Extended Data Table 1. Baseline demographics for participants who were SARS-CoV-2 seronegative at baseline, stratified by HIV status.

Characteristic	Overall	HIV-negative participants			PLWH		
	(N=123)	Overall (n=53)	Placebo (n=26)	Vaccine (n=27)	Overall (n=70)	Placebo (n=33)	Vaccine (n=37)
Median (IQR) age, years	36 (31–44)	33 (25–43)	32 (26–44)	34 (23–42)	38 (33–46)	40 (36–46)	35 (32–45)
Male, n (%)	52 (42.3)	32 (60.4)	16 (61.5)	16 (59.3)	20 (28.6)	8 (24.2)	12 (32.4)
Race, n (%)							
Black	122 (99.2)	53 (100)	26 (100)	27 (100)	69 (98.6)	33 (100)	36 (97.3)
White	1 (0.8)	0	0	0	1 (1.4)	0	1 (2.7)
BMI, kg/m^2, n (%)							
<18	10 (8.1)	6 (11.3)	4 (15.4)	2 (7.4)	4 (5.7)	1 (3)	3 (8.1)
18–24.9	52 (42.3)	24 (45.3)	13 (50)	11 (40.7)	28 (40)	12 (36.4)	16 (43.2)
25–29.9	36 (29.3)	11 (20.8)	3 (11.5)	8 (29.6)	25 (35.7)	11 (33.3)	14 (37.8)
30–39.9	25 (20.3)	12 (22.6)	6 (23.1)	6 (22.2)	13 (18.6)	9 (27.3)	4 (10.8)
Smoker, n (%)	50 (40.7)	25 (47.2)	12 (46.2)	13 (48.1)	25 (35.7)	11 (33.3)	14 (37.8)
Alcohol, n (%)	50 (40.7)	23 (43.4)	13 (50)	10 (37)	27 (38.6)	10 (30.3)	17 (45.9)
Health care worker, n (%)	3 (2.4)	1 (1.9)	1 (3.8)	0	2 (2.9)	1 (3)	1 (2.7)
Hypertension, n (%)	7 (5.7)	1 (1.9)	0	1 (3.7)	6 (8.6)	2 (6.1)	4 (10.8)
Respiratory system, n (%)	10 (8.1)	0 (0)	0	0	10 (14.3)	7 (21.2)	3 (8.1)
HbA1c, n (%)							
Low	8 (6.5)	2 (3.8)	0	2 (7.4)	6 (8.6)	3 (9.1)	3 (8.1)
Normal	111 (90.2)	48 (90.6)	23 (88.5)	25 (92.6)	63 (90)	30 (90.9)	33 (89.2)
High	4 (3.3)	3 (5.7)	3 (11.5)	0	1 (1.4)	0	1 (2.7)
ART, n (%)[†]							
NNRTI and 2 NRTIs	NA	NA	NA	NA	41 (73.2%)	19 (70.4%)	22 (75.9%)
INSTI and 2 NRTIs	NA	NA	NA	NA	9 (16.1%)	4 (14.8%)	5 (17.2%)
Boosted PI and 1 NRTI	NA	NA	NA	NA	3 (5.4%)	2 (7.4%)	1 (3.4%)
Boosted PI and 2 NRTIs	NA	NA	NA	NA	3 (5.4%)	2 (7.4%)	1 (3.4%)
Time on ART, n (%)							
<1 year	NA	NA	NA	NA	6 (10.7%)	3 (11.1%)	3 (10.3%)
1–<5 years	NA	NA	NA	NA	21 (37.5%)	9 (33.3%)	12 (41.4%)
≥5 years	NA	NA	NA	NA	29 (51.8%)	15 (55.6%)	14 (48.3%)
Median (IQR) CD4+ count, cells/μL	NA	NA	NA	NA	690 (503–940)	593 (498–900)	746 (554–952)
Median (IQR) CD4+ percentage	NA	NA	NA	NA	35 (30–41)	34 (29–39)	36 (32–41)
Median (IQR) detectable viral load, copies/mL	NA	NA	NA	NA	10 (10–54)	10 (10–26)	30 (10–96)
Median (IQR) time between doses, days	28 (27–28)	28 (28–28)	28 (28–28)	28 (28–28)	28 (25–28)	28 (27–28)	28 (23–28)

Median (IQR) time post-boost, days	14 (14–14)	14 (14–15)	14 (14–14)	14 (14–15)	14 (14–14)	14 (14–14)	14 (14–14)

[†]Most (75%) were receiving an efavirenz-based regimen and 14.5% were receiving a dolutegravir-based regimen with 2 nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs), tenofovir and lamivudine or emtricitabine, and 1 participant received zidovidine and lamivudine. The remaining participants received a boosted protease inhibitor-based regimen, either lopinavir/ritonavir or atazanavir/ritonavir, with either 1 or 2 NRTIs, including lamivudine, zidovudine, abacavir or tenofovir.

ART= antiretroviral treatment; BMI=body mass index; HbA1c=glycated hemoglobin measurement (indicator of diabetes); HIV=human immunodeficiency virus; INSTI=integrase strand transfer inhibitor; IQR=interquartile range; n=subpopulation number; NA=not applicable; NNRTI=non-nucleoside reverse transcriptase inhibitor; NRTI= nucleoside and nucleotide reverse transcriptase inhibitors; PI, protease inhibitor; PLWH=people living with HIV.

