

**A Phase II Trial of Safety, Tolerability, and Immunogenicity of V114, a 15-Valent Pneumococcal Conjugate Vaccine, Compared to 13-Valent Pneumococcal Conjugate Vaccine (PCV13) in Healthy Infants**

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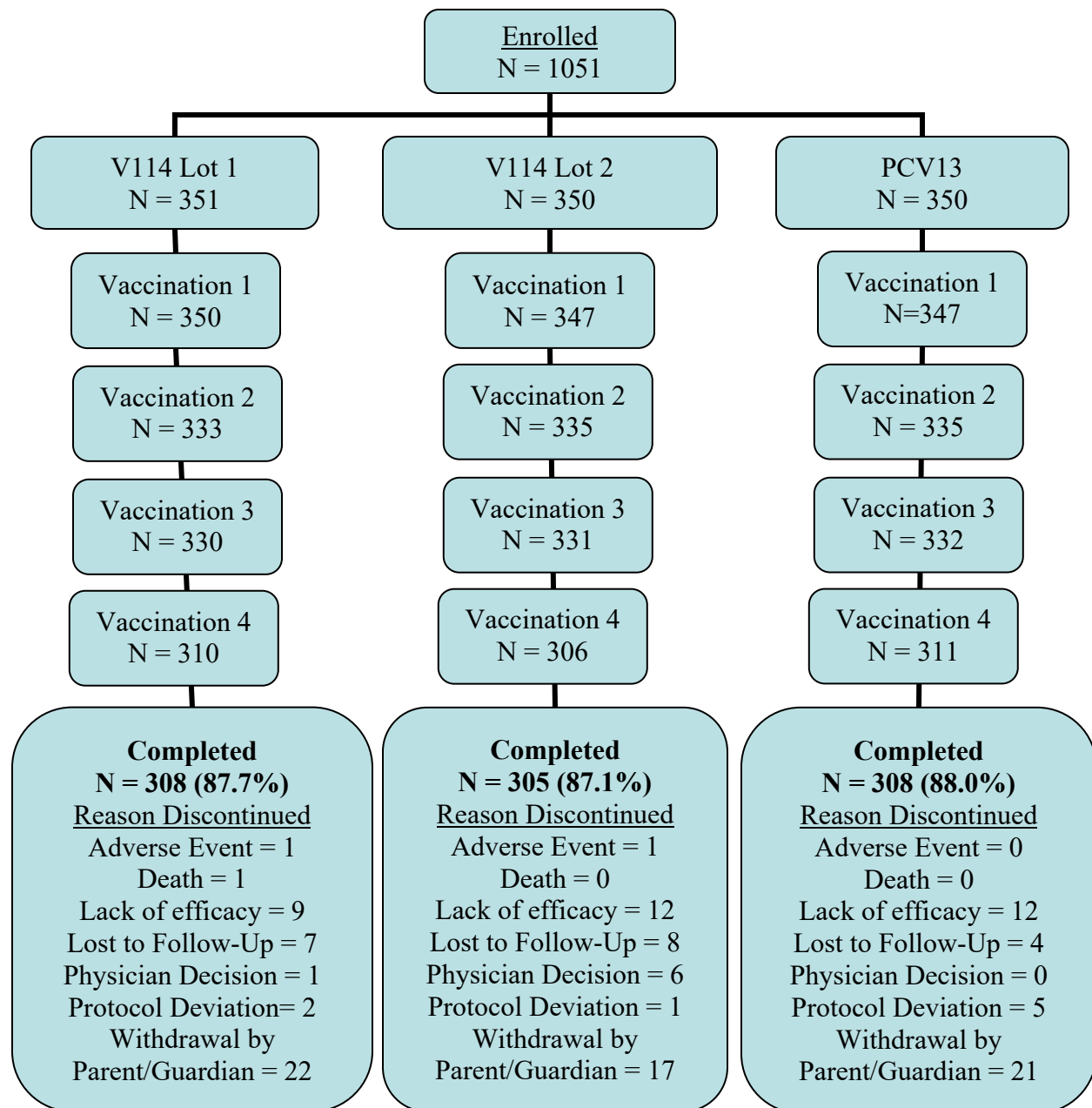
**Supplemental Digital Content 26, figure:** Serotype 23F Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4

**Supplemental Digital Content 27, figure:** Serotype 33F Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4

**Supplemental Digital Content 1, table:** Participants Meeting Rescue Criteria at 1 Month PD3

	V114 Lot 1		V114 Lot 2		PCV13		Total	
<b>Participants with PD3 Immunogenicity Data</b>	N=311	%	N=309	%	N=321	%	N=941	%
<b>Rescued Participants</b>	9	2.9	12	3.9	12	3.9	33	3.5
Rescue Criteria: IgG <0.35 µg/mL for serotype 19A (alone), or for ≥4 serotypes in common between V114 and PCV13 at 1-month PD3.								

**Supplemental Digital Content 2, figure: Participant Disposition- All Randomized Participants**



**Supplemental Digital Content 3, table:** All Randomized Participant Demographics

	V114 Lot 1	V114 Lot 2	PCV13	Total
<b>Participants in population</b>	351	350	350	1051
<b>Gender</b>				
<b>Male, n (%)</b>	187 (53.3)	164 (46.9)	177 (50.6)	528 (50.2)
<b>Female, n (%)</b>	164 (46.7)	186 (53.1)	173 (49.4)	523 (49.8)
<b>Age (in weeks)</b>				
<b>Mean</b>	8.8	8.8	8.7	8.7
<b>Race</b>				
<b>White, n (%)</b>	290 (82.6)	296 (84.6)	289 (82.6)	875 (83.3)
<b>Black or African American, n (%)</b>	34 (9.7)	24 (6.9)	33 (9.4)	91 (8.7)
<b>Multiple/Other,* n (%)</b>	27 (7.7)	30 (8.6)	28 (8.0)	85 (8.1)
<b>Ethnicity</b>				
<b>Hispanic or Latino, n (%)</b>	49 (14.0)	36 (10.3)	53 (15.1)	138 (13.1)
* Multiple/Other includes Multiracial, American Indian, Alaskan Native, Native Hawaiian, Pacific Islander, or missing.				

**Supplemental Digital Content 4, table:** Adverse Event (AE) Summary – Days 1-to-14 PD1

	V114 Lot 1		V114 Lot 2		PCV13	
	n	%	n	%	n	%
Participants with Safety Follow-Up	350		347		347	
Any Injection-site AE	164	46.9	169	48.7	137	39.5
Injection-site pain*	128	36.6	122	35.2	99	28.5
Injection-site erythema*	35	10.0	57	16.4	33	9.5
Injection-site induration*	46	13.1	47	11.5	43	12.4
Injection-site swelling*	38	10.9	54	15.6	33	9.5
Any Systemic AE	285	81.4	303	87.3	267	76.9
Irritability*	236	67.4	251	72.3	213	61.4
Somnolence*	146	41.7	177	51.0	156	45.0
Pyrexia	30	8.6	26	7.5	28	8.1
Decreased appetite*	58	16.6	87	25.1	65	18.7
Serious AEs	4	1.1	5	1.4	2	0.6
Vaccine-related† serious AEs	0	0.0	1	0.3	0	0.0
Deaths	0	0.0	0	0.0	0	0.0
* Solicited AEs (days 1 to 14 following any vaccination)						
† Determined by the investigator to be related to the vaccine						

**Supplemental Digital Content 5, table:** Adverse Event (AE) Summary – Days 1-to-14 PD2

	V114 Lot 1		V114 Lot 2		PCV13	
	n	%	n	%	n	%
Participants with Safety Follow-Up	330		331		332	
Any Injection-site AE	132	40.0	130	39.3	111	33.4
Injection-site pain*	88	26.7	84	25.4	67	20.2
Injection-site erythema*	62	18.8	57	17.2	52	15.7
Injection-site induration*	42	12.7	44	13.3	43	13.0
Injection-site swelling*	33	10.0	35	10.6	27	8.1
Any Systemic AE	246	74.5	270	81.6	263	79.2
Irritability*	199	60.3	221	66.8	207	62.3
Somnolence*	132	40.0	144	43.5	126	38.0
Pyrexia	34	10.3	42	12.7	57	17.2
Decreased appetite*	50	15.2	53	16.0	57	17.2
Serious AEs	0	0.0	0	0.0	0	0.0
Vaccine-related† serious AEs	0	0.0	0	0.0	0	0.0
Deaths	0	0.0	0	0.0	0	0.0
* Solicited AEs (days 1 to 14 following any vaccination)						
† Determined by the investigator to be related to the vaccine						

**Supplemental Digital Content 6, table:** Adverse Event (AE) Summary – Days 1-to-14 PD3

	V114 Lot 1		V114 Lot 2		PCV13	
	n	%	n	%	n	%
Participants with Safety Follow-Up	327		326		331	
Any Injection-site AE	125	38.2	133	40.8	125	37.8
Injection-site pain*	72	22.0	82	25.2	66	19.9
Injection-site erythema*	62	19.0	64	19.6	58	17.5
Injection-site induration*	53	16.2	45	13.8	53	16.0
Injection-site swelling*	38	11.6	35	10.7	32	9.7
Any Systemic AE	239	73.1	252	77.3	246	74.3
Irritability*	171	52.3	194	59.5	179	54.1
Somnolence*	85	26.0	106	32.5	90	27.2
Pyrexia	38	11.6	61	18.7	60	18.1
Decreased appetite*	60	18.3	57	17.5	55	16.6
Serious AEs	0	0.0	2		0	0.0
Vaccine-related† serious AEs	0	0.0	0	0.0	0	0.0
Deaths	0	0.0	0	0.0	0	0.0
* Solicited AEs (days 1 to 14 following any vaccination)						
† Determined by the investigator to be related to the vaccine						



