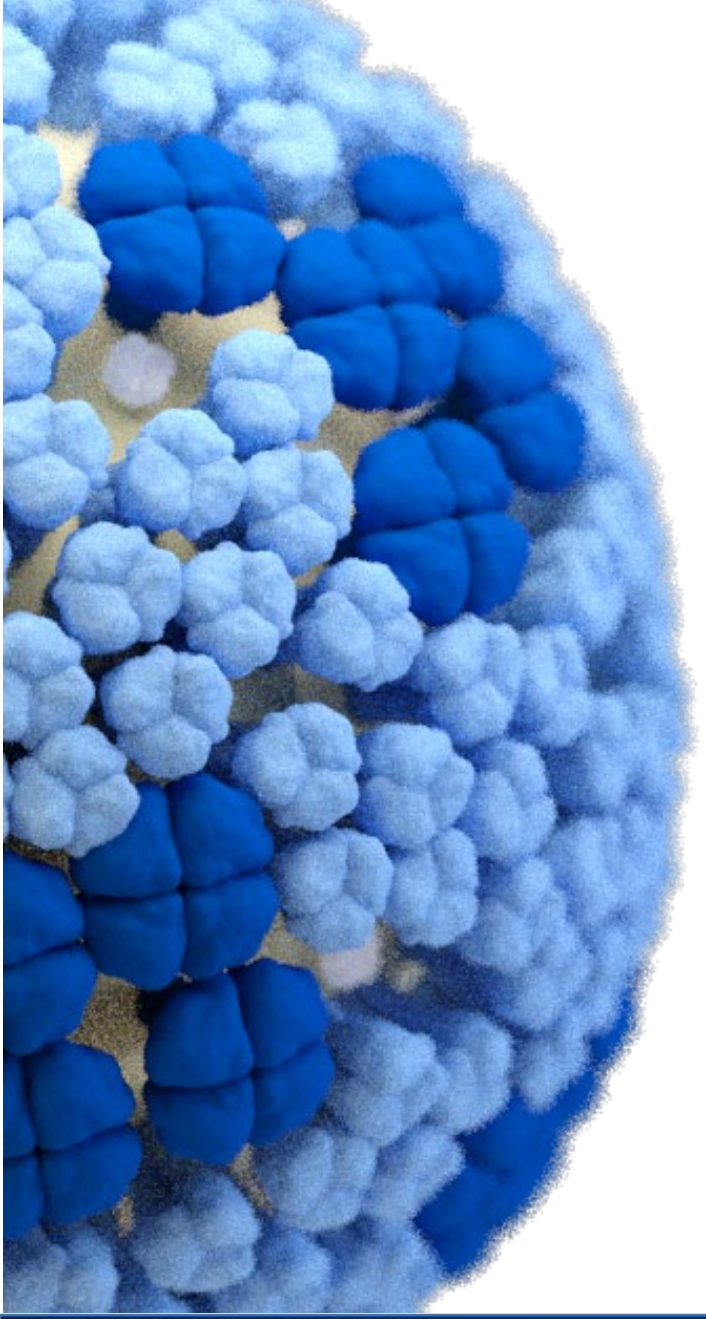
VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ



