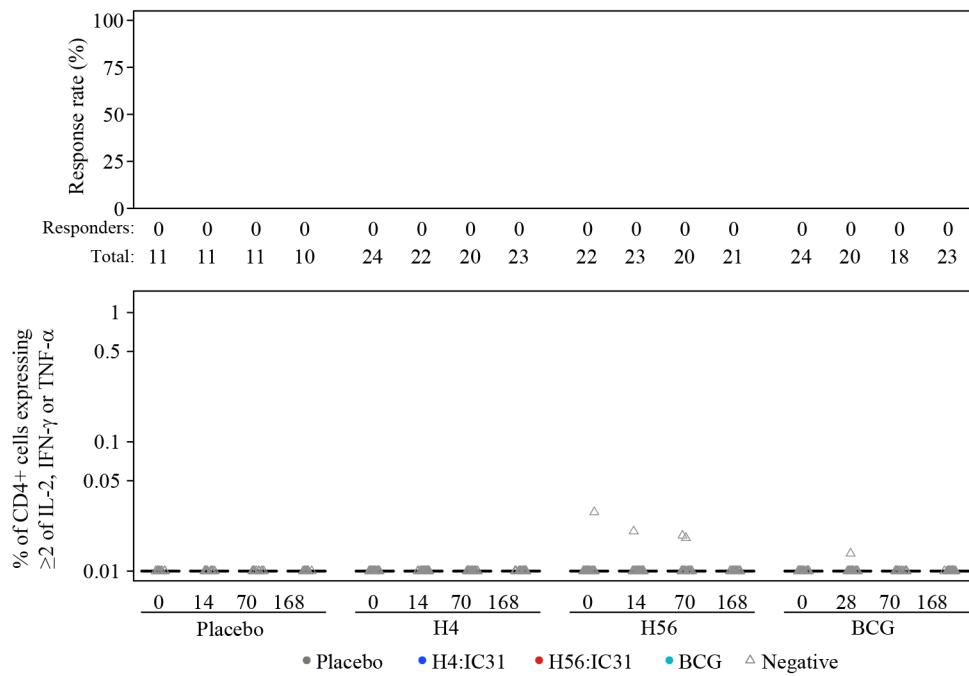


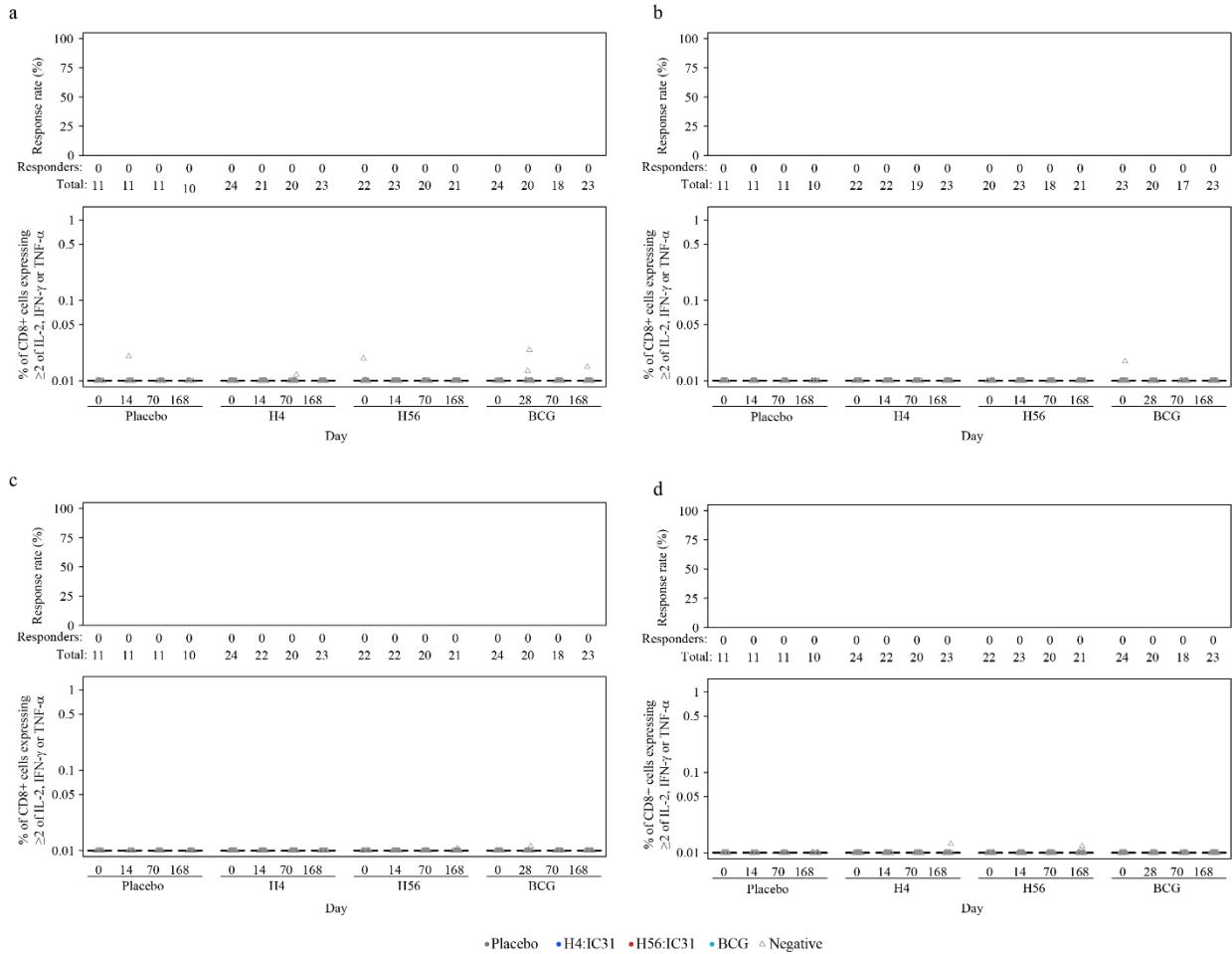
Supplemental Material

Supplemental figures

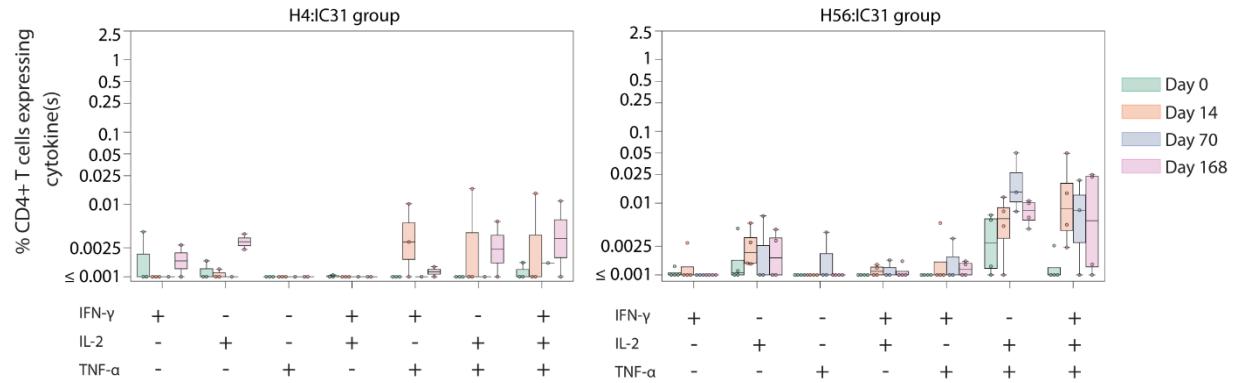
Supplemental tables



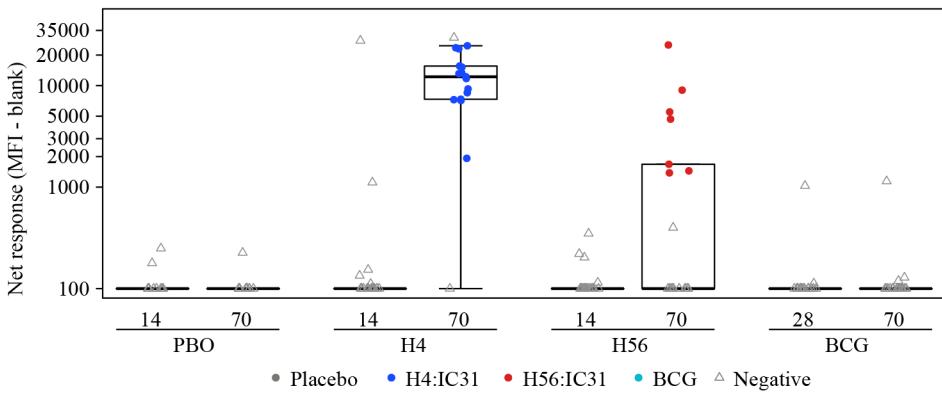
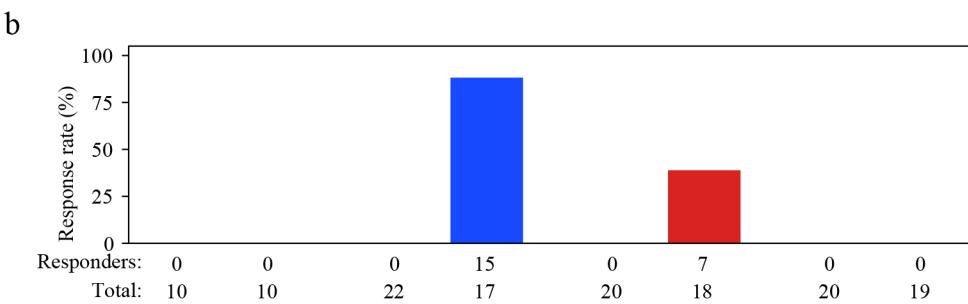
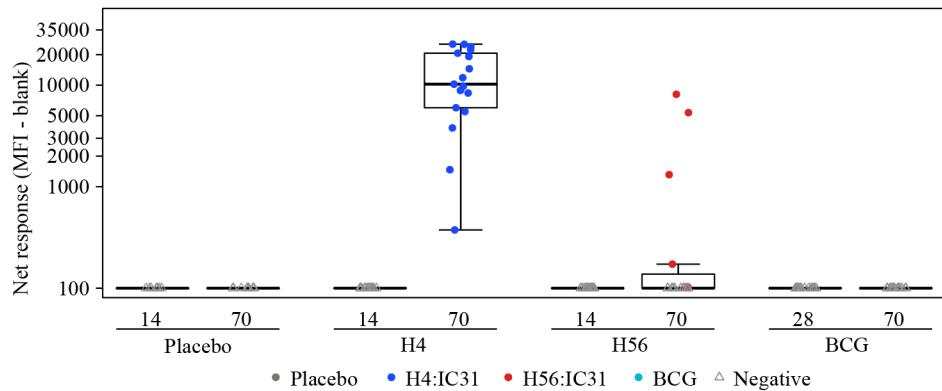
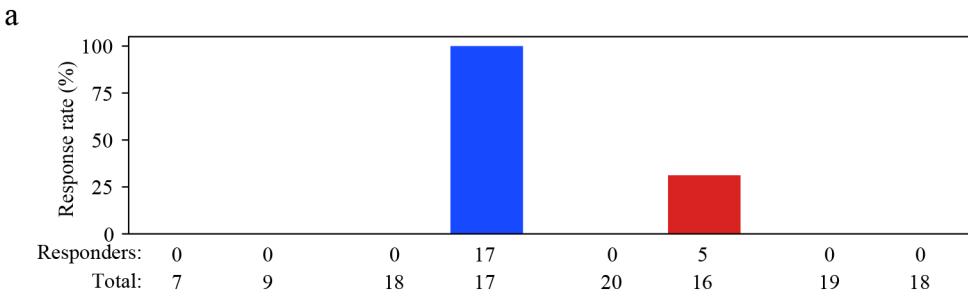
Supplemental Figure 1. Antigen-specific CD4+ T-cell responses after re-stimulation with vaccine-matched peptide pools. Frequency of CD4+ T cells expressing at least 2 of the cytokines IL-2, TNF- α and IFN- γ in response to Rv2660c at study days 0, 14/28, 70 and 168 after vaccination (day 28 for BCG group and day 14 for all other groups). Respective response rates are indicated above each box plot. Each box plot is based upon data from responders only and is superimposed on the distributions. The mid-line of the box denotes the median and the ends of the box denote the 25th and 75th percentiles. The whiskers that extend from the top and bottom of the box extend to the most extreme data points that are no more than 1.5 times the interquartile range. Comparisons to baseline of response rates were made using McNemar's test and magnitudes among responders with the Wilcoxon Signed rank test.