**Supplemental Digital Content 7, table:** Adverse Event (AE) Summary – Days 1-to-14 PD4

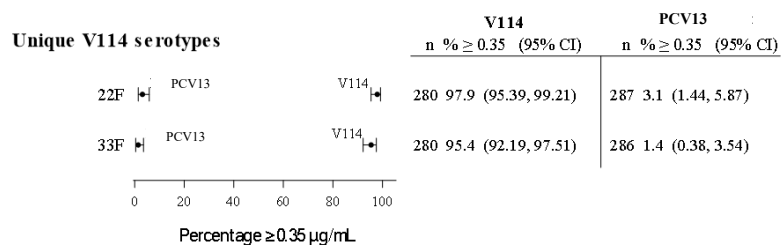
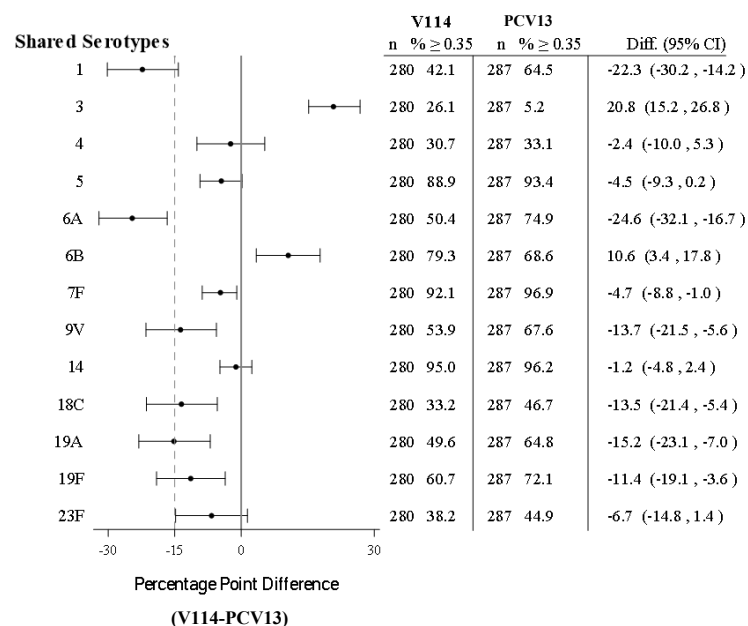
	V114 Lot 1		V114 Lot 2		PCV13	
	n	%	n	%	n	%
Participants with Safety Follow-Up	296		289		296	
Any Injection-site AE	123	41.6	122	42.2	122	41.2
Injection-site pain*	80	27.0	85	29.4	76	25.7
Injection-site erythema*	60	20.3	56	19.4	66	22.3
Injection-site induration*	51	17.2	44	15.2	55	18.6
Injection-site swelling*	40	13.5	41	14.2	40	13.5
Any Systemic AE	221	74.7	221	76.5	217	73.3
Irritability*	165	55.7	173	59.9	169	57.1
Somnolence*	85	28.7	97	33.6	75	25.3
Pyrexia	63	21.3	56	19.4	70	23.6
Decreased appetite*	66	22.3	68	23.5	57	19.3
Serious AEs	3	1.0	2	0.7	0	0.0
Vaccine-related† serious AEs	0	0.0	1	0.3	0	0.0
Deaths	0	0.0	0	0.0	0	0.0
* Solicited AEs (days 1 to 14 following any vaccination)						
† Determined by the investigator to be related to the vaccine						

**Supplemental Digital Content 8, table:** Vaccine-Related Systemic Adverse Events (Incidence  $\geq 5\%$  in Any Group) (Days 1 to 14 Following Any Vaccination)

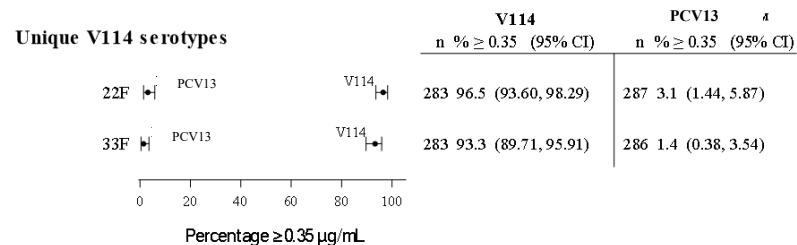
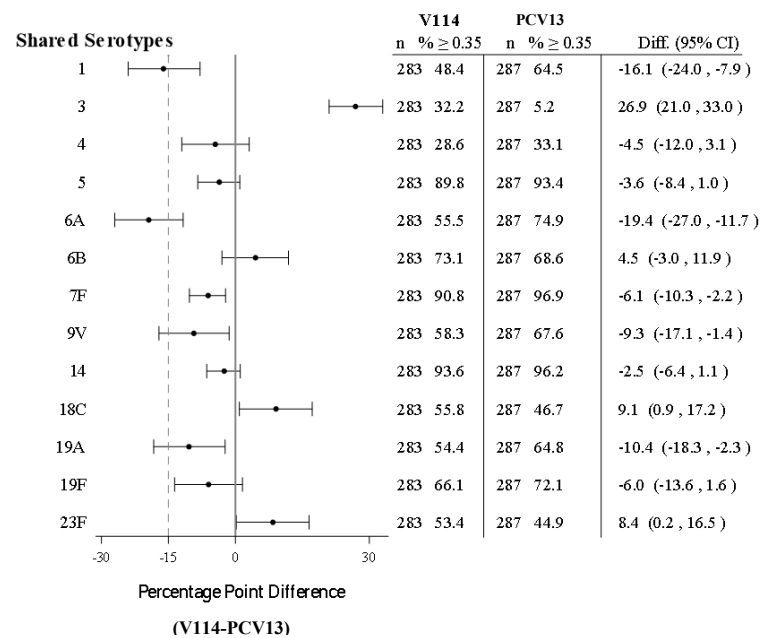
	V114 Lot 1		V114 Lot 2		PCV13		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population with follow-up	350		347		347		1,044	
with one or more adverse events	308	(88.0)	320	(92.2)	316	(91.1)	944	(90.4)
with no adverse events	42	(12.0)	27	(7.8)	31	(8.9)	100	(9.6)
Diarrhoea	14	(4.0)	8	(2.3)	20	(5.8)	42	(4.0)
Pyrexia	83	(23.7)	92	(26.5)	110	(31.7)	285	(27.3)
Decreased appetite	119	(34.0)	142	(40.9)	121	(34.9)	382	(36.6)
Somnolence	205	(58.6)	223	(64.3)	222	(64.0)	650	(62.3)
Irritability	277	(79.1)	293	(84.4)	281	(81.0)	851	(81.5)
Every subject is counted a single time for each applicable row and column.								
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.								
Irritability, decreased appetite, somnolence, and urticaria were solicited adverse events.								

# Supplemental Digital Content 9, figure: IgG Antibody Response Rates Pre-Dose 4 V114 vs. PCV13

## V114 Lot 1 vs. PCV13

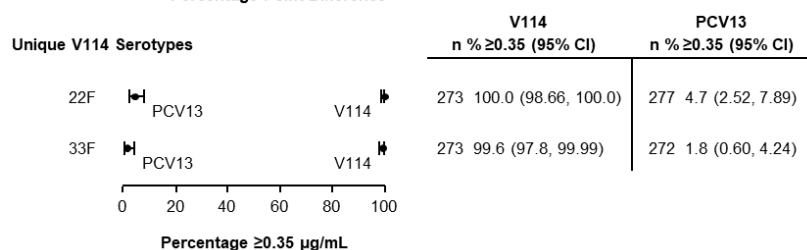
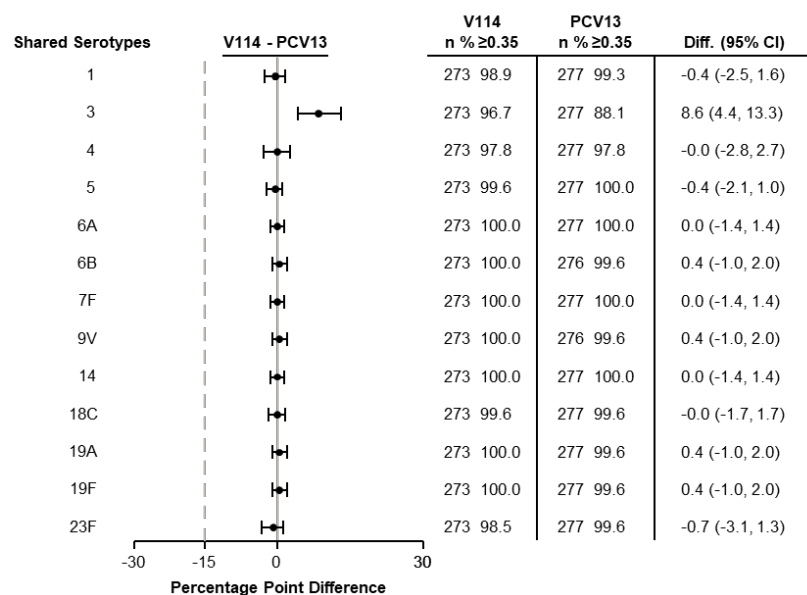


## V114 Lot 2 vs. PCV13

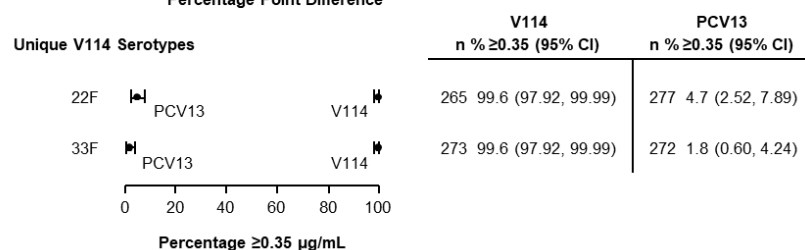
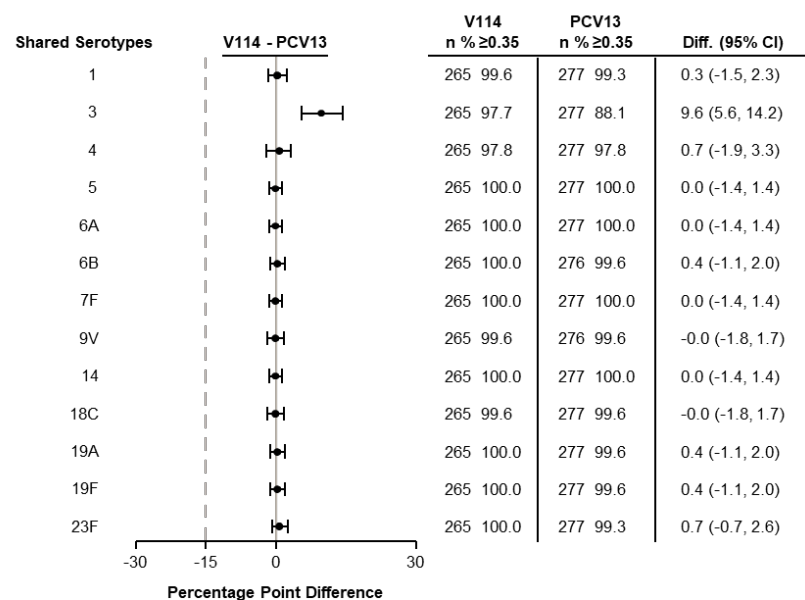