Extended Data Table 2. Baseline demographics for participants who were SARS-CoV-2 seropositive at baseline, stratified by HIV status.

Characteristic	Overall	HIV-negative participants			PLWH		
	(N=35)	Overall (n=3)	Placebo (n=2)	Vaccine (n=1)	Overall (n=32)	Placebo (n=17)	Vaccine (n=15)
Median (IQR) age, years	42 (33–47)	31 (31–34)	31 (31–31)	37 (37–37)	43 (36–47)	43 (40–47)	42 (31–47)
Male, n (%)	8 (22.9)	2 (66.7)	2 (100)	0	6 (18.8)	2 (11.8)	4 (26.7)
Race, n (%)							
Black	35 (100)	3 (100)	2 (100)	1 (100)	32 (100)	17 (100)	15 (100)
BMI, kg/m^2, n (%)							
<18	1 (2.9)	0	0	0	1 (3.1)	0	1 (6.7)
18–24.9	14 (40)	1 (33.3)	1 (50)	0	13 (40.6)	5 (29.4)	8 (53.3)
25–29.9	10 (28.6)	2 (66.7)	1 (50)	1 (100)	8 (25)	5 (29.4)	3 (20)
30–39.9	10 (28.6)	0	0	0	10 (31.2)	7 (41.2)	3 (20)
Smoker, n (%)	9 (25.7)	1 (33.3)	0	1 (100)	8 (25)	4 (23.5)	4 (26.7)
Alcohol, n (%)	20 (57.1)	1 (33.3)	0	1 (100)	19 (59.4)	10 (58.8)	9 (60)
Health care worker, n (%)	0	0	0	0	0	0	0
Hypertension, n (%)	5 (14.3)	0	0	0	5 (15.6)	5 (29.4)	0
Respiratory system, n (%)	6 (17.1)	0	0	0	6 (18.8)	3 (17.6)	3 (20)
HbA1c, n (%)							
Low	4 (11.4)	0	0	0	4 (12.5)	2 (11.8)	2 (13.3)
Normal	31 (88.6)	3 (100)	2 (100)	1 (100)	28 (87.5)	15 (88.2)	13 (86.7)
High	0	0	0	0	0	0	0
ART, n (%)[†]							
NNRTI and 2 NRTIs	NA	NA	NA	NA	15 (83.3%)	9 (81.8%)	6 (85.7%)
INSTI and 2 NRTIs	NA	NA	NA	NA	2 (11.1%)	1 (9.1%)	1 (14.3%)
Boosted PI and 1 NRTI	NA	NA	NA	NA	1 (5.6%)	1 (9.1%)	0 (0%)
Boosted PI and 2 NRTIs	NA	NA	NA	NA	0 (0%)	0 (0%)	0 (0%)
Time on ART, n (%)							
<1 year	NA	NA	NA	NA	3 (16.7%)	1 (9.1%)	2 (28.6%)
1–<5 years	NA	NA	NA	NA	7 (38.9%)	3 (27.3%)	4 (57.1%)
≥5 years	NA	NA	NA	NA	8 (44.4%)	7 (63.6%)	1 (14.3%)
Median (IQR) CD4+ count, cells/μL	NA	NA	NA	NA	714 (522–914)	731 (532–869)	696 (521–946)
Median (IQR) CD4+ percentage	NA	NA	NA	NA	37 (31–41)	37 (28–40)	37 (33–40)
Median (IQR) detectable viral load, copies/mL	NA	NA	NA	NA	16 (10–43)	10 (10–28)	46 (28–94)
Median (IQR) time between doses, days	28 (26–28)	28 (28–28)	28 (28–28)	27 (27–27)	28 (25–28)	28 (25–28)	28 (24–28)
Median (IQR) time post-boost, days	14 (14–14)	15 (14–16)	16 (15–16)	14 (14–14)	14 (14–14)	14 (14–14)	14 (14–14)

[†]Most (75%) were receiving an efavirenz-based regimen and 14.5% were receiving a dolutegravir-based regimen with 2 nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs), tenofovir and lamivudine or emtricitabine, and 1 participant received zidovidine and lamivudine. The remaining participants received a boosted protease inhibitor-based regimen, either lopinavir/ritonavir or atazanavir/ritonavir, with either 1 or 2 NRTIs, including lamivudine, zidovudine, abacavir or tenofovir.

ART= antiretroviral treatment; BMI=body mass index; HbA1c=glycated hemoglobin measurement (indicator of diabetes); HIV=human immunodeficiency virus; INSTI=integrase strand transfer inhibitor; IQR=interquartile range; NA=not applicable; NNRTI=non-nucleoside reverse transcriptase inhibitor; NRTI= nucleoside and nucleotide reverse transcriptase inhibitors; PI, protease inhibitor; PLWH=people living with HIV.

Extended Data Table 3. AEs reported by HIV-negative participants stratified by treatment group.