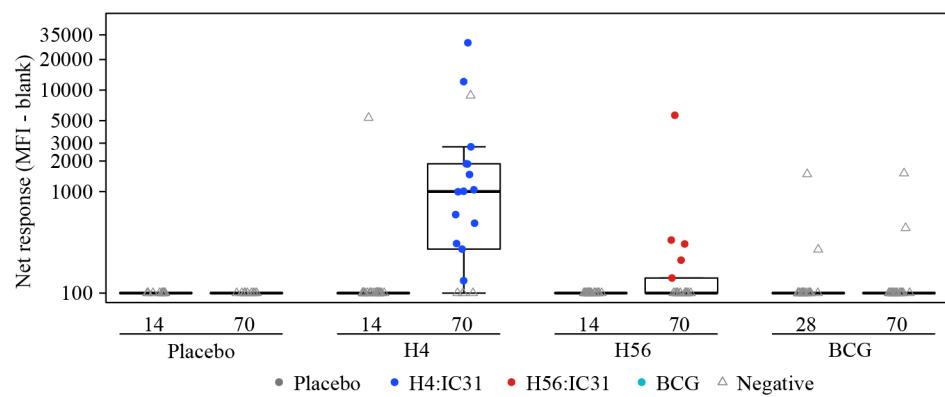
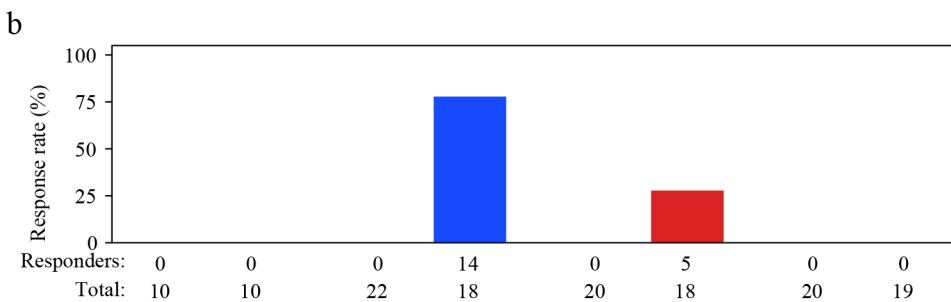
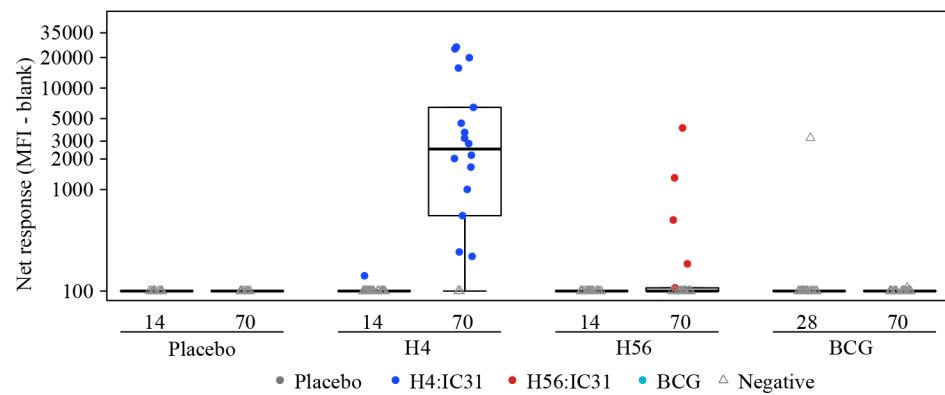
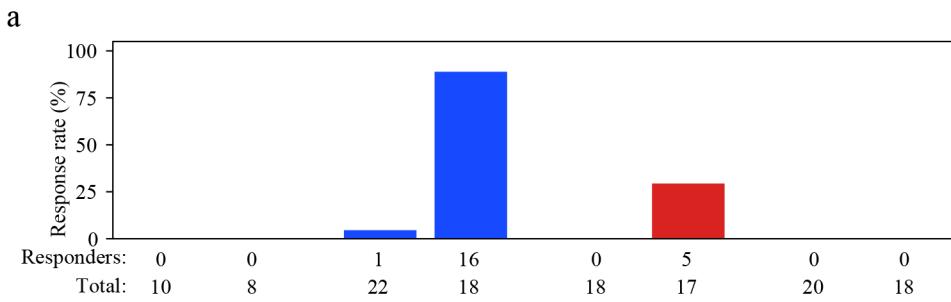
Supplemental Figure 2. Antigen-specific CD8+ T-cell responses in the H4:IC31, H56:IC31, BCG revaccinated and placebo groups. Frequency of CD8+ T cells expressing at least 2 of the cytokines IL-2, TNF- α and IFN- γ in response to (a) Ag85B, (b) TB10.4, (c) ESAT-6 or (d) Rv2660c at study days 0, 14/28, 70 and 168 after vaccination (day 28 for BCG group and day 14 for all other groups). Respective response rates are indicated above each box plot. Each box plot is based upon data from responders only and are superimposed on the distributions. The mid-line of the box denotes the median and the ends of the box denote the 25th and 75th percentiles. The whiskers that extend from the top and bottom of the box extend to the most extreme data points that are no more than 1.5 times the interquartile range.