**Supplemental Digital Content 10, figure: IgG Antibody Response Rates 1 Month PD4 V114 vs. PCV13**

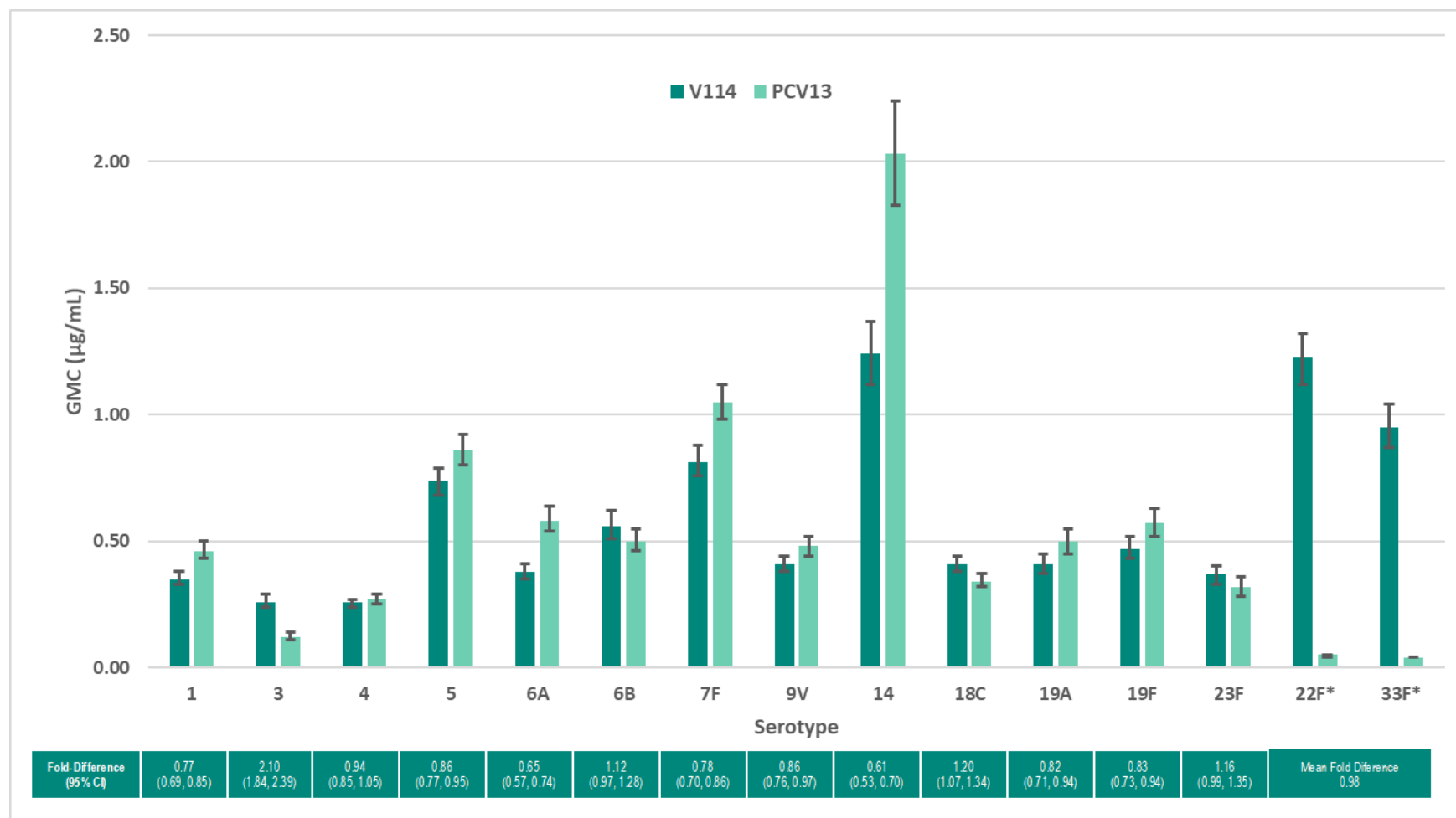
**V114 Lot 1 vs PCV13**



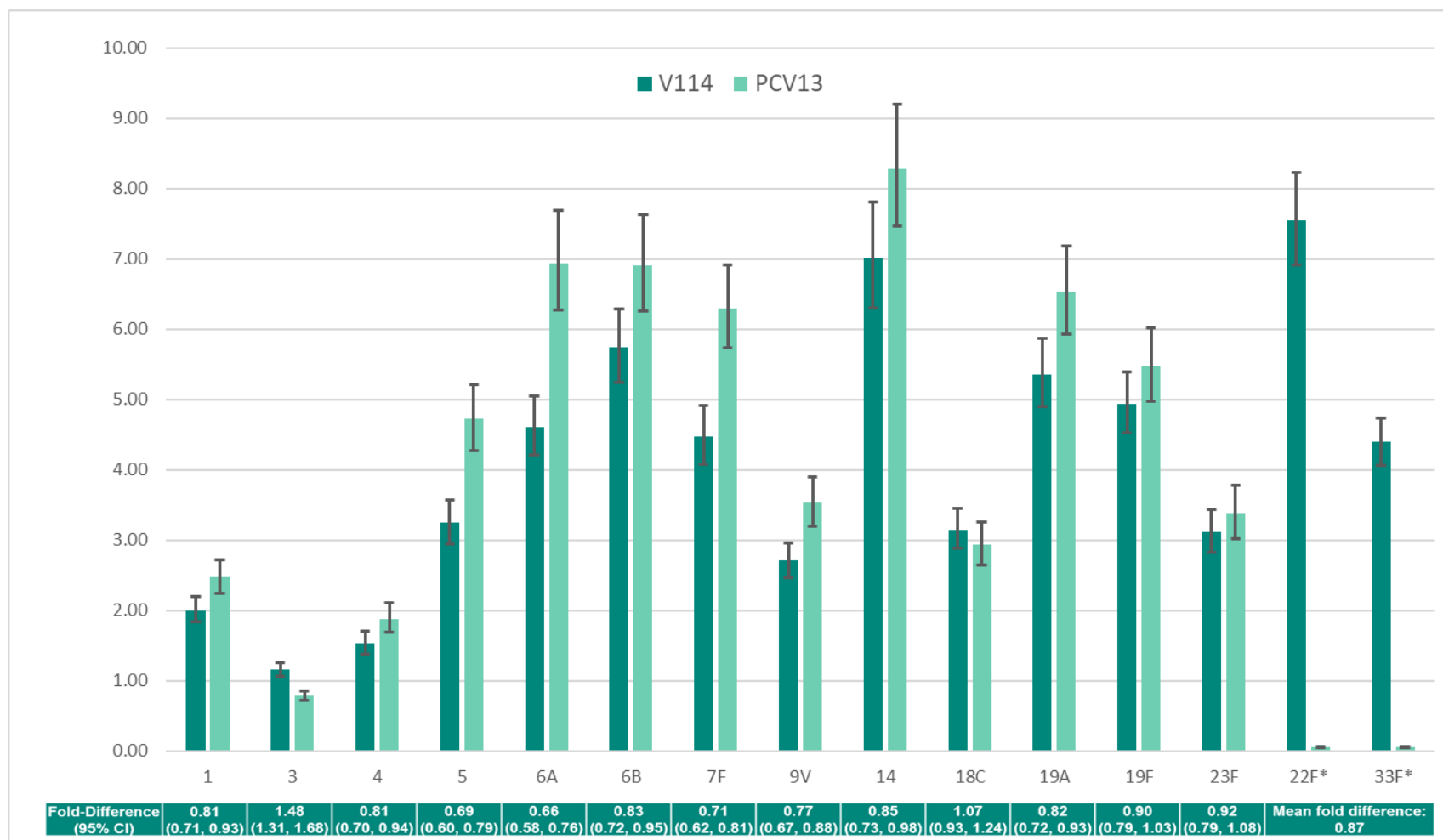
**V114 Lot 2 vs PCV13**



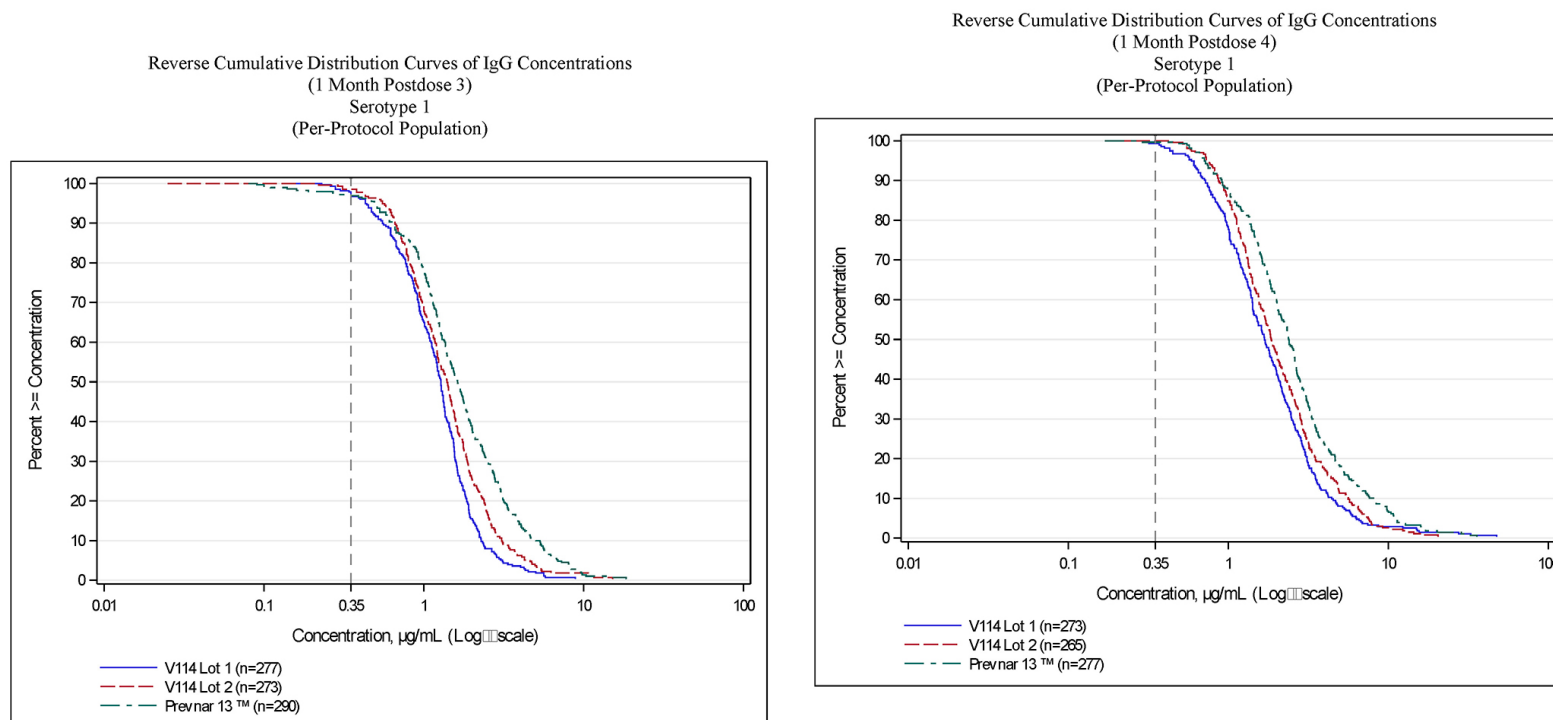
**Supplemental Digital Content 11, figure: IgG GMC Antibody Responses Pre-Dose 4 V114 Lot 2 vs. PCV13**



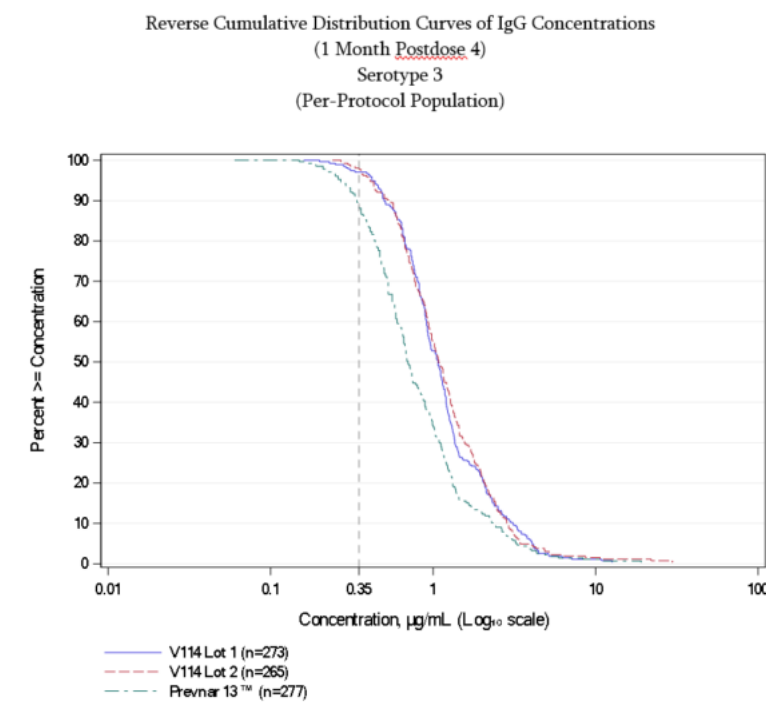