	Incidence risk (%)		
	Overall (N=58)	**Placebo (n=29)**	**Vaccine (n=29)**
AE	**237 (401.7)**	**142 (489.7)**	**95 (327.6)**
General disorders and administration site conditions	**78 (134.5)**	**46 (158.6)**	**32 (110.3)**
General system disorders NEC	77 (132.8)	46 (158.6)	31 (106.9)
Body temperature conditions	1 (1.7)	0 (<0.1)	1 (3.4)
Injury, poisoning and procedural complications	**1 (1.7)**	**1 (3.4)**	**0 (<0.1)**
Injuries NEC	1 (1.7)	1 (3.4)	0 (<0.1)
Investigations	**1 (1.7)**	**1 (3.4)**	**0 (<0.1)**
Microbiology and serology investigations	1 (1.7)	1 (3.4)	0 (<0.1)
Reproductive system and breast disorders	**1 (1.7)**	**0 (<0.1)**	**1 (3.4)**
Vulvovaginal disorders (excl infections and inflammations)	1 (1.7)	0 (<0.1)	1 (3.4)
Vascular disorders	**1 (1.7)**	**0 (<0.1)**	**1 (3.4)**
Vascular hypertensive disorders	1 (1.7)	0 (<0.1)	1 (3.4)
Nervous system disorders	**43 (74.1)**	**28 (96.6)**	**15 (51.7)**
Headaches	35 (60.3)	23 (79.3)	12 (41.4)
Cranial nerve disorders (excl neoplasms)	5 (8.6)	3 (10.3)	2 (6.9)
Neurological disorders NEC	3 (5.2)	2 (6.9)	1 (3.4)
Gastrointestinal disorders	**33 (56.9)**	**18 (62.1)**	**15 (51.7)**
Gastrointestinal signs and symptoms	18 (31)	9 (31)	9 (31)
Gastrointestinal motility and defaecation conditions	13 (22.4)	8 (27.6)	5 (17.2)
Gastrointestinal vascular conditions	1 (1.7)	1 (3.4)	0 (<0.1)
Oral soft tissue conditions	1 (1.7)	0 (<0.1)	1 (3.4)
Infections and infestations	**27 (46.6)**	**18 (62.1)**	**9 (31)**
Infections - pathogen unspecified	23 (39.7)	16 (55.2)	7 (24.1)
Bacterial infectious disorders	1 (1.7)	1 (3.4)	0 (<0.1)
Fungal infectious disorders	1 (1.7)	1 (3.4)	0 (<0.1)
Mycobacterial infectious disorders	1 (1.7)	0 (<0.1)	1 (3.4)
Viral infectious disorders	1 (1.7)	0 (<0.1)	1 (3.4)
Respiratory, thoracic and mediastinal disorders	**27 (46.6)**	**19 (65.5)**	**8 (27.6)**
Respiratory disorders NEC	13 (22.4)	9 (31)	4 (13.8)
Respiratory tract signs and symptoms	7 (12.1)	4 (13.8)	3 (10.3)
Upper respiratory tract disorders (excl infections)	7 (12.1)	6 (20.7)	1 (3.4)
Musculoskeletal and connective tissue disorders	**17 (29.3)**	**8 (27.6)**	**9 (31)**
Muscle disorders	9 (15.5)	4 (13.8)	5 (17.2)
Joint disorders	5 (8.6)	3 (10.3)	2 (6.9)
Musculoskeletal and connective tissue disorders NEC	3 (5.2)	1 (3.4)	2 (6.9)
Skin and subcutaneous tissue disorders	**6 (10.3)**	**2 (6.9)**	**4 (13.8)**

Epidermal and dermal conditions	6 (10.3)	2 (6.9)	4 (13.8)
Ear and labyrinth disorders	**1 (1.7)**	**0 (<0.1)**	**1 (3.4)**
External ear disorders (excl congenital)	1 (1.7)	0 (<0.1)	1 (3.4)
Immune system disorders	**1 (1.7)**	**1 (3.4)**	**0 (<0.1)**
Allergic conditions	1 (1.7)	1 (3.4)	0 (<0.1)

Incidence risk calculation is based on 58 trial participants (29 placebo and 29 vaccine). This excludes 13 participants who were SARS-CoV-2 seropositive at baseline.

AE=adverse event; HIV=human immunodeficiency virus; NEC=not elsewhere classified; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Extended Data Table 4. AEs reported by PLWH, stratified by treatment group.