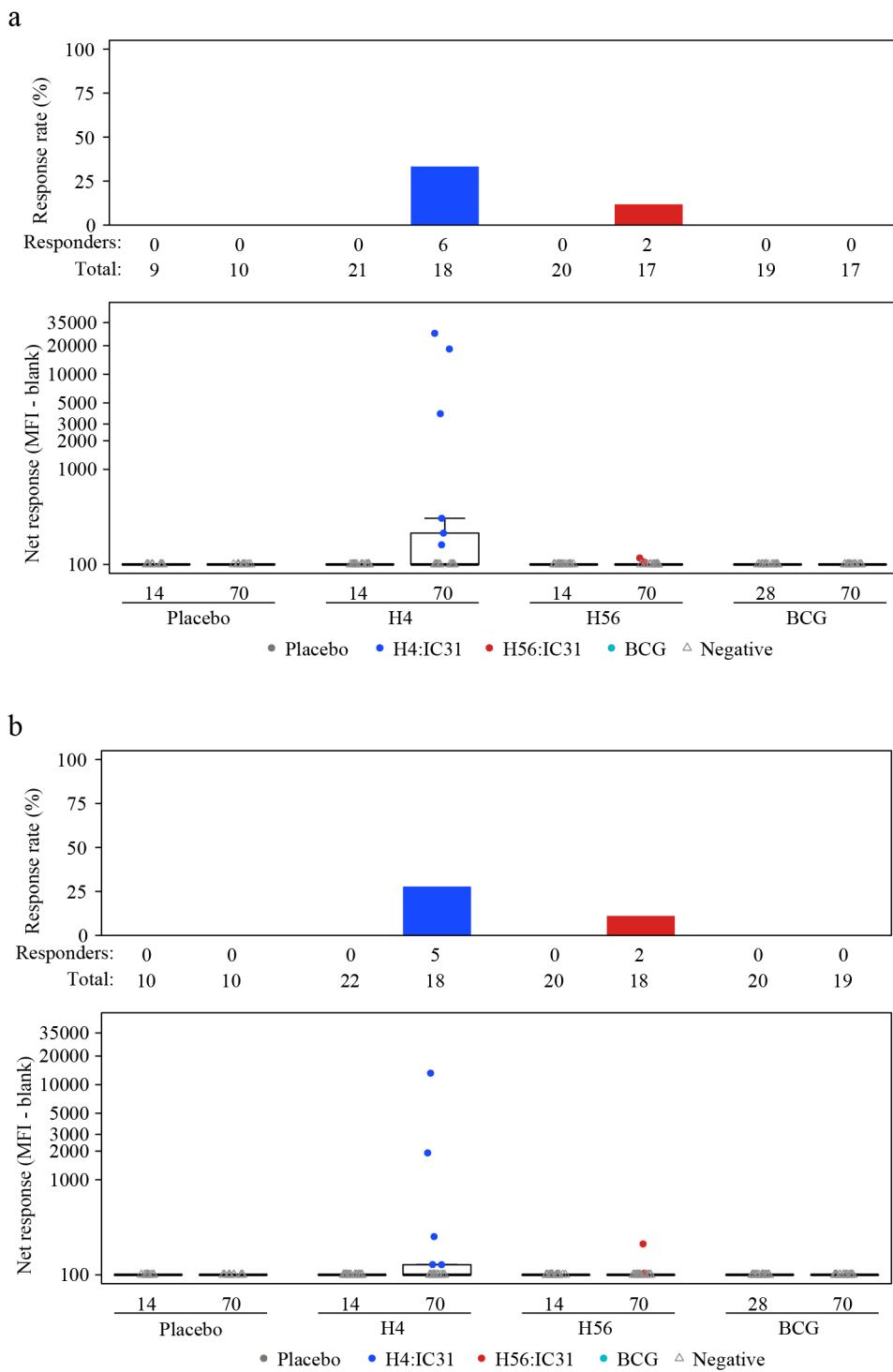
Supplemental Figure 3. Cytokine expression of stimulated CD4+ T cells. Boxplots show the median and interquartile (IQR) of the percentage of CD4+ T cells expressing the combination of cytokines indicated on the x-axis. The magnitude is background-subtracted. Panels show Ag85B-specific responses among H4:IC31 and H56:IC31 recipients. These data are only from the H4:IC31 (n=3) and H56:IC31 (n=5) group participants that received only the first of the two injections specified by the protocol.



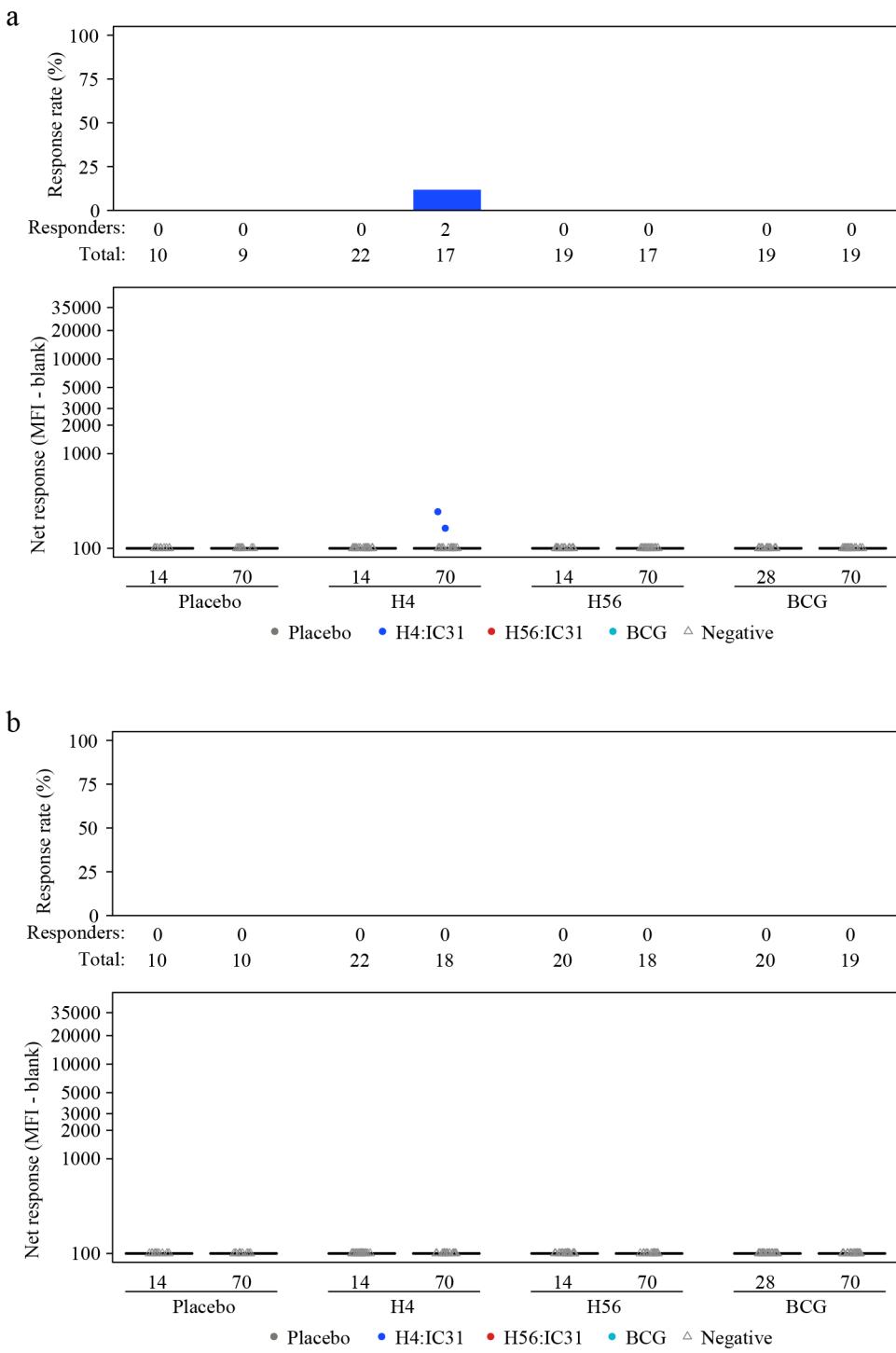
Supplemental Figure 4. H4- and H56-specific IgG1 binding antibody. Levels of binding antibody were measured using a binding antibody multiplex assay. Boxplots show the median and IQR of the net response on a log scale. Panels show response rates and net response magnitude to the H4 recombinant fusion protein (a) and the H56 recombinant fusion protein (b).