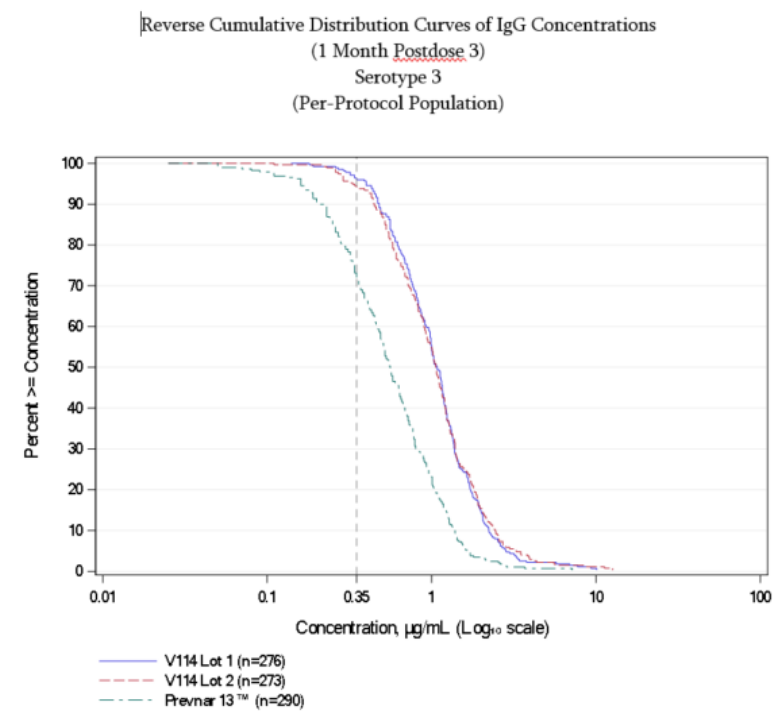
**Supplemental Digital Content 12, figure: IgG GMC Antibody Responses 1 Month PD4 V114 Lot 2 vs. PCV13**



**Supplemental Digital Content 13, figure:** Serotype 1 Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4

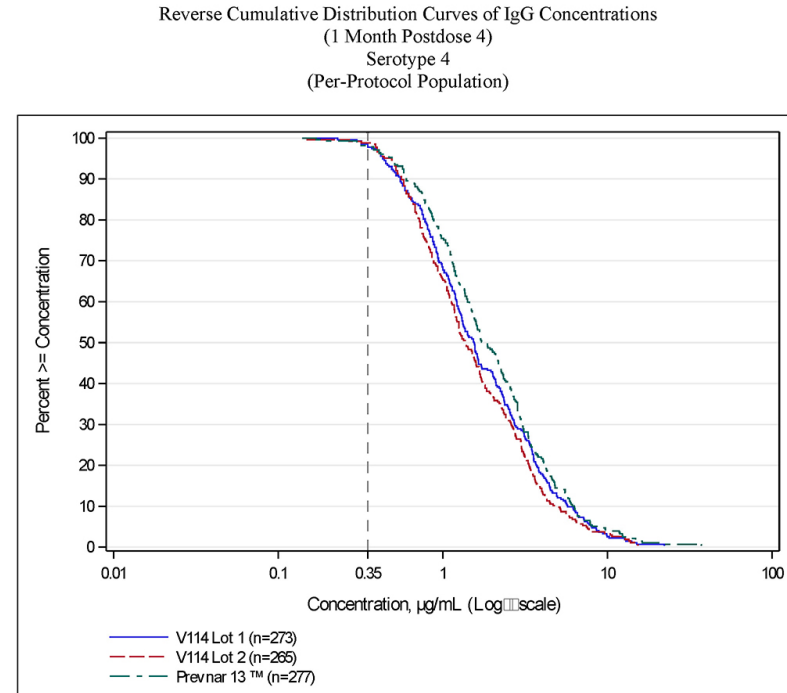
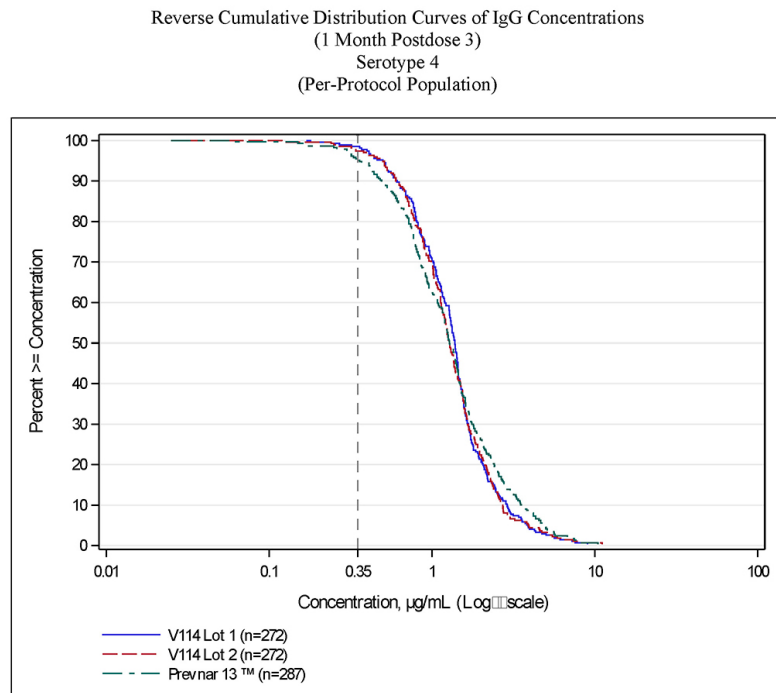