	Incidence risk		
	Overall (N=103)	**Placebo (n=51)**	**Vaccine (n=52)**
AE	**164 (159.2)**	**78 (152.9)**	**86 (165.4)**
General disorders and administration site conditions	**44 (42.7)**	**22 (43.1)**	**22 (42.3)**
General system disorders NEC	41 (39.8)	20 (39.2)	21 (40.4)
Administration site reactions	3 (2.9)	2 (3.9)	1 (1.9)
Blood and lymphatic system disorders	**2 (1.9)**	**0 (<0.1)**	**2 (3.8)**
Anemias nonhemolytic and marrow depression	2 (1.9)	0 (<0.1)	2 (3.8)
Ear and labyrinth disorders	**2 (1.9)**	**0 (<0.1)**	**2 (3.8)**
Aural disorders NEC	2 (1.9)	0 (<0.1)	2 (3.8)
Eye disorders	**2 (1.9)**	**0 (<0.1)**	**2 (3.8)**
Eye disorders NEC	1 (1)	0 (<0.1)	1 (1.9)
Ocular infections, irritations and inflammations	1 (1)	0 (<0.1)	1 (1.9)
Injury, poisoning and procedural complications	**2 (1.9)**	**2 (3.9)**	**0 (<0.1)**
Injuries NEC	2 (1.9)	2 (3.9)	0 (<0.1)
Vascular disorders	**2 (1.9)**	**0 (<0.1)**	**2 (3.8)**
Vascular hypertensive disorders	2 (1.9)	0 (<0.1)	2 (3.8)
Skin and subcutaneous tissue disorders	**1 (1)**	**0 (<0.1)**	**1 (1.9)**
Skin appendage conditions	1 (1)	0 (<0.1)	1 (1.9)
Nervous system disorders	**26 (25.2)**	**10 (19.6)**	**16 (30.8)**
Headaches	22 (21.4)	9 (17.6)	13 (25)
Neurological disorders NEC	4 (3.9)	1 (2)	3 (5.8)
Infections and infestations	**25 (24.3)**	**12 (23.5)**	**13 (25)**
Infections - pathogen unspecified	22 (21.4)	11 (21.6)	11 (21.2)
Viral infectious disorders	2 (1.9)	1 (2)	1 (1.9)
Bacterial infectious disorders	1 (1)	0 (<0.1)	1 (1.9)
Gastrointestinal disorders	**19 (18.4)**	**8 (15.7)**	**11 (21.2)**
Gastrointestinal motility and defaecation conditions	14 (13.6)	6 (11.8)	8 (15.4)
Gastrointestinal signs and symptoms	3 (2.9)	1 (2)	2 (3.8)
Dental and gingival conditions	1 (1)	1 (2)	0 (<0.1)
Gastrointestinal vascular conditions	1 (1)	0 (<0.1)	1 (1.9)
Musculoskeletal and connective tissue disorders	**13 (12.6)**	**8 (15.7)**	**5 (9.6)**
Musculoskeletal and connective tissue disorders NEC	5 (4.9)	4 (7.8)	1 (1.9)
Joint disorders	4 (3.9)	1 (2)	3 (5.8)
Muscle disorders	4 (3.9)	3 (5.9)	1 (1.9)
Investigations	**10 (9.7)**	**9 (17.6)**	**1 (1.9)**
Water, electrolyte and mineral investigations	5 (4.9)	4 (7.8)	1 (1.9)
Hepatobiliary investigations	4 (3.9)	4 (7.8)	0 (<0.1)
Enzyme investigations NEC	1 (1)	1 (2)	0 (<0.1)
Metabolism and nutrition disorders	8 (7.8)	4 (7.8)	4 (7.7)

Electrolyte and fluid balance conditions	8 (7.8)	4 (7.8)	4 (7.7)
Respiratory, thoracic and mediastinal disorders	5 (4.9)	2 (3.9)	3 (5.8)
Respiratory disorders NEC	4 (3.9)	2 (3.9)	2 (3.8)
Respiratory tract signs and symptoms	1 (1)	0 (<0.1)	1 (1.9)
Reproductive system and breast disorders	3 (2.9)	1 (2)	2 (3.8)
Menstrual cycle and uterine bleeding disorders	1 (1)	1 (2)	0 (<0.1)
Reproductive tract disorders NEC	1 (1)	0 (<0.1)	1 (1.9)
Uterine, pelvic and broad ligament disorders	1 (1)	0 (<0.1)	1 (1.9)

Incidence risk calculation is based on 103 trial participants (51 placebo and 52 vaccine). This excludes 13 participants who were SARS-CoV-2 seropositive at baseline.

AE=adverse event; HIV=human immunodeficiency virus; NEC=not elsewhere classified; PLWH=people living with HIV; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Extended Data Table 5. SAEs reported by HIV-negative participants and PLWH.

Group	Treatment	Classification	Relatedness	Diagnosis
HIV-negative participants	Vaccine	Important medical event	Definite	Severe fever (40.5°C, resolved with paracetamol)
		Hospitalization/prolongation	Not related	Right angle of mandible fracture
		Important medical event	Not related	Pulmonary tuberculosis
		Hospitalization/prolongation	Not related	Chest pain
	Placebo	Death	Not related	Suicide
		Hospitalization/prolongation	Not related	Left axillary abscess
PLWH	Placebo	Important medical event	Unlikely	Severely elevated ALT

ALT=alanine aminotransferase; HIV=human immunodeficiency virus; PLWH=people living with HIV; SAE=serious adverse event.

Extended Data Table 6. Number of participants with a positive SARS-CoV-2 PCR test, stratified by HIV status and time since vaccine dose.

	HIV-negative participants (n=70)				**PLWH (n=104)**			
	Time from vaccine dose, days							
	≤0	**>0 to ≤28**	**>28 to ≤42**	**>42**	**≤0**	**>0 to ≤28**	**>28 to ≤42**	**>42**
PCR− throughout trial	46				96			
Symptom severity in PCR+								
Asymptomatic	4 (3P/1V)	2 (2V)	0	0	0	0	1 (1V)	0
Mild	3 (1P/2V)	3 (2P/1V)	0	2 (2P)	1 (1P)	2 (1P/1V)	1 (1P)	1 (1V)
Moderate	0	-	0	0	0	0	1 (1V)	0
Other (displayed some symptoms, but did not meet protocol definition of mild COVID-19 disease)	5 (3P/2V)	4 (3P/1V)	0	1 (1P)	0	0	0	1 (1V)

COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; P=placebo; PCR=polymerase chain reaction; PLWH=people living with HIV; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; V=vaccine.

Extended Data Table 7. FLS IgG responses in participants who were SARS-CoV-2 seronegative at baseline, stratified by HIV status.