Influenza B/Yamagata Viruses

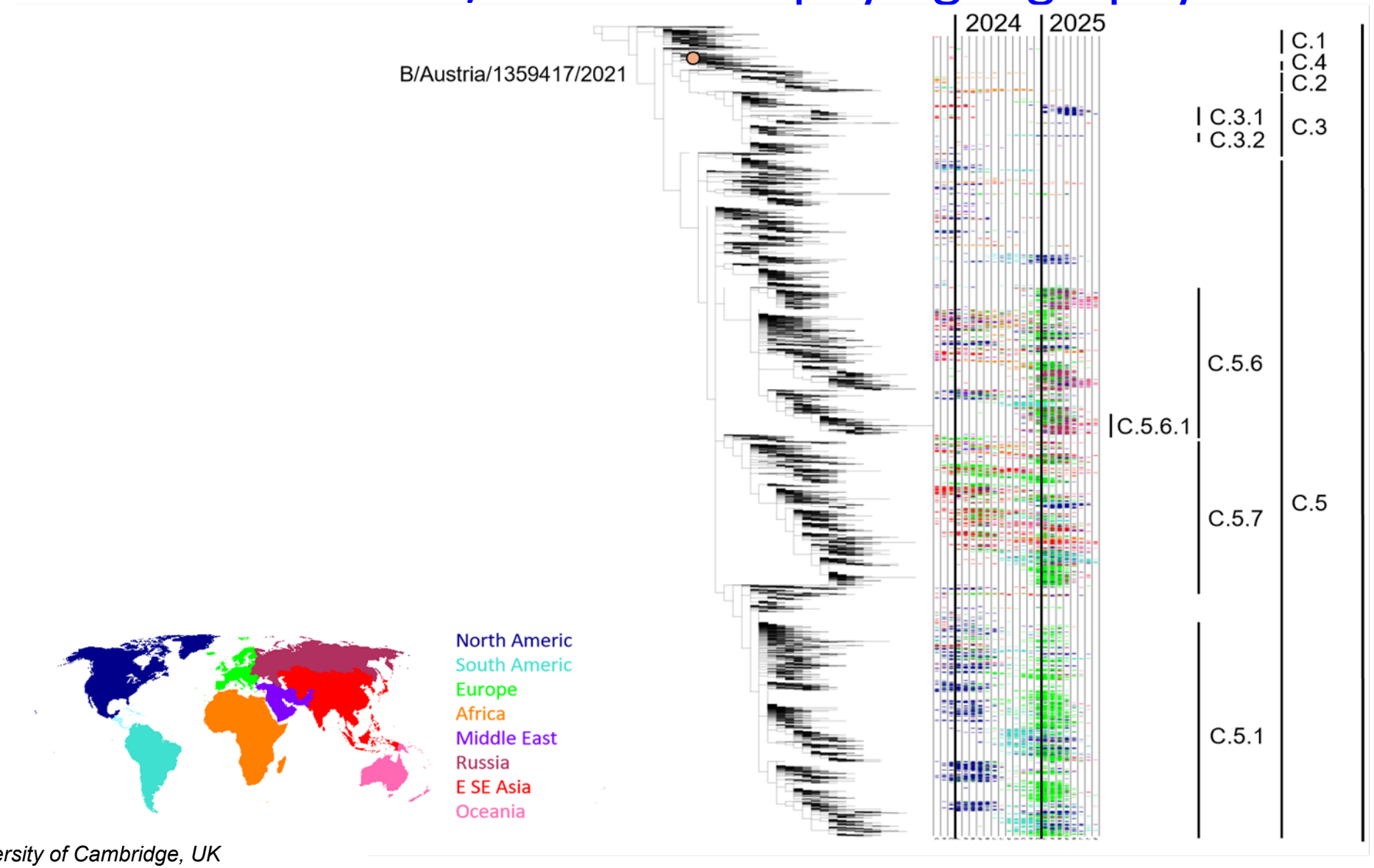
B/Yamagata lineage summary

- There have been no confirmed detections of circulating B/Yamagata/16/88 lineage viruses after March 2020.
- It continues to be recommended globally that the B/Yamagata lineage antigen should be excluded from influenza vaccines as it is no longer warranted.
- There will no longer be updated recommendations for the B/Yamagata lineage component.



Influenza B/Victoria Viruses

B/Victoria HA phylogeography



Source: University of Cambridge, UK

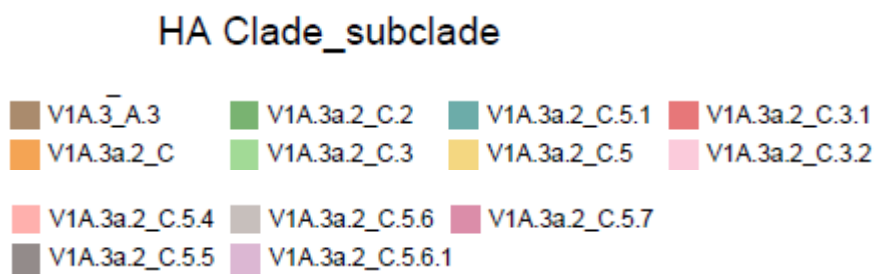
Based on HA sequence availability from GISAID EpiFlu™