**Supplemental Digital Content 14, figure:** Serotype 3 Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4

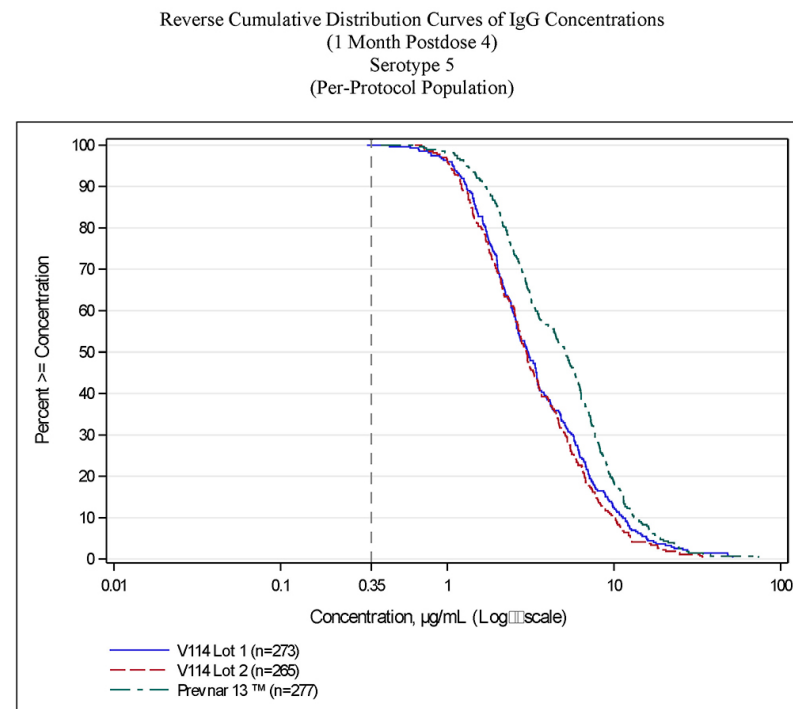
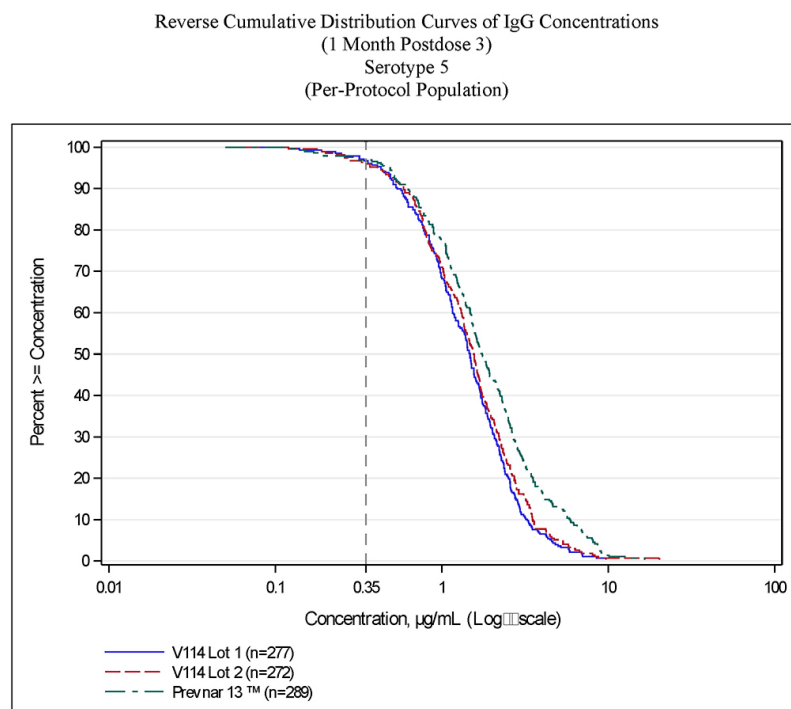




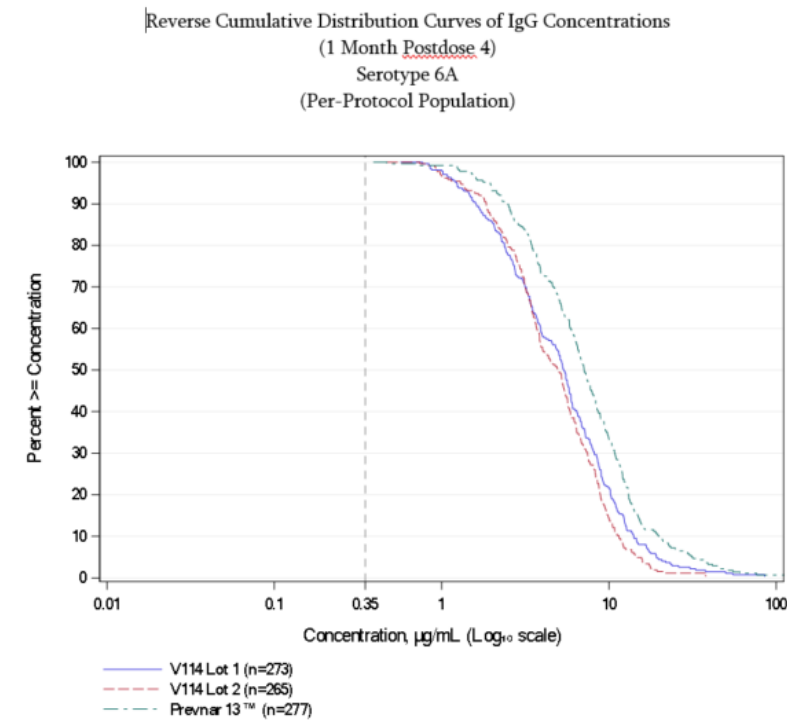
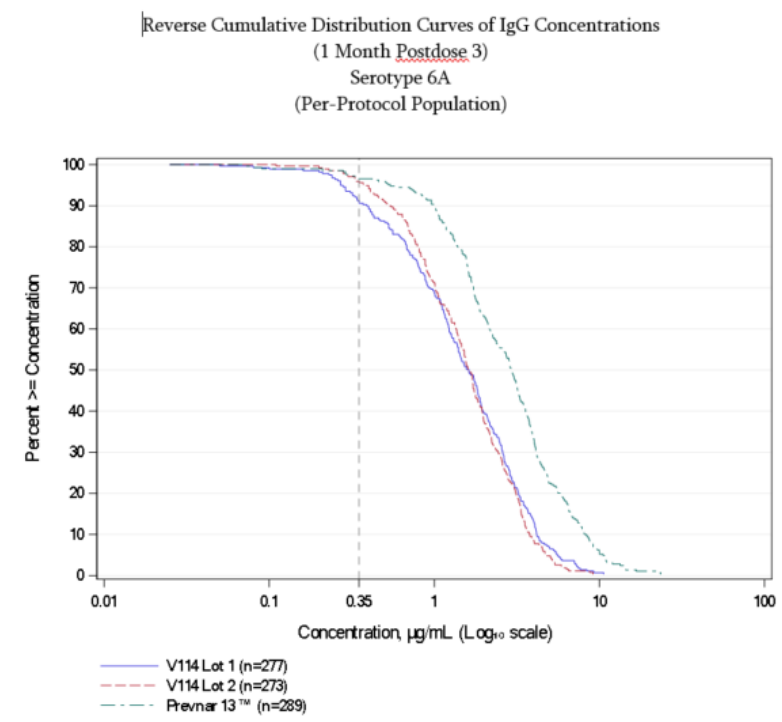
**Supplemental Digital Content 15, figure:** Serotype 4 Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



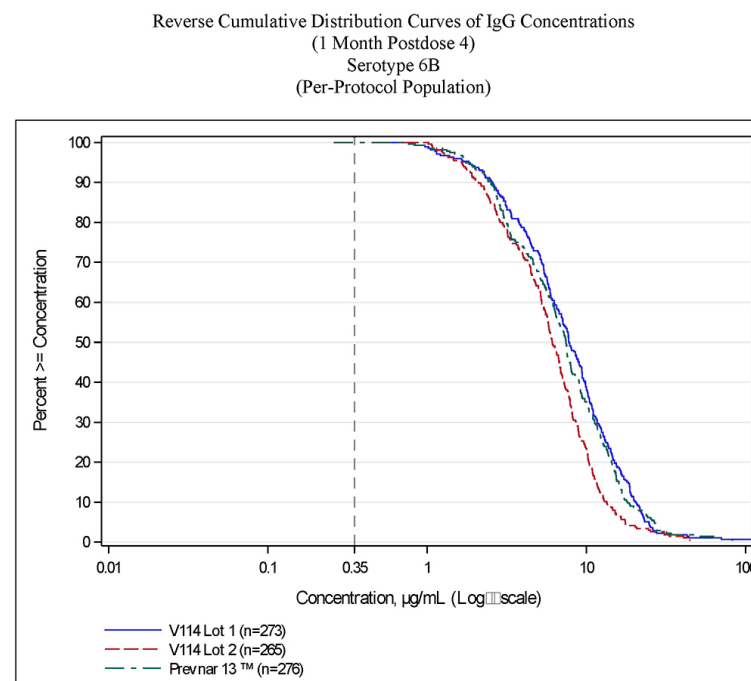
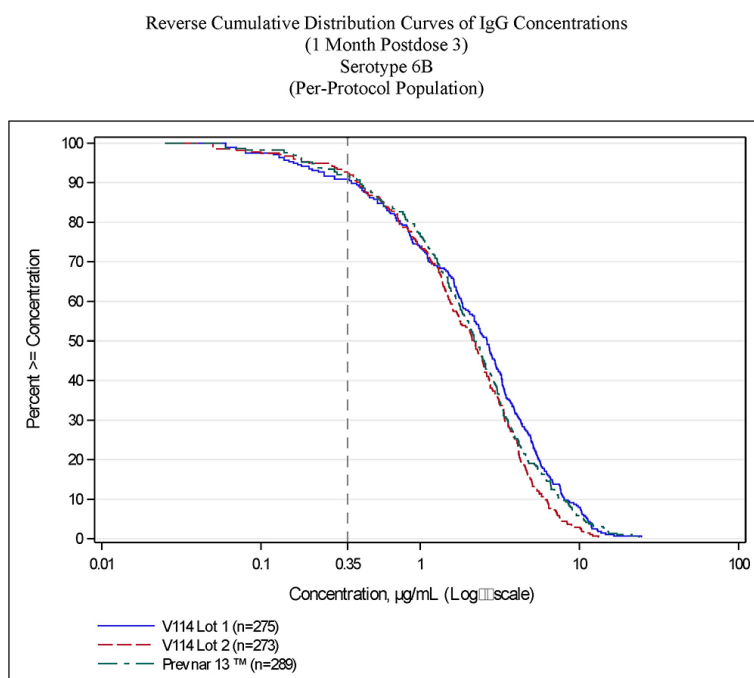
**Supplemental Digital Content 16, figure:** Serotype 5 Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