Arm	Measure	Day 0 (baseline)	
		HIV-negative participants	**PLWH**
Placebo	GMC, (95% CI), BAU/mL	1.5 (0.9–2.6); n=26	1.2 (0.7–2.0); n=33
	% seropositive	3.8 (0.7–18.9); 1/26	0 (0–10.4); 0/33
Vaccine	GMC, (95% CI), BAU/mL	1.3 (0.9–1.9); n=27	1.34 (0.8–2.3); n=37
	% seropositive	0 (0–12.5); 0/27	8.1 (2.8–21.3); 3/37
		Day 28 (booster dose)	
		HIV-negative participants	**PLWH**
Placebo	GMC, (95% CI), BAU/mL	1.5 (0.7–3.6); n=20	2.1 (1.1–4.2); n=33
	% seropositive	10 (2.8–30.1); 2/20	9.1 (3.1–23.6); 3/33
	% seroresponsive[†]	0 (0–79.3); 0/1	–
Vaccine	GMC, (95% CI), BAU/mL	112.3 (61.7–204.4); n=23	163.7 (89.9–298.1); n=36
	% seropositive	78.3 (58.1–90.3); 18/23	86.1 (71.3–93.9); 31/36
	% seroresponsive	–	100 (43.9–100); 3/3
		Day 42 (14 days post booster)	
		HIV-negative participants	**PLWH**
Placebo	GMC, (95% CI), BAU/mL	1.5 (0.7–3.3); n=21	1.91 (0.9–4.1); n=30
	% seropositive	9.5 (2.7–28.9); 2/21	6.7 (1.8–21.3); 2/30
	% seroresponsive	0 (0–65.8); 0/2	0 (0–56.1); 0/3
Vaccine	GMC, (95% CI), BAU/mL	504.9 (337.1–756.2); n=23	453.1 (267.4–767.7); n=32
	% seropositive	95.7 (79–99.2); 22/23	93.8 (79.9-98.3); 30/32
	% seroresponsive	72.2 (49.1–87.5); 13/18	63.0 (44.2–78.5); 17/27

[†]Samples considered seroresponsive if $\geq$2-fold increase.

BAU=binding antibody unit; CI=confidence interval; FLS=full-length spike; GMC=geometric mean concentration; HIV=human immunodeficiency virus; IgG=immunoglobulin G; PLWH=people living with HIV; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Extended Data Table 8. RBD IgG response in participants who were SARS-CoV-2 seronegative at baseline, stratified by HIV status.

Arm	Measure	Day 0 (baseline)	
		HIV-negative participants	**PLWH**
Placebo	GMC (95% CI), BAU/mL	1.0 (0.5–1.9); n=26	0.6 (0.3–0.9); n=33
Vaccine	GMC, (95% CI), BAU/mL	1.2 (0.9–1.7); n=27	0.8 (0.5–1.3); n=37
		Day 28 (booster dose)	
		HIV-negative participants	**PLWH**
Placebo	GMC, (95% CI), BAU/mL	1.2 (0.5–2.9); n=20	1.0 (0.5–2.1); n=33
	% seropositive	10 (2.8–30.1); 2/20	9.1 (3.1–23.6); 3/33
Vaccine	GMC, (95% CI), BAU/mL	51.1 (24.3–107.4); n=23	80.0 (40.3–158.8); n=36
	% seropositive	65.2 (44.9–81.2); 15/23	69.4 (53.1–82); 25/36
		Day 42 (14 days post booster)	
		HIV-negative participants	**PLWH**
Placebo	GMC, (95% CI), BAU/mL	1.1 (0.5–2.8); n=21	0.9 (0.4–2.1); n=30
	% seropositive	9.5 (2.7−28.9); 2/21	6.7 (1.8–21.3); 2/30
	% seroresponsive[†]	0 (0–65.8); 0/2	0 (0–56.1); 0/3
Vaccine	GMC, (95% CI), BAU/mL	364.2 (238.6–555.8); n=23	347.8 (195.0–620.4); n=32
	% seropositive	95.7 (79–99.2); 22/23	87.5 (71.9–95); 28/32
	% seroresponsive	66.7 (41.7–84.8); 10/15	68.2 (47.3–83.6); 15/22

[†]Samples considered seroresponsive if ≥2-fold increase.

BAU=binding antibody unit; CI=confidence interval; GMC=geometric mean concentration; HIV=human immunodeficiency virus; IgG=immunoglobulin G; PLWH=people living with HIV; RBD=receptor-binding domain; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Extended Data Table 9. FLS IgG responses in PLWH, stratified by SARS-CoV-2 serostatus at baseline.