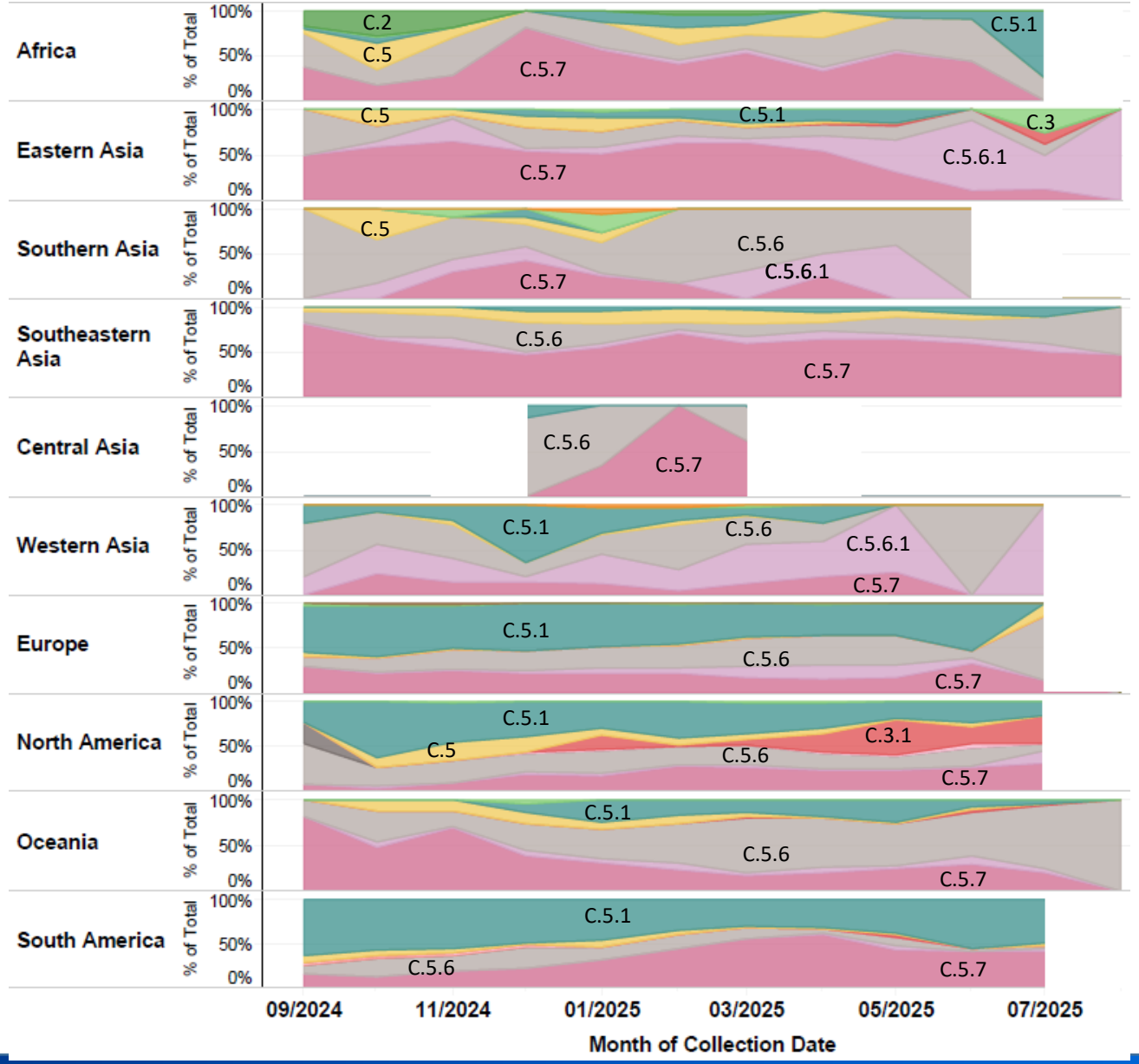
https://clades.nextstrain.org/

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

B/Victoria Extended Diversity Plot by Geographic Region

Sep. 1, 2024 - Present

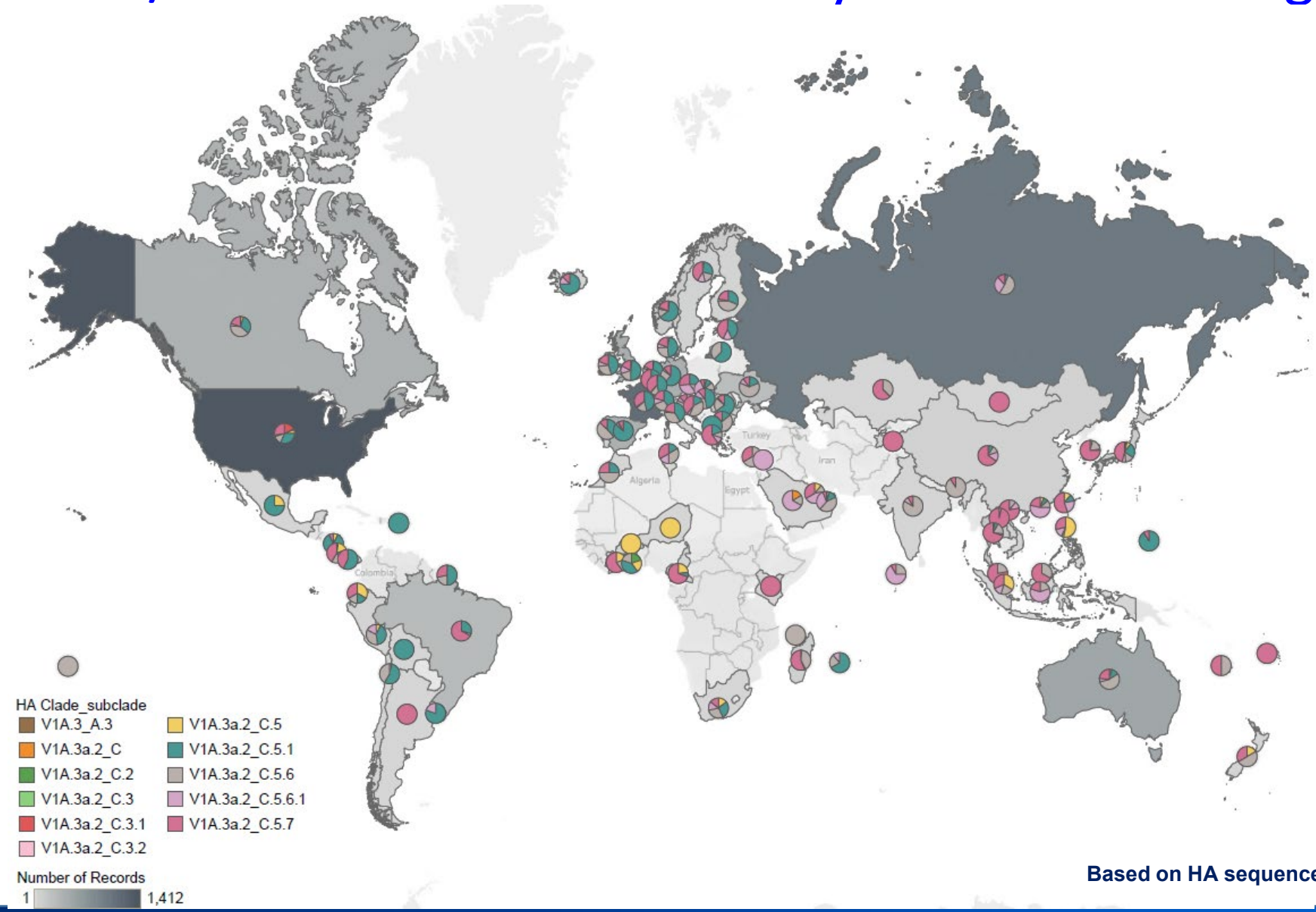




https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™

Global B/Victoria HA clade diversity: Feb 2025 to Aug 2025



https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™

Antigenic analysis of B/Victoria viruses in **HI** assays

Antisera to southern hemisphere 2025 vaccine virus antigens

WHO CC	B/Austria/1359417/2021-like Cell Clade V1A.3a.2	Low (≥ 8 fold)
CDC	185 (80%)	47 (20%)
CNIC	203 (99%)	2 (1%)
FCI	211 (100%)	0 (0%)
NIID	92 (95%)	5 (5%)
VIDRL	807 (98%)	13 (2%)
TOTAL	1498 (96%)	67 (4%)