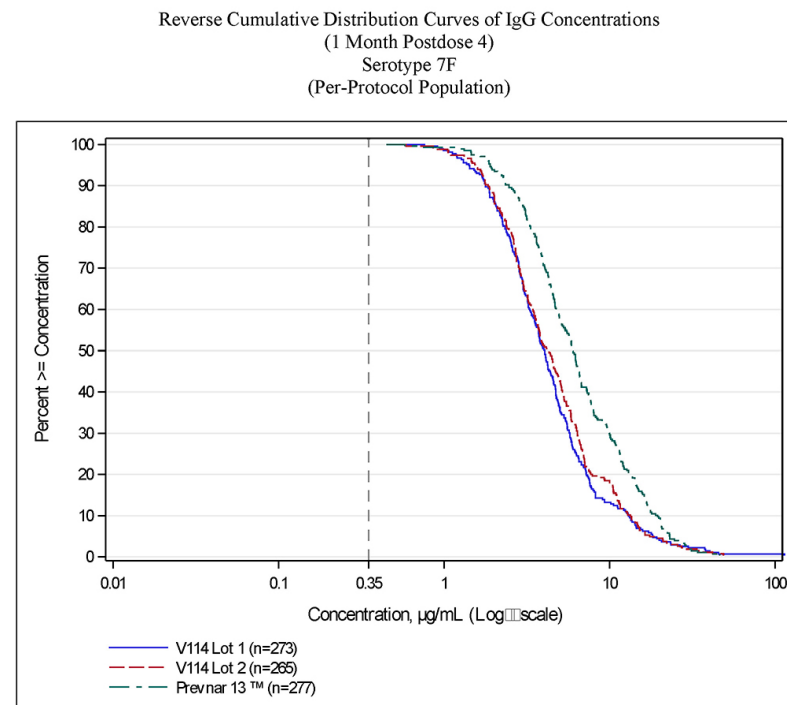
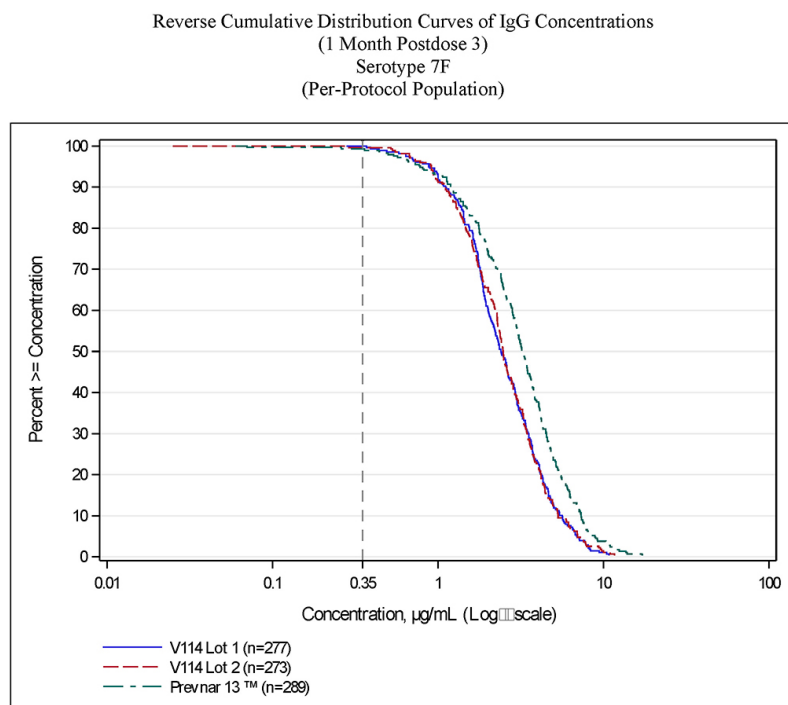
**Supplemental Digital Content 17, figure:** Serotype 6A Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



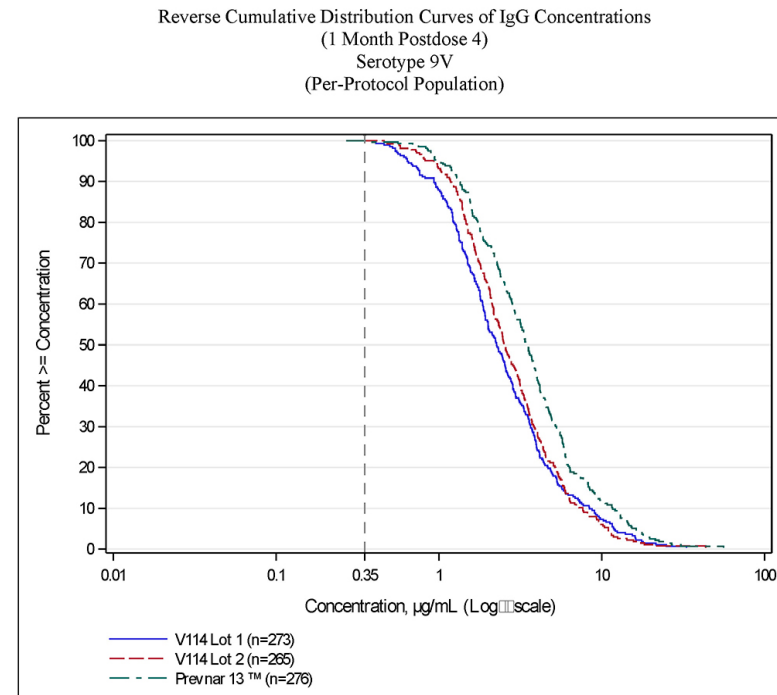
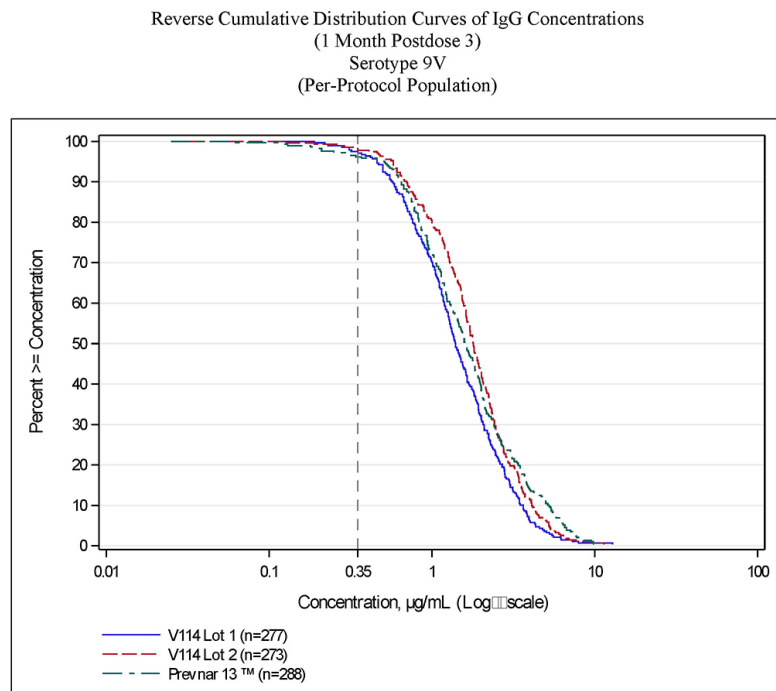
**Supplemental Digital Content 18, figure:** Serotype 6B Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



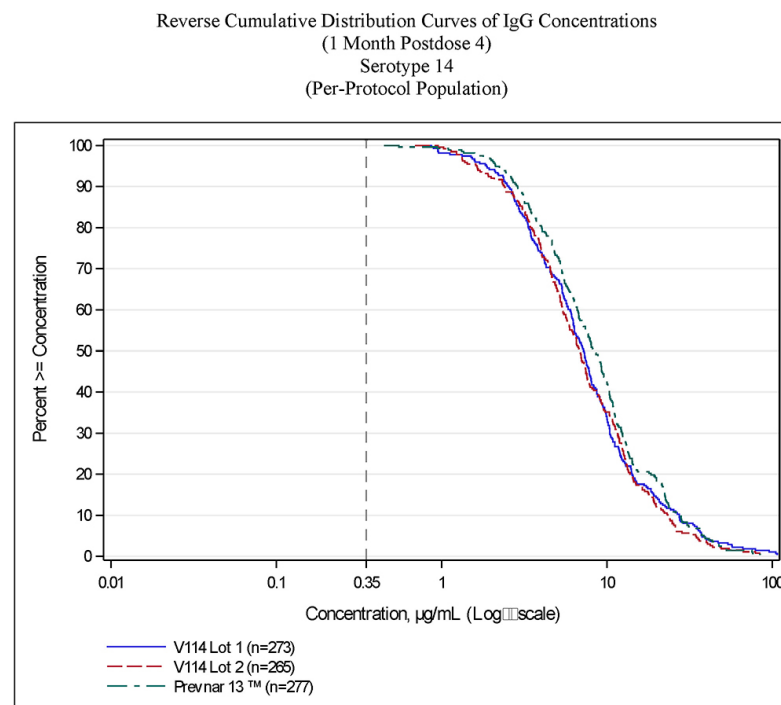
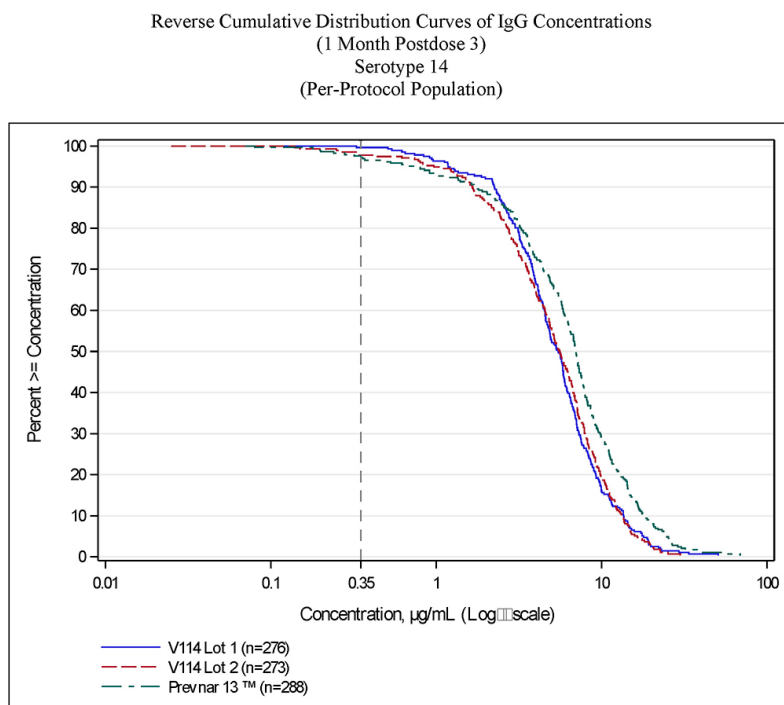
**Supplemental Digital Content 19, figure:** Serotype 7F Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