Arm	Measure	Day 0 (baseline)	
		SARS-CoV-2 seronegative	**SARS-CoV-2 seropositive**
Placebo	GMC, (95% CI), BAU/mL	1.2 (0.7–2.0); n=33	194.5 (130.1–290.9); n=17
	% seropositive	0 (0–10.4); 0/33	100 (81.6–100); 17/17
	% seroresponsive[†]	–	–
Vaccine	GMC, (95% CI), BAU/mL	1.3 (0.8–2.3); n=37	208.8 (111.9–389.8); n=15
	% seropositive	8.1 (2.8–21.3); 3/37	100 (79.6–100); 15/15
	% seroresponsive	–	–
		Day 28 (booster dose)	
		SARS-CoV-2 seronegative	**SARS-CoV-2 seropositive**
Placebo	GMC, (95% CI), BAU/mL	2.1 (1.1–4.2); n=33	220.6 (137.2–354.8); n=16
	% seropositive	9.1 (3.1–23.6); 3/33	100 (80.6–100); 16/16
	% seroresponsive	–	6.2 (1.1–28.3); 1/16
Vaccine	GMC, (95% CI), BAU/mL	163.7 (89.9–298.1); n=36	2942.2 (1803.1–4801.1); n=15
	% seropositive	86.1 (71.3–93.9); 31/36	100 (79.6–100); 15/15
	% seroresponsive	100 (43.9–100); 3/3	86.7 (62.1–96.3); 13/15
		Day 42 (14 days post booster)	
		SARS-CoV-2 seronegative	**SARS-CoV-2 seropositive**
Placebo	GMC, (95% CI), BAU/mL	1.9 (0.9–4.1); n=30	211.8 (129.7–345.9); n=16
	% seropositive	6.7 (1.8–21.3); 2/30	100 (80.6–100); 16/16
	% seroresponsive	0 (0–56.1); 0/3	0 (0–19.4); 0/16
Vaccine	GMC, (95% CI), BAU/mL	453.1 (267.4–767.7); n=32	3782.34 (2229.1–6417.9); n=15
	% seropositive	93.8 (79.9–98.3); 30/32	100 (79.6–100); 15/15
	% seroresponsive	63.0 (44.2–78.5); 17/27	20.0 (7.0–45.2); 3/15

[†]Samples considered seroresponsive if ≥2-fold increase.

BAU=binding antibody unit; CI=confidence interval; FLS=full-length spike GMC=geometric mean concentration; HIV=human immunodeficiency virus; IgG=immunoglobulin G; PLWH=people living with HIV; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Extended Data Table 10. RBD IgG responses in PLWH, stratified by SARS-CoV-2 serostatus at baseline.

Arm	Measure	Day 0 (baseline)	
		SARS-CoV-2 seronegative	**SARS-CoV-2 seropositive**
Placebo	GMC, (95% CI), BAU/mL	0.5 (0.3–0.9); n=33	162.3 (95.5–275.9); n=17
	% seropositive	0 (0–10.4); 0/33	100 (81.6–100); 17/17
Vaccine	GMC, (95% CI), BAU/mL	0.8 (0.5–1.3); n=37	136.4 (77.1–241.4); n=15
	% seropositive	0 (0–9.4); 0/37	100 (79.6–100); 15/15
		Day 28 (booster dose)	
		SARS-CoV-2 seronegative	**SARS-CoV-2 seropositive**
Placebo	GMC, (95% CI), BAU/mL	1.0 (0.5–2.1); n=33	188.4 (112.5–315.6); n=16
	% seropositive	9.1 (3.1–23.6); 3/33	100 (80.6–100); 16/16
	% seroresponsive[†]	–	6.2 (1.1–28.3); 1/16
Vaccine	GMC, (95% CI), BAU/mL	80.0 (40.3–158.8); n=36	2378.7 (1237.9–4571.0); n=15
	% seropositive	69.4 (53.1–82.0); 25/36	100 (79.6–100); 15/15
	% seroresponsive	–	93.3 (70.2–98.8); 14/15
		Day 42 (14 days post booster)	
		SARS-CoV-2 seronegative	**SARS-CoV-2 seropositive**
Placebo	GMC, (95% CI), BAU/mL	0.9 (0.4–2.1); n=30	166.8 (94.0–296.2); n=16
	% seropositive	6.7 (1.8–21.3); 2/30	93.8 (71.7–98.9); 15/16
	% seroresponsive	0 (0–56.1); 0/3	0 (0–19.4); 0/16
Vaccine	GMC, (95% CI), BAU/mL	347.8 (195.0–620.4); n=32	3183.2 (1628.6–6221.7); n=15
	% seropositive	87.5 (71.9–95.0); 28/32	100 (79.6–100); 15/15
	% seroresponsive	68.2 (47.3–83.6); 15/22	40.0 (19.8–64.3); 6/15

[†]Samples considered seroresponsive if $\geq$2-fold increase.

BAU=binding antibody unit; CI=confidence interval; GMC=geometric mean concentration; HIV=human immunodeficiency virus; IgG=immunoglobulin G; PLWH=people living with HIV; RBD=receptor-binding domain; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Extended Data Table 11. Neutralizing antibody responses in HIV-negative participants who were SARS-CoV-2 seronegative at baseline.