Supplemental Figure 5. H4- and H56-specific IgG3 binding antibody. Levels of binding antibody were measured using a binding antibody multiplex assay. Boxplots show the median and IQR of the net response on a log scale. Panels show response rates and net response magnitude to the H4 recombinant fusion protein (a) and the H56 recombinant fusion protein (b).



Supplemental Figure 6. H4- and H56-specific IgG4 binding antibody. Levels of binding antibody were measured using a binding antibody multiplex assay. Boxplots show the median and IQR of the net response on a log scale. Panels show response rates and net response magnitude to the H4 recombinant fusion protein (a) and the H56 recombinant fusion protein (b).



Supplemental Figure 7. H4- and H56-specific IgG2 binding antibody. Levels of binding antibody were measured using a binding antibody multiplex assay. Boxplots show the median and IQR of the net response on a log scale. Panels show response rates and net response magnitude to the H4 recombinant fusion protein (a) and the H56 recombinant fusion protein (b).

Supplemental Table 1. Overall incidence of related adverse events (solicited and unsolicited) by severity and dose at onset.

Variable	Placebo (N=12)	BCG (N=24)	H4:IC31 (N=24)	H56:IC31 (N=24)
Participants with at least 1 AE				
After any vaccination				
N1 ^a	12	24	24	24
Mild, n (%) ^b	4 (33·3)	15 (62·5)	14 (58·3)	7 (29·2)
Moderate, n (%) ^b	2 (16·7)	8 (33·3)	3 (12·5)	8 (33·3)
Severe, n (%) ^b	0	0	0	0
After study day 0 vaccination				
N1 ^a	12	24	24	24
Mild, n (%) ^b	5 (41·7)	15 (62·5)	13 (54·2)	8 (33·3)
Moderate, n (%) ^b	1 (8·3)	8 (33·3)	2 (8·3)	7 (29·2)
Severe, n (%) ^b	0	0	0	0
After study day 56 vaccination				
N1 ^a	11	NA	21	19
Mild, n (%) ^b	2 (18·2)	NA	7 (33·3)	6 (31·6)
Moderate, n (%) ^b	1 (9·1)	NA	1 (4·8)	1 (5·3)
Severe, n (%) ^b	0	NA	0	0

NA=not applicable

a. N1=Total number of participants within each treatment group in the Safety Analysis Set who received the applicable study vaccination.

b. Percentages based on N1.

Supplemental ICS Tables. Descriptive tables of the ICS data and longitudinal comparisons.