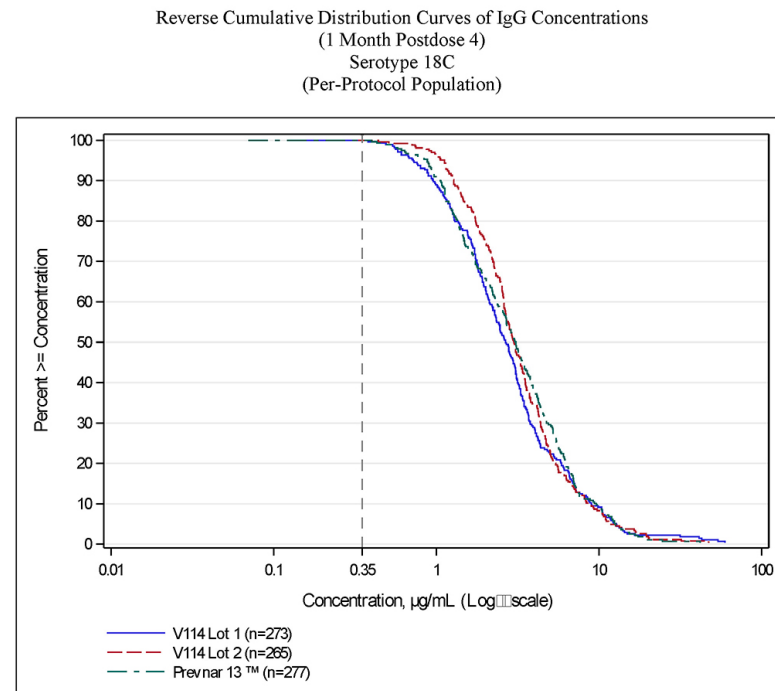
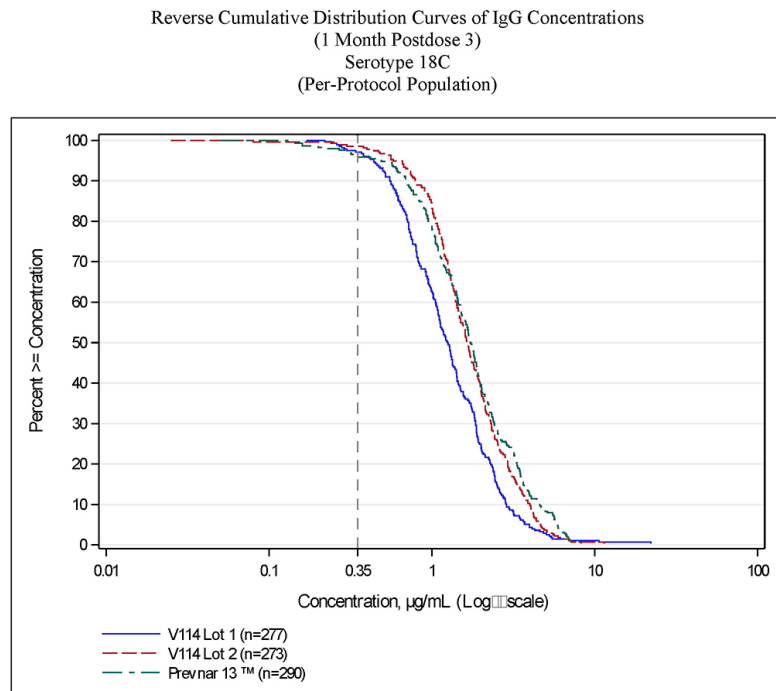
**Supplemental Digital Content 20, figure:** Serotype 9V Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



**Supplemental Digital Content 21, figure: Serotype 14 Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4**

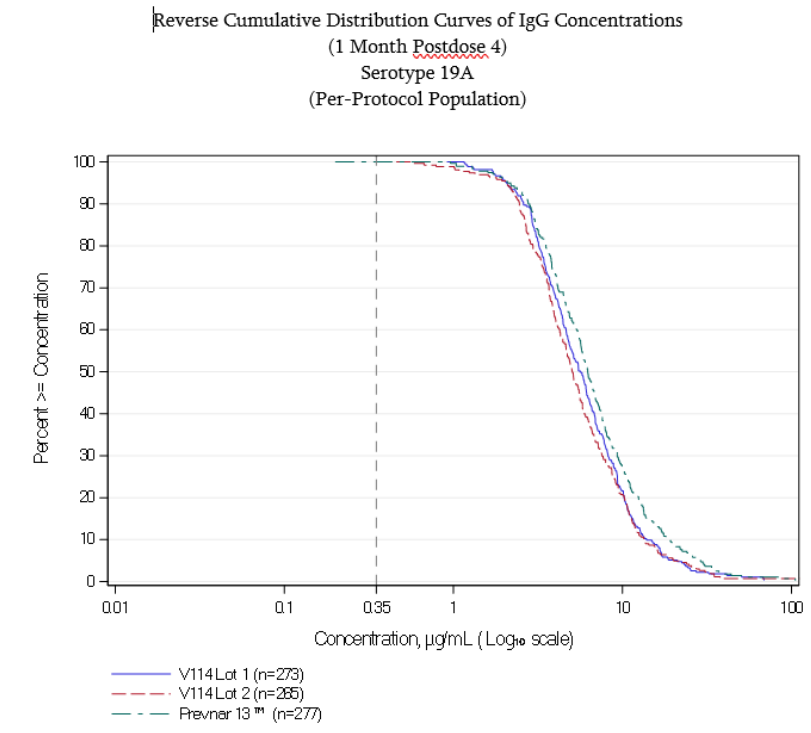
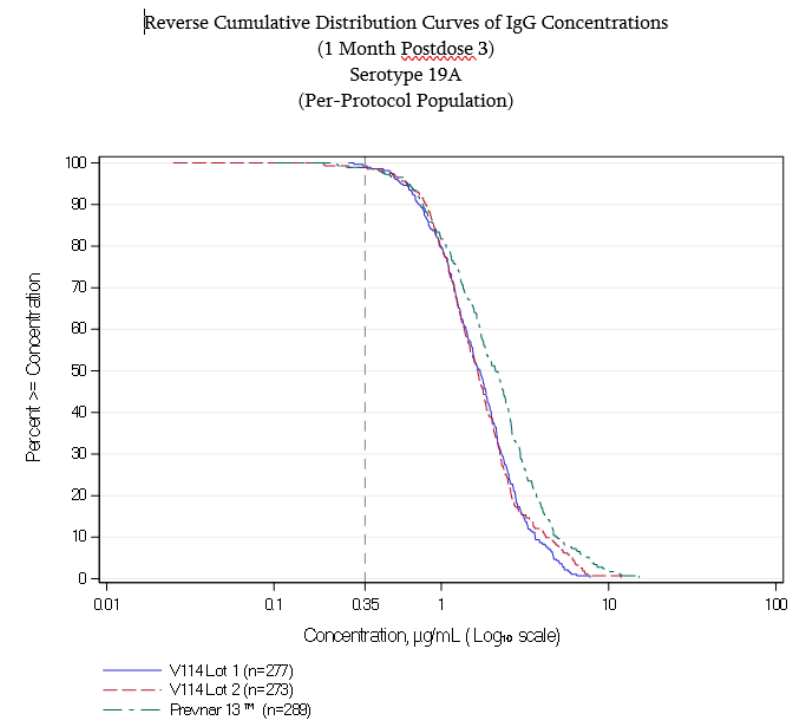