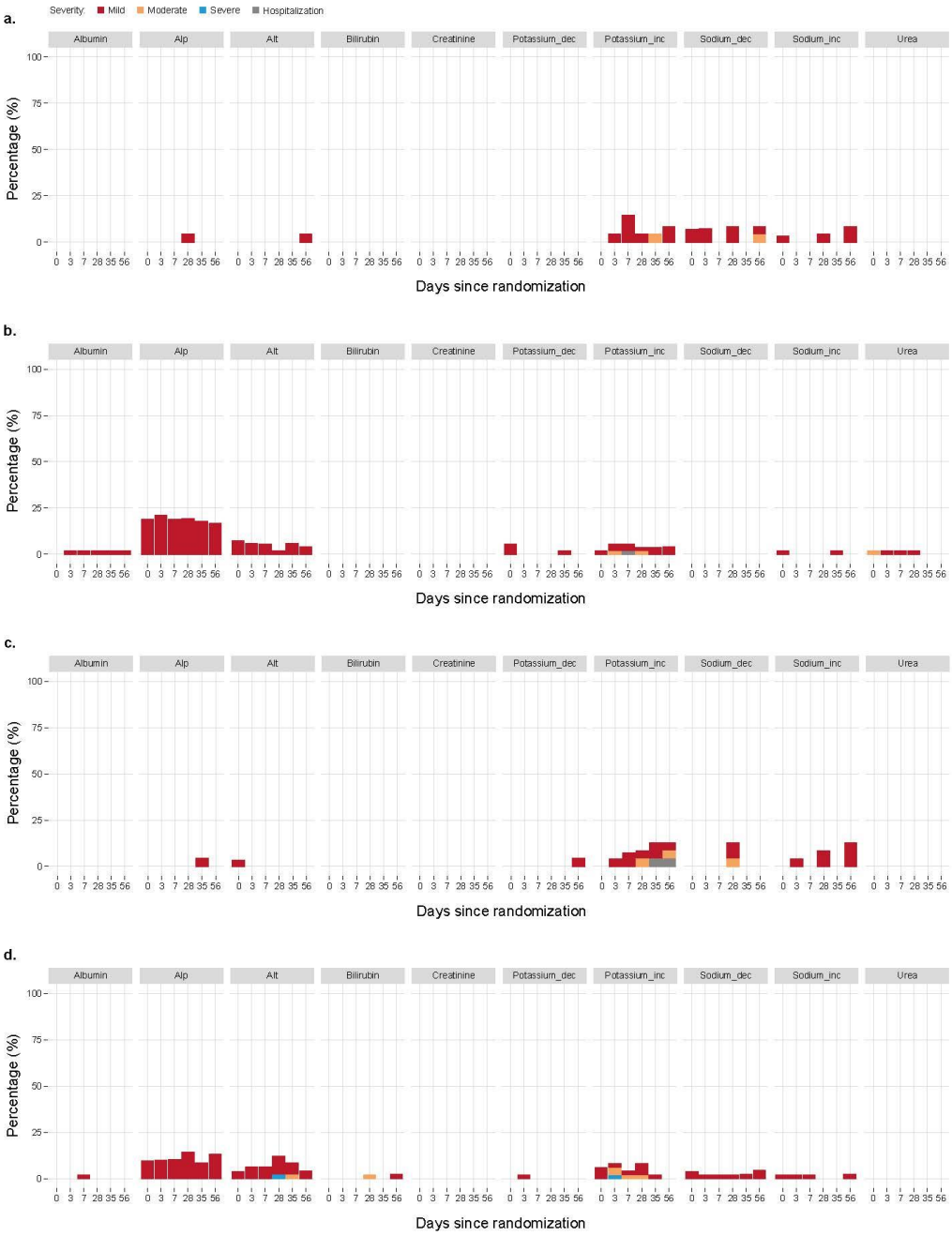
Arm	Measure	Day 0 (baseline)
Vaccine	GMT ID50, (95% CI)	31.2 (1.9–526.6); n=2
	% seropositive	8 (2.2–25); 2/25
	% seroresponsive[†]	–
	Measure	**Day 28 (booster dose)**
	GMT ID50, (95% CI)	135 (54.5–334.2); n=13
	% seropositive	59.1 (38.7–76.7); 13/22
	% seroresponsive	0 (0–65.8); 0/2
	Measure	**Day 42 (14 days post booster)**
	GMT ID50, (95% CI)	316.4 (184.8–541.8); n=20
	% seropositive	95.2 (77.3–99.2); 20/21
	% seroresponsive	50 (25.4–74.6); 6/12

GMT are only described for RBD-seropositive participants. Twenty-six samples were analyzed and one participant's result were unattainable at each time point due to background activity.

[†]Samples considered seroresponsive if $\geq$2-fold increase.