WHO CC	B/Austria/1359417/2021-like Egg Clade V1A.3a.2	Low (≥ 8 fold)
CDC	184 (79%)	48 (21%)
CNIC	200 (98%)	5 (2%)
FCI	211 (100%)	0 (0%)
NIID	92 (95%)	5 (5%)
VIDRL	814 (99%)	6 (1%)
TOTAL	1501 (96%)	64 (4%)

"Low" represented titers ≥ 8-fold lower than vaccine strain homologous titer

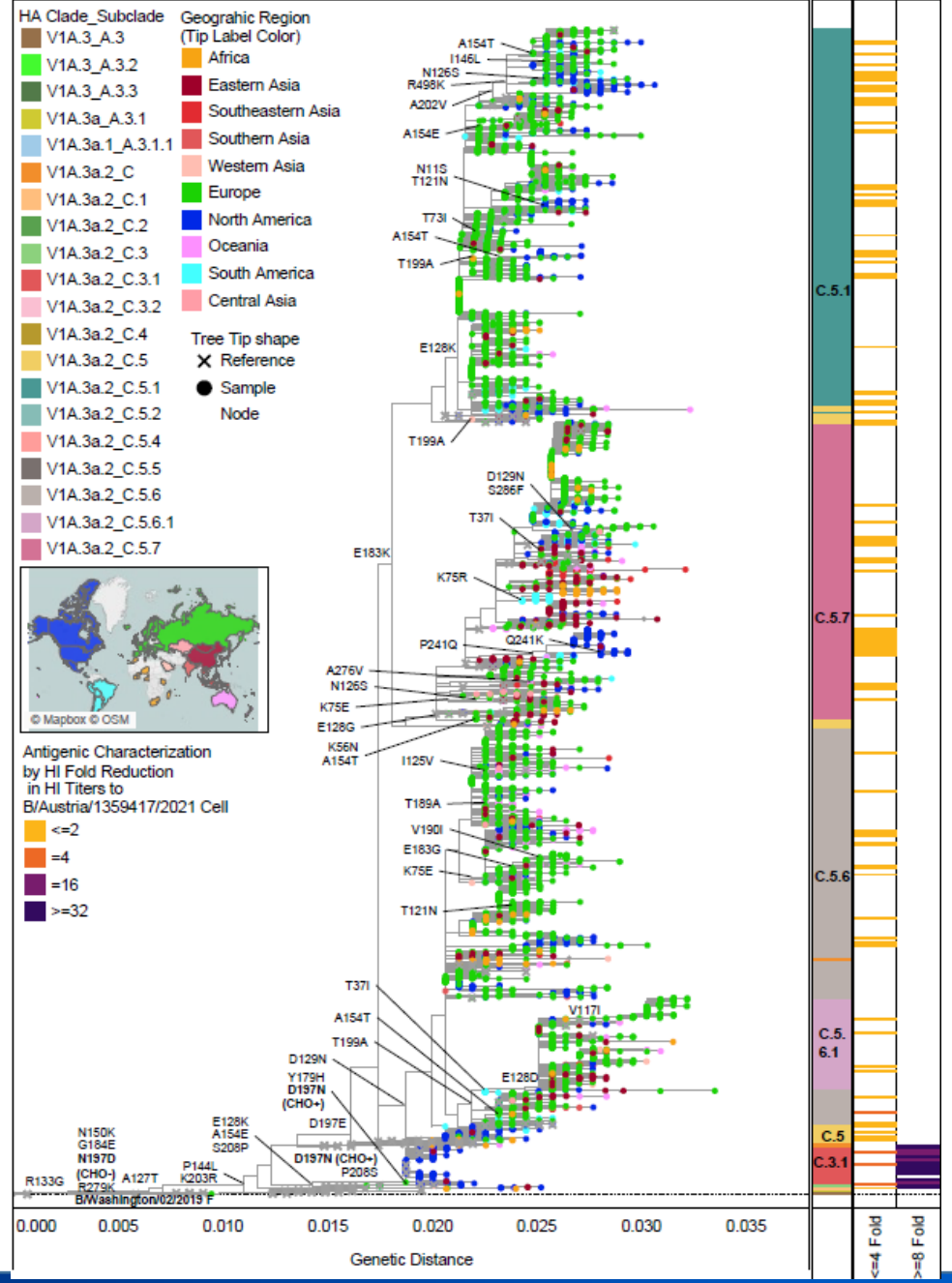
VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