**Supplemental Digital Content 22, figure:** Serotype 18C Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4

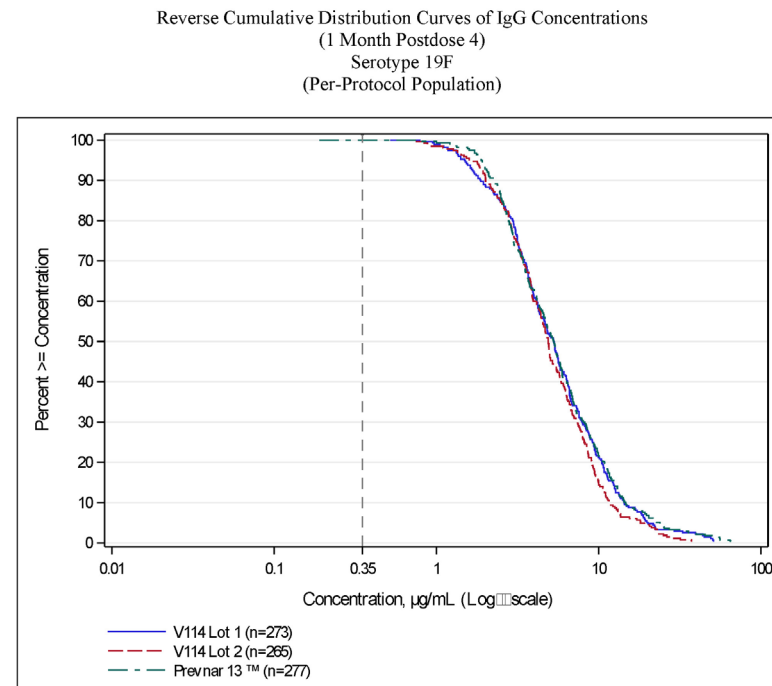
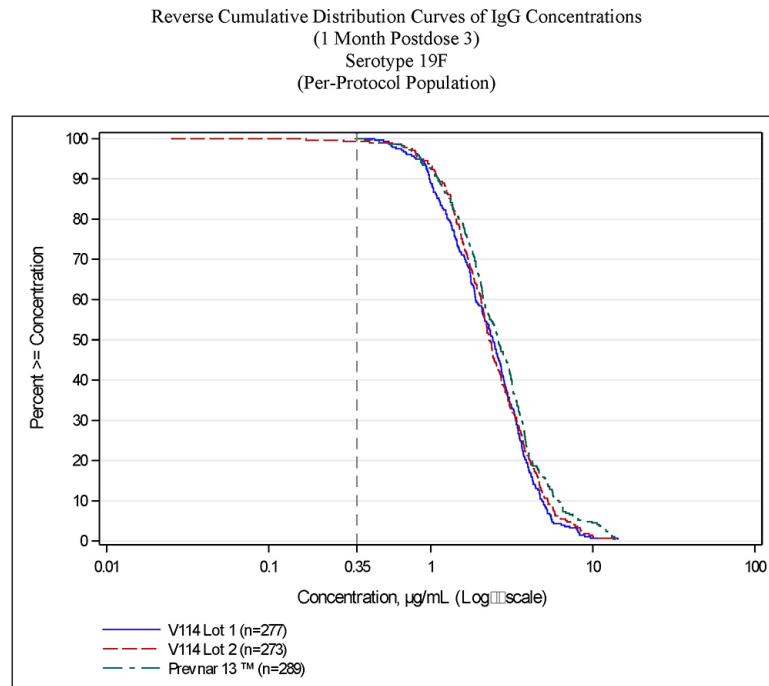




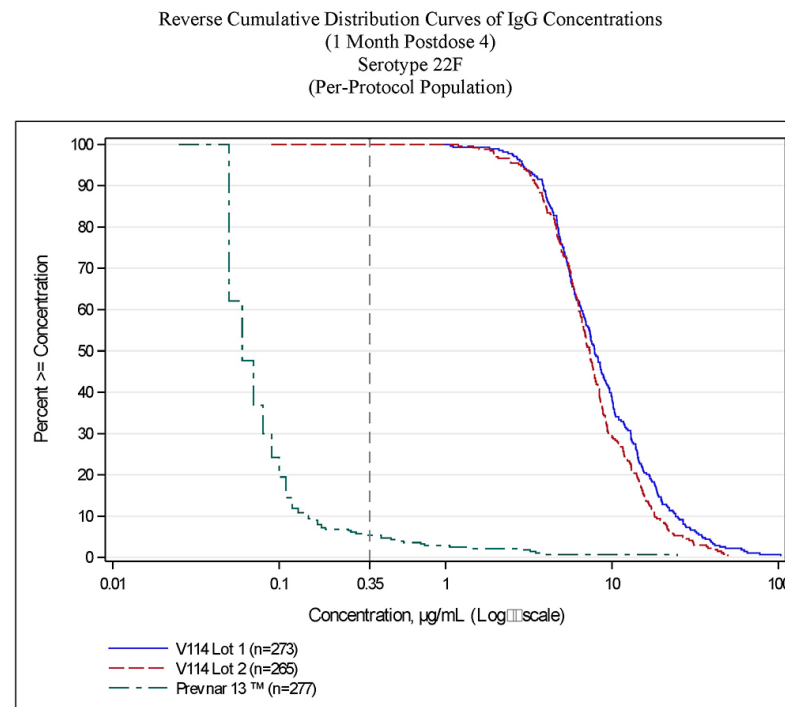
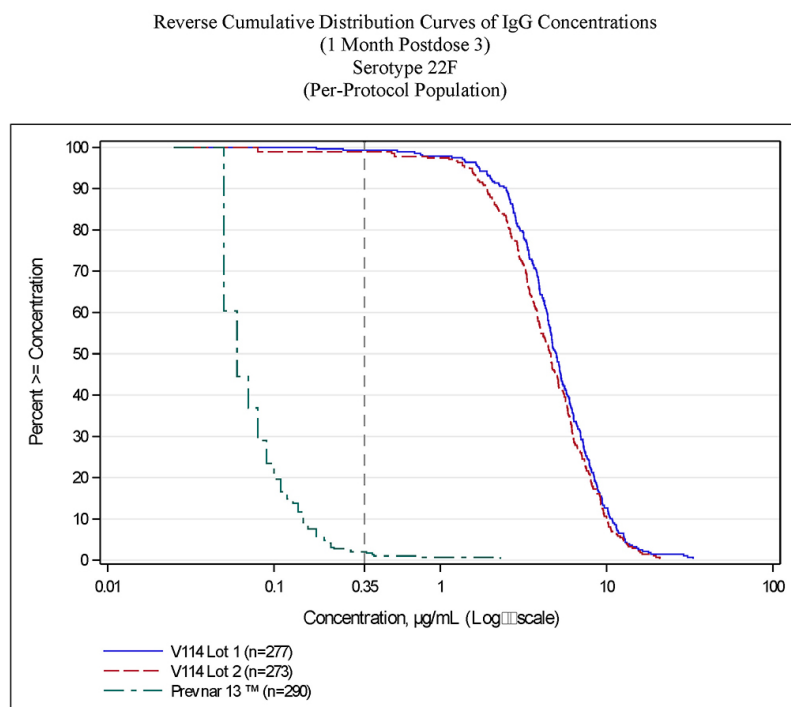
**Supplemental Digital Content 23, figure: Serotype 19A Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4**



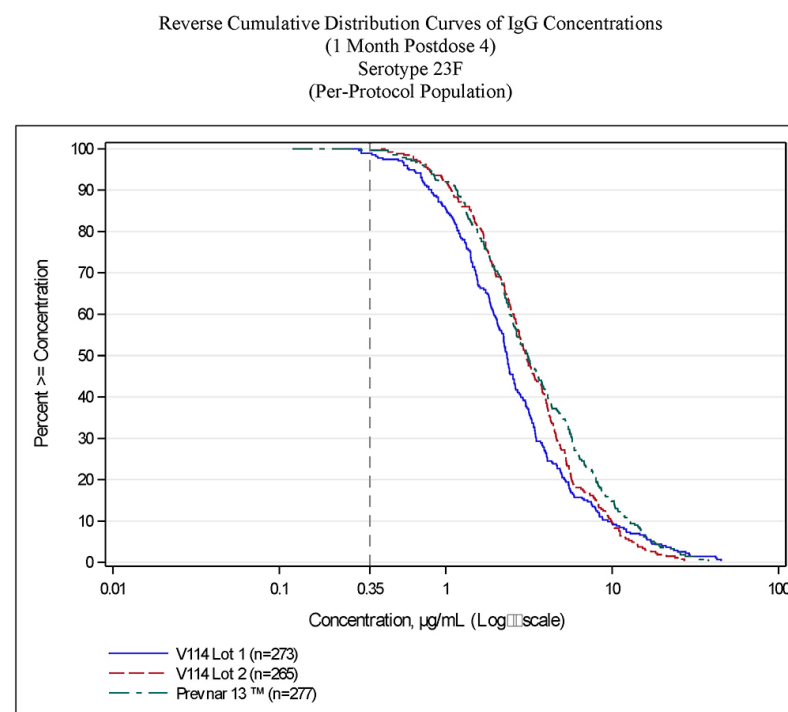
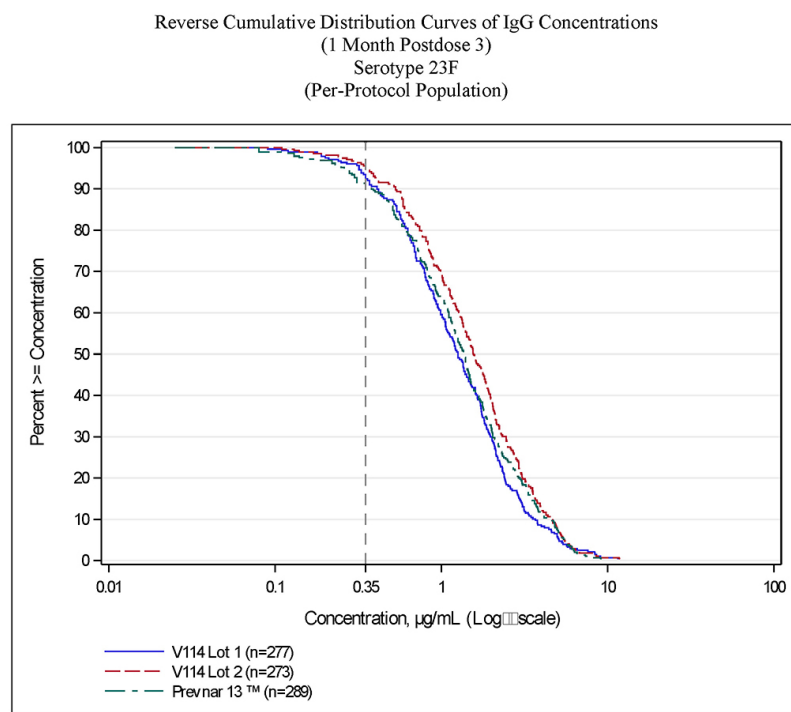
**Supplemental Digital Content 24, figure:** Serotype 19F Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



**Supplemental Digital Content 25, figure** Serotype 22F Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4



**Supplemental Digital Content 26, figure: Serotype 23F Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4**



**Supplemental Digital Content 27, figure:** Serotype 33F Reverse Cumulative Distribution Curves of IgG Concentrations 1 Month PD3 and 1 Month PD4