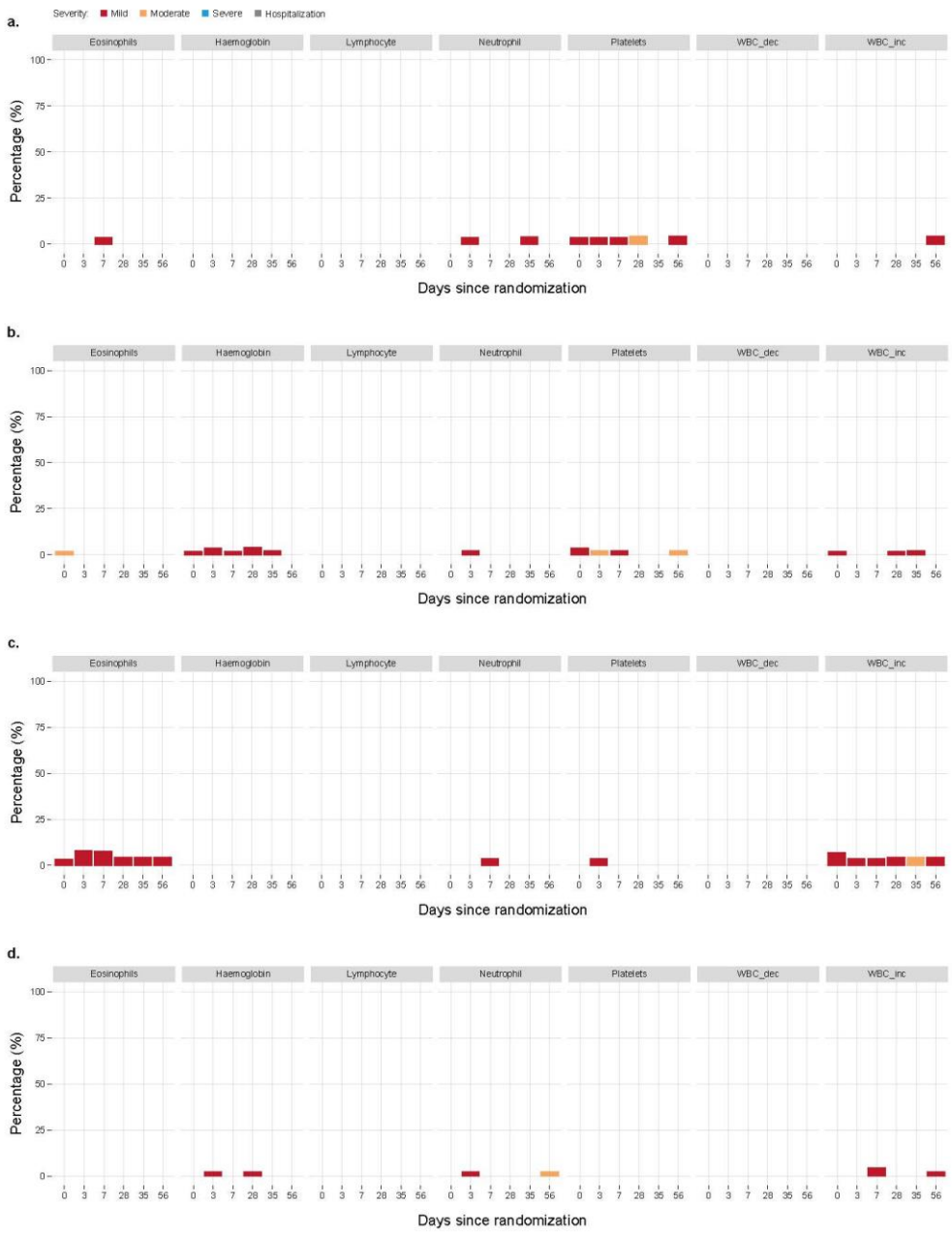
CI=confidence interval; GMT=geometric mean titre; HIV=human immunodeficiency virus; ID50=inhibitory dilution (50%); RBD= receptor-binding domain; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Extended Data Figure 1. Laboratory biochemistry abnormalities in a) HIV-negative participants who received the vaccine b) PLWH who received the vaccine c) HIV-negative participants who received placebo and d) PLWH who received placebo.



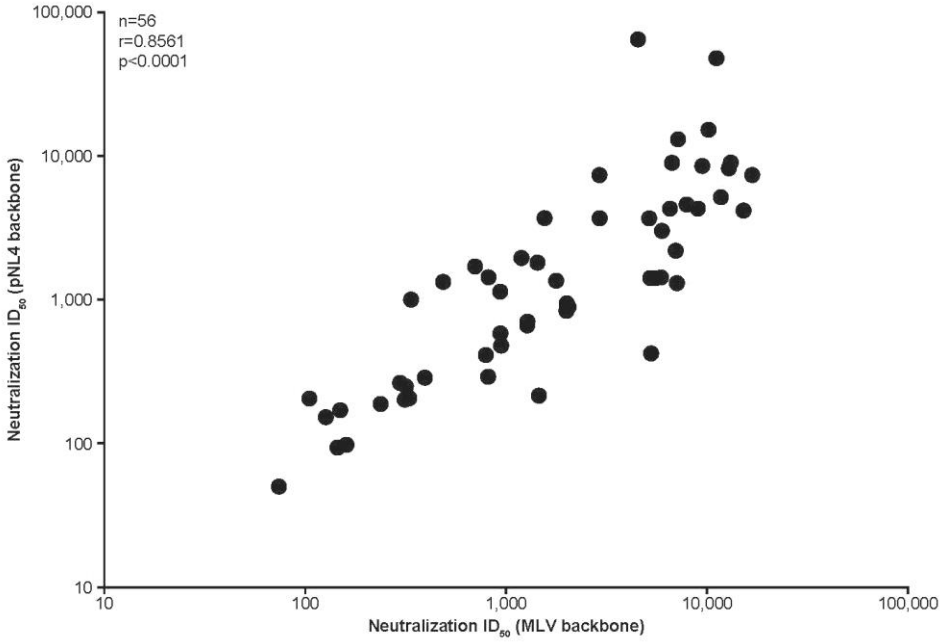
Alp=alkaline phosphatase; Alt, alanine aminotransferase; HIV=human immunodeficiency virus; PLWH=people living with HIV.

Extended Data Figure 2. Laboratory hematology abnormalities in a) HIV-negative participants who received the vaccine b) PLWH who received the vaccine c) HIV-negative participants who received placebo and d) PLWH who received placebo.



HIV=human immunodeficiency virus; PLWH=people living with HIV; WBC=white blood cell.

Extended Data Figure 3. Concordance of MLV backbone and pNL4 backbone neutralization assays.



The SARS-CoV-2 spike was used to generate pseudotyped particles in two different lentiviral backbones, pNL4 or MLV, and ID50 titers were compared head-to-head. The figure demonstrates high levels of concordance for 56 samples tested in the two different neutralization assays.
HIV=human immunodeficiency virus; ID50=inhibitory dilution (50%); MLV=murine leukaemia virus; pNL4=HIV vector pNL4; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.