See following file.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
CH	CD4+	BCG-Pasteur	2_of_3_IFNg_IL2_TNF α	0	Placebo	4/11 = 36.4%	(15.2%, 64.6%)
					H4:IC31	5/23 = 21.7%	(9.7%, 41.9%)
					H56:IC31	7/22 = 31.8%	(16.4%, 52.7%)
					BCG	6/24 = 25.0%	(12.0%, 44.9%)
				14	Placebo	2/10 = 20.0%	(5.7%, 51.0%)
					H4:IC31	1/22 = 4.5%	(0.8%, 21.8%)
					H56:IC31	6/22 = 27.3%	(13.2%, 48.2%)
				28	BCG	10/20 = 50.0%	(29.9%, 70.1%)
				70	Placebo	2/11 = 18.2%	(5.1%, 47.7%)
					H4:IC31	4/20 = 20.0%	(8.1%, 41.6%)
					H56:IC31	10/20 = 50.0%	(29.9%, 70.1%)
					BCG	10/18 = 55.6%	(33.7%, 75.4%)
				168	Placebo	4/10 = 40.0%	(16.8%, 68.7%)
					H4:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					H56:IC31	7/20 = 35.0%	(18.1%, 56.7%)
					BCG	6/18 = 33.3%	(16.3%, 56.3%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
Ag85B	2_of_3_IFNg_IL2_TNFa			0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/24 = 0.0%	(0.0%, 13.8%)
					H56:IC31	1/22 = 4.5%	(0.8%, 21.8%)
					BCG	0/24 = 0.0%	(0.0%, 13.8%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	3/21 = 14.3%	(5.0%, 34.6%)
					H56:IC31	6/23 = 26.1%	(12.5%, 46.5%)
				28	BCG	0/20 = 0.0%	(0.0%, 16.1%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	12/20 = 60.0%	(38.7%, 78.1%)
					H56:IC31	13/20 = 65.0%	(43.3%, 81.9%)
					BCG	0/18 = 0.0%	(0.0%, 17.6%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	15/23 = 65.2%	(44.9%, 81.2%)
					H56:IC31	9/21 = 42.9%	(24.5%, 63.5%)
					BCG	2/23 = 8.7%	(2.4%, 26.8%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
		ESAT-6	2_of_3_IFNg_IL2_TNFa	0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/24 = 0.0%	(0.0%, 13.8%)
					H56:IC31	1/22 = 4.5%	(0.8%, 21.8%)
					BCG	0/24 = 0.0%	(0.0%, 13.8%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					H56:IC31	1/22 = 4.5%	(0.8%, 21.8%)
				28	BCG	0/20 = 0.0%	(0.0%, 16.1%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					H56:IC31	3/20 = 15.0%	(5.2%, 36.0%)
					BCG	0/18 = 0.0%	(0.0%, 17.6%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	1/23 = 4.3%	(0.8%, 21.0%)
					H56:IC31	2/21 = 9.5%	(2.7%, 28.9%)
					BCG	0/23 = 0.0%	(0.0%, 14.3%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
Rv2660c		2_of_3_IFNg_IL2_TNFa		0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/24 = 0.0%	(0.0%, 13.8%)
					H56:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					BCG	0/24 = 0.0%	(0.0%, 13.8%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					H56:IC31	0/23 = 0.0%	(0.0%, 14.3%)
				28	BCG	0/20 = 0.0%	(0.0%, 16.1%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					H56:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					BCG	0/18 = 0.0%	(0.0%, 17.6%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	0/23 = 0.0%	(0.0%, 14.3%)
					H56:IC31	0/21 = 0.0%	(0.0%, 15.5%)
					BCG	0/23 = 0.0%	(0.0%, 14.3%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
TB 10.4		2_of_3_IFNg_IL2_TNF α		0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					H56:IC31	5/20 = 25.0%	(11.2%, 46.9%)
					BCG	1/23 = 4.3%	(0.8%, 21.0%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	2/22 = 9.1%	(2.5%, 27.8%)
					H56:IC31	2/23 = 8.7%	(2.4%, 26.8%)
				28	BCG	4/20 = 20.0%	(8.1%, 41.6%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	7/19 = 36.8%	(19.1%, 59.0%)
					H56:IC31	3/18 = 16.7%	(5.8%, 39.2%)
					BCG	2/17 = 11.8%	(3.3%, 34.3%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	7/23 = 30.4%	(15.6%, 50.9%)
					H56:IC31	2/21 = 9.5%	(2.7%, 28.9%)
					BCG	4/23 = 17.4%	(7.0%, 37.1%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
CMV		2_of_3_IFNg_IL2_TNF α		0	Placebo	9/11 = 81.8%	(52.3%, 94.9%)
					H4:IC31	13/22 = 59.1%	(38.7%, 76.7%)
					H56:IC31	9/17 = 52.9%	(31.0%, 73.8%)
					BCG	17/21 = 81.0%	(60.0%, 92.3%)
				14	Placebo	6/10 = 60.0%	(31.3%, 83.2%)
					H4:IC31	15/20 = 75.0%	(53.1%, 88.8%)
					H56:IC31	13/22 = 59.1%	(38.7%, 76.7%)
				28	BCG	15/18 = 83.3%	(60.8%, 94.2%)
				70	Placebo	7/10 = 70.0%	(39.7%, 89.2%)
					H4:IC31	9/17 = 52.9%	(31.0%, 73.8%)
					H56:IC31	10/13 = 76.9%	(49.7%, 91.8%)
					BCG	14/16 = 87.5%	(64.0%, 96.5%)
				168	Placebo	7/ 9 = 77.8%	(45.3%, 93.7%)
					H4:IC31	13/16 = 81.3%	(57.0%, 93.4%)
					H56:IC31	9/12 = 75.0%	(46.8%, 91.1%)
					BCG	12/13 = 92.3%	(66.7%, 98.6%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
CD8+	BCG-Pasteur	2_of_3_IFNg_IL2_TNF α		0	Placebo	1/11 = 9.1%	(1.6%, 37.7%)
					H4:IC31	5/23 = 21.7%	(9.7%, 41.9%)
					H56:IC31	2/22 = 9.1%	(2.5%, 27.8%)
					BCG	5/24 = 20.8%	(9.2%, 40.5%)
				14	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	5/22 = 22.7%	(10.1%, 43.4%)
					H56:IC31	2/22 = 9.1%	(2.5%, 27.8%)
				28	BCG	2/20 = 10.0%	(2.8%, 30.1%)
				70	Placebo	1/11 = 9.1%	(1.6%, 37.7%)
					H4:IC31	6/20 = 30.0%	(14.5%, 51.9%)
					H56:IC31	1/20 = 5.0%	(0.9%, 23.6%)
					BCG	4/18 = 22.2%	(9.0%, 45.2%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	5/20 = 25.0%	(11.2%, 46.9%)
					H56:IC31	1/20 = 5.0%	(0.9%, 23.6%)
					BCG	0/18 = 0.0%	(0.0%, 17.6%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
Ag85B		2_of_3_IFNg_IL2_TNFa		0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/24 = 0.0%	(0.0%, 13.8%)
					H56:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					BCG	0/24 = 0.0%	(0.0%, 13.8%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/21 = 0.0%	(0.0%, 15.5%)
					H56:IC31	0/23 = 0.0%	(0.0%, 14.3%)
				28	BCG	0/20 = 0.0%	(0.0%, 16.1%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					H56:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					BCG	0/18 = 0.0%	(0.0%, 17.6%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	0/23 = 0.0%	(0.0%, 14.3%)
					H56:IC31	0/21 = 0.0%	(0.0%, 15.5%)
					BCG	0/23 = 0.0%	(0.0%, 14.3%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
ESAT-6	2_of_3_IFNg_IL2_TNFa			0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/24 = 0.0%	(0.0%, 13.8%)
					H56:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					BCG	0/24 = 0.0%	(0.0%, 13.8%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					H56:IC31	0/22 = 0.0%	(0.0%, 14.9%)
				28	BCG	0/20 = 0.0%	(0.0%, 16.1%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					H56:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					BCG	0/18 = 0.0%	(0.0%, 17.6%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	0/23 = 0.0%	(0.0%, 14.3%)
					H56:IC31	0/21 = 0.0%	(0.0%, 15.5%)
					BCG	0/23 = 0.0%	(0.0%, 14.3%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
Rv2660c	2_of_3_IFNg_IL2_TNFa			0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/24 = 0.0%	(0.0%, 13.8%)
					H56:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					BCG	0/24 = 0.0%	(0.0%, 13.8%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					H56:IC31	0/23 = 0.0%	(0.0%, 14.3%)
				28	BCG	0/20 = 0.0%	(0.0%, 16.1%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					H56:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					BCG	0/18 = 0.0%	(0.0%, 17.6%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	0/23 = 0.0%	(0.0%, 14.3%)
					H56:IC31	0/21 = 0.0%	(0.0%, 15.5%)
					BCG	0/23 = 0.0%	(0.0%, 14.3%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
TB	10.4	2_of_3_IFNg_IL2_TNFa		0	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					H56:IC31	0/20 = 0.0%	(0.0%, 16.1%)
					BCG	0/23 = 0.0%	(0.0%, 14.3%)
				14	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/22 = 0.0%	(0.0%, 14.9%)
					H56:IC31	0/23 = 0.0%	(0.0%, 14.3%)
				28	BCG	0/20 = 0.0%	(0.0%, 16.1%)
				70	Placebo	0/11 = 0.0%	(0.0%, 25.9%)
					H4:IC31	0/19 = 0.0%	(0.0%, 16.8%)
					H56:IC31	0/18 = 0.0%	(0.0%, 17.6%)
					BCG	0/17 = 0.0%	(0.0%, 18.4%)
				168	Placebo	0/10 = 0.0%	(0.0%, 27.8%)
					H4:IC31	0/23 = 0.0%	(0.0%, 14.3%)
					H56:IC31	0/21 = 0.0%	(0.0%, 15.5%)
					BCG	0/23 = 0.0%	(0.0%, 14.3%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