B/Victoria Integrated Genotype and Phenotype Analysis

Clade	Subclade	HA Amino Acid changes compared to B/Austria/1359417/2021
V1A.3a.2	C	
	C.1	H122Q
	C.2	T182A, D197E, T221A
	C.3	E128K, A154E, S208P
	C.5	D197E
	C.5.1	E183K, D197E
	C.5.3	V87A, D129G, E183K, D197E
	C.5.4	V117I, E128K, A154T, D197E, K326R
	C.5.5	R80G, E184K, D197E
	C.5.6	D129N, D197E
	C.5.7	E128G, E183K, D197E

https://clades.nextstrain.org/

Based on HA sequence availability from GISAID EpiFlu™



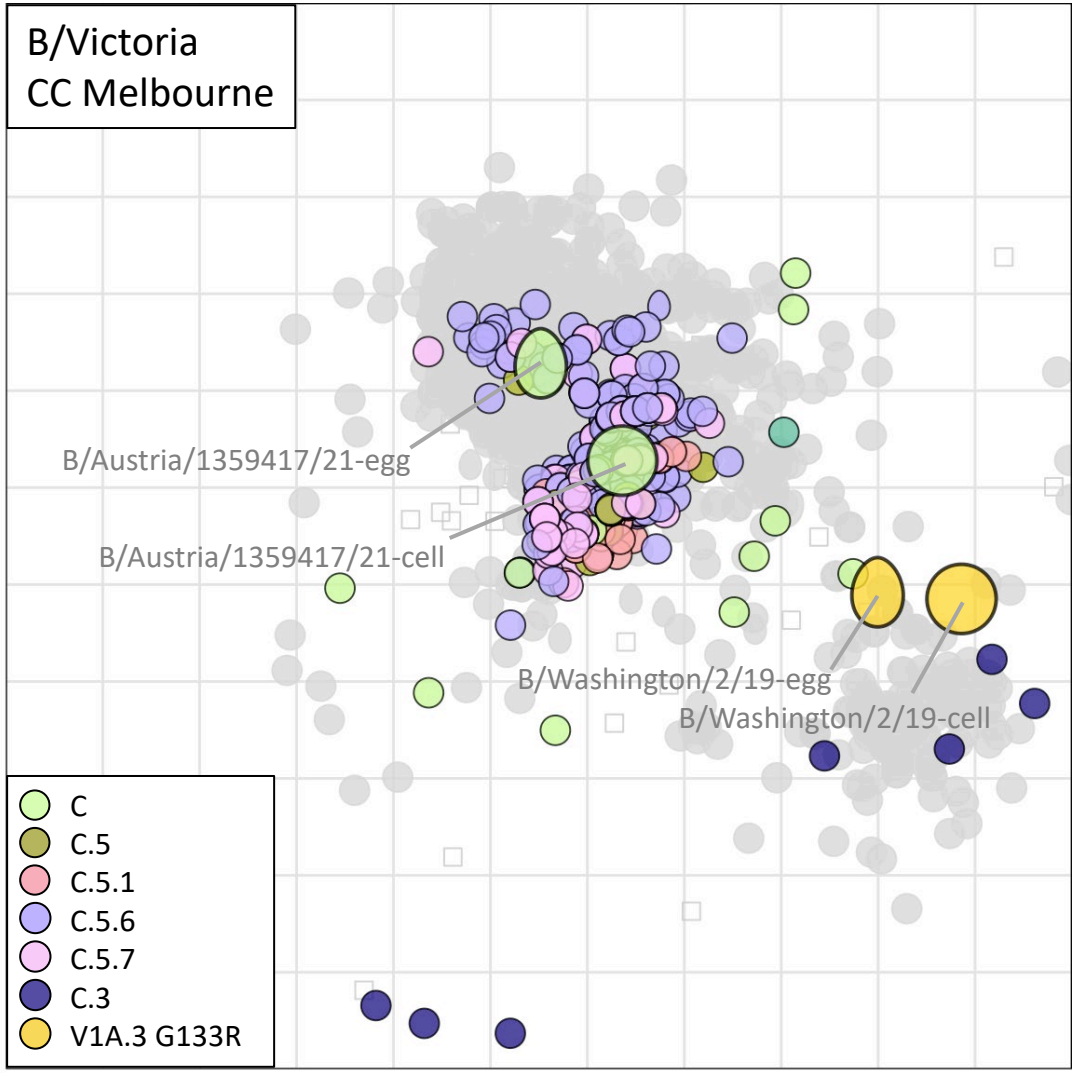
C.5.1

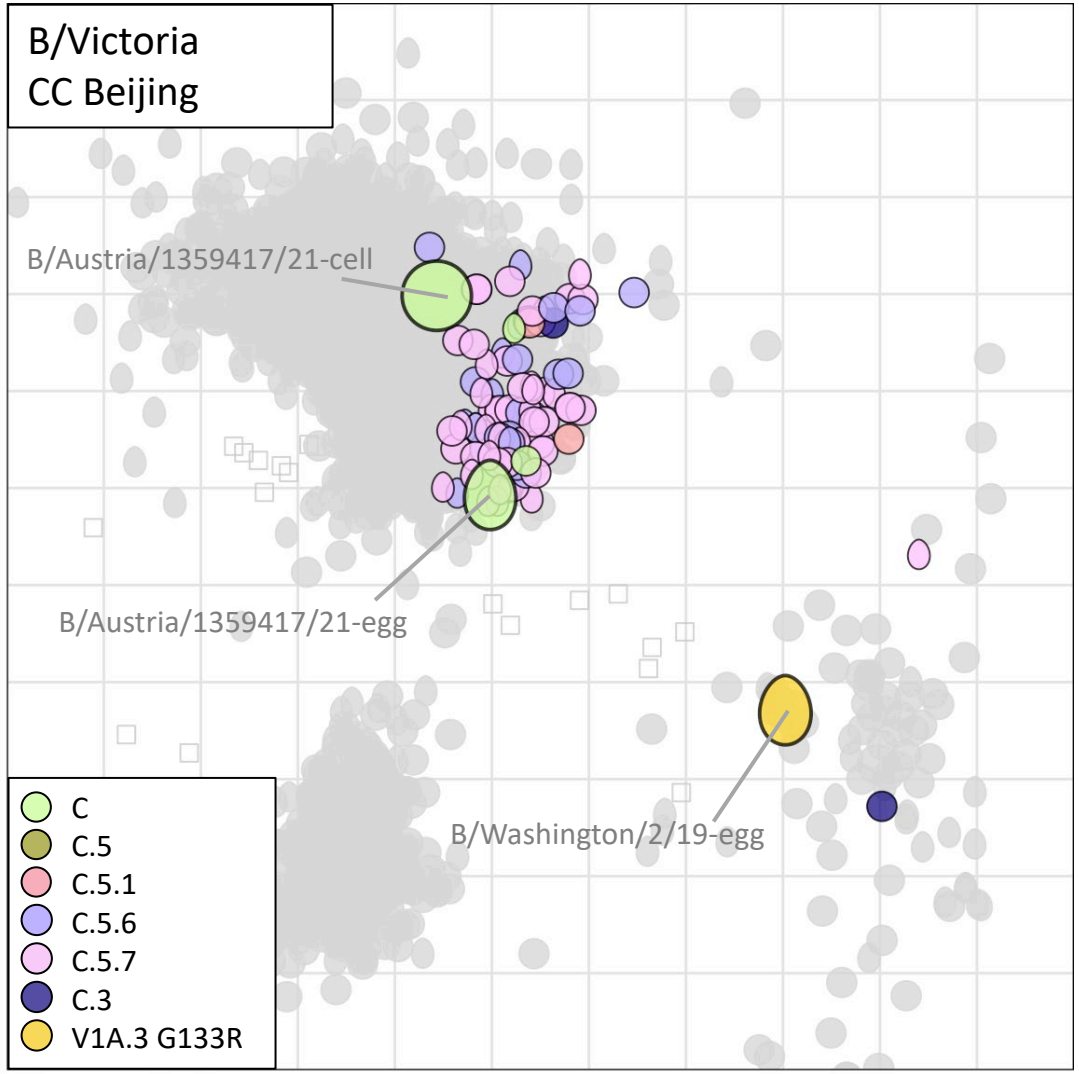
C.5.7

C.5, C.5.6, C.5.6.1

C.3.1 and C.3.2

B/Victoria antigenic cartography

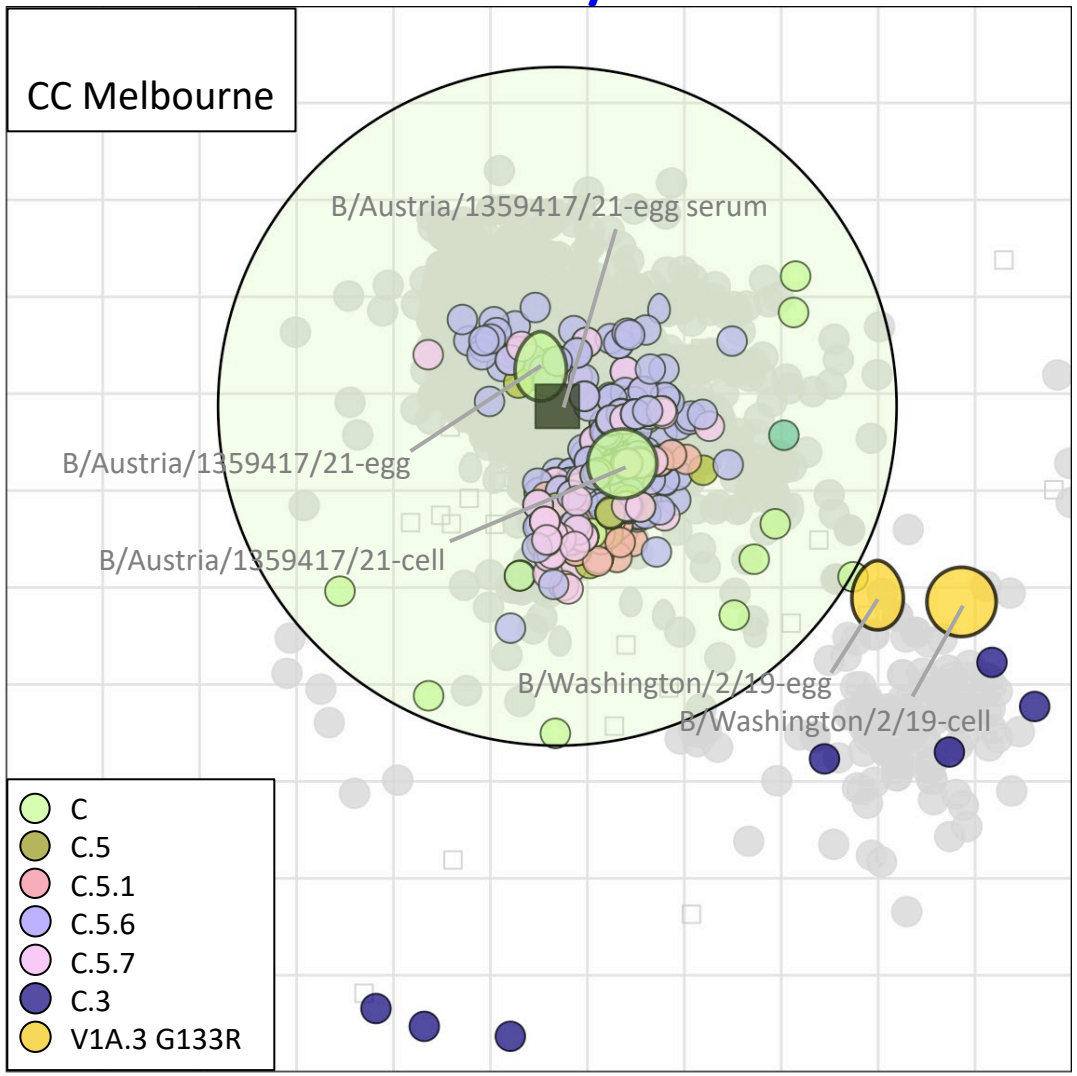


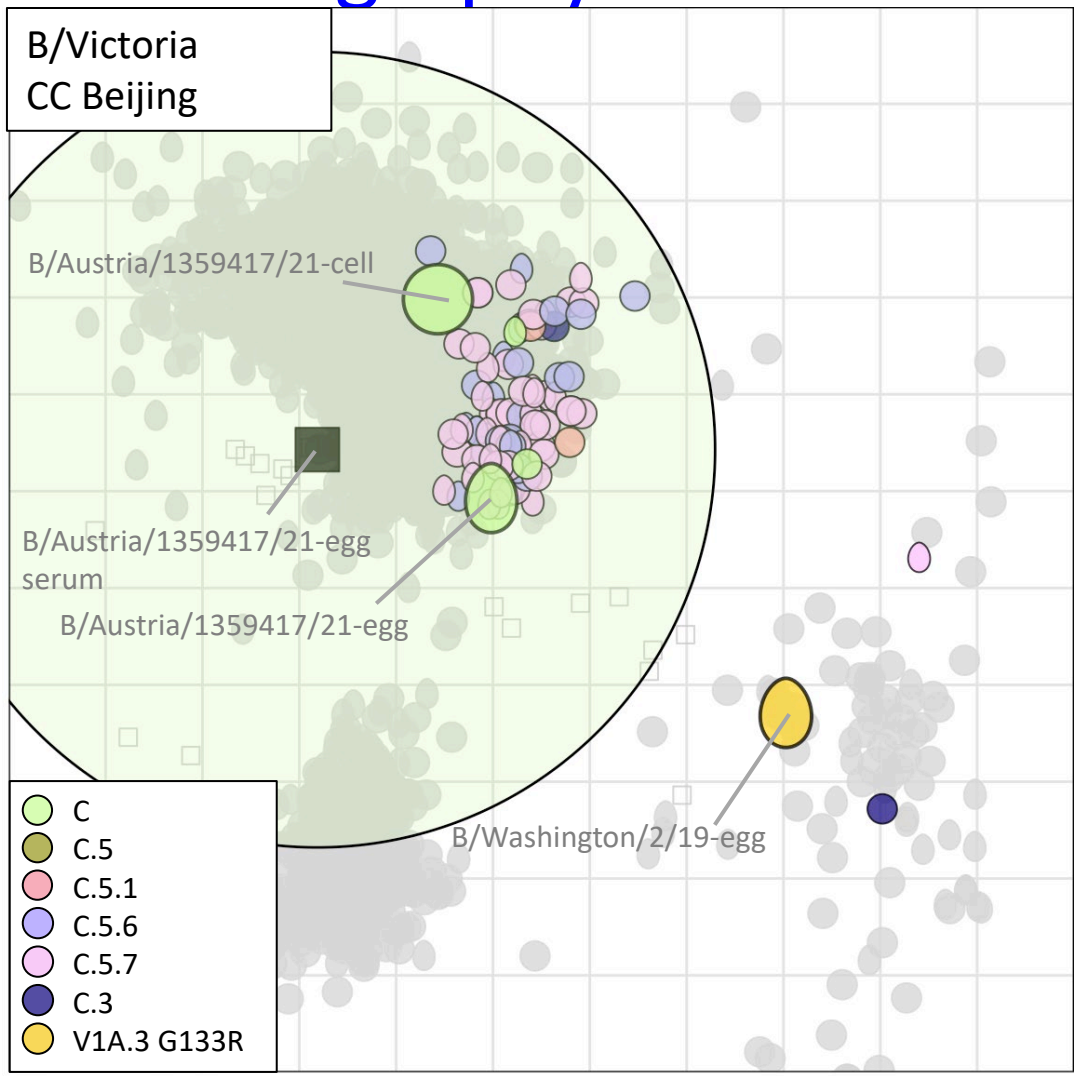


Source: University of Cambridge

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

B/Victoria antigenic cartography





Serum circles (within 8-fold of homologous titers)

Source: University of Cambridge

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Human post-vaccination serum analysis of B/Victoria viruses