Lab PT Report

Data as of February 5, 2018

Table 1

ICS Response Rates Using MIMOSA

Lab	Tcell	Peptide Pool	Cytokine	Day	Group	Response Rate	95% CI
CMV		2_of_3_IFNg_IL2_TNFa		0	Placebo	9/11 = 81.8%	(52.3%, 94.9%)
					H4:IC31	19/22 = 86.4%	(66.7%, 95.3%)
					H56:IC31	17/17 = 100.0%	(81.6%, 100.0%)
					BCG	19/21 = 90.5%	(71.1%, 97.3%)
				14	Placebo	10/10 = 100.0%	(72.2%, 100.0%)
					H4:IC31	18/20 = 90.0%	(69.9%, 97.2%)
					H56:IC31	22/22 = 100.0%	(85.1%, 100.0%)
				28	BCG	17/18 = 94.4%	(74.2%, 99.0%)
				70	Placebo	10/10 = 100.0%	(72.2%, 100.0%)
					H4:IC31	15/17 = 88.2%	(65.7%, 96.7%)
					H56:IC31	12/13 = 92.3%	(66.7%, 98.6%)
					BCG	13/16 = 81.3%	(57.0%, 93.4%)
				168	Placebo	9/ 9 = 100.0%	(70.1%, 100.0%)
					H4:IC31	15/16 = 93.8%	(71.7%, 98.9%)
					H56:IC31	12/12 = 100.0%	(75.8%, 100.0%)
					BCG	12/13 = 92.3%	(66.7%, 98.6%)

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

95% confidence intervals are constructed using Wilson's score method.

HVTN 602 / AERAS A-042: A randomized, placebo-controlled, partially blinded phase 1b clinical trial to evaluate the safety and immunogenicity of BCG revaccination, H4:IC31, and H56:IC31 in healthy, HIV-1-uninfected adolescent participants

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
CH	CD4+	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0	Placebo	4/11 = 36.36%	4/11 = 36.36%	
					H4:IC31	5/23 = 21.74%	5/23 = 21.74%	
					H56:IC31	6/22 = 27.27%	7/22 = 31.82%	
					BCG	4/24 = 16.67%	6/24 = 25.00%	
				14	Placebo	2/10 = 20.00%	2/10 = 20.00%	0/10 = 0.00%
					H4:IC31	1/22 = 4.55%	1/22 = 4.55%	0/22 = 0.00%
					H56:IC31	6/22 = 27.27%	6/22 = 27.27%	2/22 = 9.09%
				28	BCG	10/20 = 50.00%	10/20 = 50.00%	7/20 = 35.00%
				70	Placebo	2/11 = 18.18%	2/11 = 18.18%	0/11 = 0.00%
					H4:IC31	3/20 = 15.00%	4/20 = 20.00%	0/20 = 0.00%
					H56:IC31	9/20 = 45.00%	10/20 = 50.00%	0/20 = 0.00%
					BCG	10/18 = 55.56%	10/18 = 55.56%	8/18 = 44.44%
				168	Placebo	3/10 = 30.00%	4/10 = 40.00%	0/10 = 0.00%
					H4:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					H56:IC31	6/20 = 30.00%	7/20 = 35.00%	2/20 = 10.00%
					BCG	6/18 = 33.33%	6/18 = 33.33%	4/18 = 22.22%
Ag85B		2_of_3_IFNg_IL2_TNFa		0	Placebo	0/11 = 0.00%	0/11 = 0.00%	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

HVTN 602 / AERAS A-042: A randomized, placebo-controlled, partially blinded phase 1b clinical trial to evaluate the safety and immunogenicity of BCG revaccination, H4:IC31, and H56:IC31 in healthy, HIV-1-uninfected adolescent participants

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
					H4:IC31	0/24 = 0.00%	0/24 = 0.00%	
					H56:IC31	1/22 = 4.55%	1/22 = 4.55%	
					BCG	0/24 = 0.00%	0/24 = 0.00%	
				14	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	3/21 = 14.29%	3/21 = 14.29%	2/21 = 9.52%
					H56:IC31	6/23 = 26.09%	6/23 = 26.09%	1/23 = 4.35%
				28	BCG	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	12/20 = 60.00%	12/20 = 60.00%	12/20 = 60.00%
					H56:IC31	13/20 = 65.00%	13/20 = 65.00%	10/20 = 50.00%
					BCG	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	16/23 = 69.57%	15/23 = 65.22%	13/23 = 56.52%
					H56:IC31	8/21 = 38.10%	9/21 = 42.86%	6/21 = 28.57%
					BCG	2/23 = 8.70%	2/23 = 8.70%	2/23 = 8.70%
ESAT-6	2_of_3_IFNg_IL2_TNFa	0	Placebo			0/11 = 0.00%	0/11 = 0.00%	
			H4:IC31			0/24 = 0.00%	0/24 = 0.00%	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
					H56:IC31	1/22 = 4.55%	1/22 = 4.55%	
					BCG	0/24 = 0.00%	0/24 = 0.00%	
				14	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/22 = 0.00%	0/22 = 0.00%	0/22 = 0.00%
					H56:IC31	1/22 = 4.55%	1/22 = 4.55%	1/22 = 4.55%
				28	BCG	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					H56:IC31	3/20 = 15.00%	3/20 = 15.00%	3/20 = 15.00%
					BCG	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	1/23 = 4.35%	1/23 = 4.35%	1/23 = 4.35%
					H56:IC31	2/21 = 9.52%	2/21 = 9.52%	2/21 = 9.52%
					BCG	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
Rv2660c	2_of_3_IFNg_IL2_TNF α	0	Placebo			0/11 = 0.00%	0/11 = 0.00%	
			H4:IC31			0/24 = 0.00%	0/24 = 0.00%	
			H56:IC31			0/22 = 0.00%	0/22 = 0.00%	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