				C - AUT/1358417 - CELL						C.3.1 - TAS/31-LIKE								C.5.1 - KS/05 - CELL		+A154T +R498K KAN/AC2411 - CELL	C.5.8				C.5.8.1 - HC/1-LIKE			C.5.7 - TX/18-LIKE					+K75E +N128S HX/1253 - CELL
				CDC	CBER	CNIC	MHRA	NIID	VIDRL	TAS/31 CELL CDC	CBER	CNIC	MHRA	NIID	VIDRL	KAN/AC2414 CELL MHRA	NIID	PA/14 CELL CDC	CDC	CBER	NIID	+K75E BTN/02139 - CELL VIDRL	+I125V VIC/260 - CELL VIDRL	+T199A MO/03-LIKE MO/03 CELL CDC	CHE/329 CELL MHRA	HC/1 CELL NIID	CAN/118 CELL VIDRL	HY/1780 CELL CNIC	TX/19 CELL CDC	CBER	MHRA	NAG/2107 CELL NIID	VIC/399 CELL VIDRL	CELL CNIC
B/AUSTRIA/1359417/2021 CELL	Adult	ccIIV4 (cell)	Australia	128	101	103	151	573	284	53	50	36	√	256	89	√	189	49	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
		IIV4 (egg)	Australia	121	87	85	125	338	223	43	45	29	√	135	76	√	121	41	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
		IIV3 (egg)	Peru	232						96								73	√					√					√					
			South Africa	219						55								36	√					√					√					
	Elderly	aIIV4 (egg-adjuvant)	Australia	63	26	44	171	320	135	√	X	27	√	√	55	89	171	40	√	X	√	√	√	√	83	√	√	√	√	X	√	√	√	√
										4 (80.0)	2 (66.7)	3 (100.0)	0 (0.0)	2 (66.7)	3 (100.0)	1 (33.3)	3 (100.0)	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Statistically non-inferior = √

Statistically non-inferior but reference virus GMT < 40 = X

GMT Ratio Lower-Bound (90% CI)

0.000 — 1.000

Geometric Mean Titer (GMT) ratios between reference and test antigens are calculated with 90% (CI) confidence intervals for each cohort and panel location. Unadjusted model results are shown. If the CI lower bound is greater than 50%, it is statistically non-inferior (95% confidence level); otherwise, it is *possibly* inferior. Heat map cells are colored using the GMT ratio lower bound. Blue indicates statistical non-inferiority and orange denotes *possible* inferiority. Numbers shown are post-vaccination GMTs for the unadjusted model. They are shown for *reference antigens* and possibly inferior test antigens (consolidated by passage-type). Marks, √ or X, denote statistically significant non-inferiority when the reference virus GMT is ≥40 or <40, respectively. **Number** and **percent** (in parentheses) of *possibly* inferior responses are summarized below the heat map.

Included Strains: B/AUSTRIA/1359417/2021 (AUT/1359417); B/BHUTAN/02139/2025 (BTN/02139); B/CANBERRA/118/2025 (CAN/118); B/HENAN-XIANGCHENG/1253/2025 (HX/1253); B/HIROSHIMA-C/1/2025 (HC/1); B/HUNAN-YUHUA/1780/2025 (HY/1780); B/KANAGAWA/AC2411/2025 (KAN/AC2411); B/KANAGAWA/AC2414/2025 (KAN/AC2414); B/KANSAS/05/2024 (KS/05); B/MISSOURI/03/2024 (MO/03); B/NAGANO/2107/2025 (NAG/2107); B/PENNSYLVANIA/14/2025 (PA/14); B/SWITZERLAND/329/2024 (CHE/329); B/TASMANIA/31/2025 (TAS/31); B/TEXAS/19/2024 (TX/19); B/VICTORIA/260/2025 (VIC/260); B/VICTORIA/399/2025 (VIC/399).

B/Victoria lineage antiviral susceptibility

Neuraminidase inhibitors

- Of 1,567 influenza B/Victoria lineage viruses collected since 1 February 2025 that were examined for neuraminidase inhibitor (NAI) susceptibility by genetic and/or phenotypic analyses, **five** showed evidence of reduced or highly reduced inhibition by NAIs.

Endonuclease inhibitors

- Of 1,638 B/Victoria lineage viruses collected and analyzed in this period, **no** viruses showed evidence of reduced susceptibility to baloxavir.

VCM Information meeting: https://www.youtube.com/live/jKlthy3YYNQ

Influenza B/Victoria lineage summary (1)

Phylogenetics of B/Victoria lineage HA genes

- All circulating viruses belonged to clade 3a.2
- The most predominant HA subclades: C.5.1, C.5.6 and C.5.7
- C.5.6.1, C.3.1 and C.3.2 circulated at lower proportions

Antigenic characteristics of B/Victoria lineage viruses

- Post-infection ferret antisera raised against B/Austria/1359417/2021-like viruses (3a.2 HA) inhibited the vast majority of recently circulating 3a.2 viruses well
- Viruses within HA subclades C.3.1 and C.3.2 which share HA substitution D197N (adds putative glycosylation site) were recognized poorly

Influenza B/Victoria lineage summary (2)

Human serology studies

- Recent subclades C.5.1, C.5.6, C.5.6.1 and C.5.7 were well inhibited by post vaccination human sera to B/Austria/1359417/2021-like (3a.2_C)
- Titers against subclade C.3.1 were significantly reduced in most assays

The data supported B/Austria/1359417/2021-like (3a.2_C) viruses to remain as the B/Victoria lineage vaccine antigens for the 2026 southern hemisphere.

Support and Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Additional Slides