HVTN 602 / AERAS A-042: A randomized, placebo-controlled, partially blinded phase 1b clinical trial to evaluate the safety and immunogenicity of BCG revaccination, H4:IC31, and H56:IC31 in healthy, HIV-1-uninfected adolescent participants

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
					BCG	0/24 = 0.00%	0/24 = 0.00%	
				14	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/22 = 0.00%	0/22 = 0.00%	0/22 = 0.00%
					H56:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
				28	BCG	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					H56:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					BCG	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	0/23 = 0.00%	0/23 = 0.00%	1/23 = 4.35%
					H56:IC31	0/21 = 0.00%	0/21 = 0.00%	0/21 = 0.00%
					BCG	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
TB 10.4	2_of_3_IFNg_IL2_TNF α	0	Placebo	0	Placebo	0/11 = 0.00%	0/11 = 0.00%	
					H4:IC31	0/22 = 0.00%	0/22 = 0.00%	
					H56:IC31	5/20 = 25.00%	5/20 = 25.00%	
					BCG	1/23 = 4.35%	1/23 = 4.35%	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
				14	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	2/22 = 9.09%	2/22 = 9.09%	1/22 = 4.55%
					H56:IC31	2/23 = 8.70%	2/23 = 8.70%	0/23 = 0.00%
				28	BCG	4/20 = 20.00%	4/20 = 20.00%	4/20 = 20.00%
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	7/19 = 36.84%	7/19 = 36.84%	7/19 = 36.84%
					H56:IC31	3/18 = 16.67%	3/18 = 16.67%	0/18 = 0.00%
					BCG	2/17 = 11.76%	2/17 = 11.76%	1/17 = 5.88%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	7/23 = 30.43%	7/23 = 30.43%	6/23 = 26.09%
					H56:IC31	3/21 = 14.29%	2/21 = 9.52%	0/21 = 0.00%
					BCG	4/23 = 17.39%	4/23 = 17.39%	2/23 = 8.70%
CMV	2_of_3_IFNg_IL2_TNF α	0		Placebo	8/11 = 72.73%	9/11 = 81.82%		
				H4:IC31	12/22 = 54.55%	13/22 = 59.09%		
				H56:IC31	9/17 = 52.94%	9/17 = 52.94%		
				BCG	16/21 = 76.19%	17/21 = 80.95%		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

HVTN 602 / AERAS A-042: A randomized, placebo-controlled, partially blinded phase 1b clinical trial to evaluate the safety and immunogenicity of BCG revaccination, H4:IC31, and H56:IC31 in healthy, HIV-1-uninfected adolescent participants

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
				14	Placebo	5/10 = 50.00%	6/10 = 60.00%	0/10 = 0.00%
					H4:IC31	12/20 = 60.00%	15/20 = 75.00%	2/20 = 10.00%
					H56:IC31	13/22 = 59.09%	13/22 = 59.09%	2/22 = 9.09%
				28	BCG	11/18 = 61.11%	15/18 = 83.33%	4/18 = 22.22%
				70	Placebo	7/10 = 70.00%	7/10 = 70.00%	1/10 = 10.00%
					H4:IC31	7/17 = 41.18%	9/17 = 52.94%	1/17 = 5.88%
					H56:IC31	9/13 = 69.23%	10/13 = 76.92%	1/13 = 7.69%
					BCG	13/16 = 81.25%	14/16 = 87.50%	3/16 = 18.75%
				168	Placebo	6/ 9 = 66.67%	7/ 9 = 77.78%	1/ 9 = 11.11%
					H4:IC31	10/16 = 62.50%	13/16 = 81.25%	4/16 = 25.00%
					H56:IC31	8/12 = 66.67%	9/12 = 75.00%	0/12 = 0.00%
					BCG	12/13 = 92.31%	12/13 = 92.31%	3/13 = 23.08%
CD8+	BCG-Pasteur	2_of_3_IFNg_IL2_TNF α		0	Placebo	1/11 = 9.09%	1/11 = 9.09%	
					H4:IC31	3/23 = 13.04%	5/23 = 21.74%	
					H56:IC31	1/22 = 4.55%	2/22 = 9.09%	
					BCG	5/24 = 20.83%	5/24 = 20.83%	
				14	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
					H4:IC31	4/22 = 18.18%	5/22 = 22.73%	0/22 = 0.00%
					H56:IC31	2/22 = 9.09%	2/22 = 9.09%	0/22 = 0.00%
				28	BCG	2/20 = 10.00%	2/20 = 10.00%	1/20 = 5.00%
				70	Placebo	1/11 = 9.09%	1/11 = 9.09%	0/11 = 0.00%
					H4:IC31	3/20 = 15.00%	6/20 = 30.00%	0/20 = 0.00%
					H56:IC31	1/20 = 5.00%	1/20 = 5.00%	0/20 = 0.00%
					BCG	4/18 = 22.22%	4/18 = 22.22%	0/18 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	3/20 = 15.00%	5/20 = 25.00%	1/20 = 5.00%
					H56:IC31	1/20 = 5.00%	1/20 = 5.00%	0/20 = 0.00%
					BCG	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
Ag85B	2_of_3_IFNg_IL2_TNFa	0	Placebo			0/11 = 0.00%	0/11 = 0.00%	
			H4:IC31			0/24 = 0.00%	0/24 = 0.00%	
			H56:IC31			0/22 = 0.00%	0/22 = 0.00%	
			BCG			0/24 = 0.00%	0/24 = 0.00%	
			14	Placebo		0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
				H4:IC31		0/21 = 0.00%	0/21 = 0.00%	0/21 = 0.00%

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
					H56:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
				28	BCG	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					H56:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					BCG	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
					H56:IC31	0/21 = 0.00%	0/21 = 0.00%	0/21 = 0.00%
					BCG	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
ESAT-6	2_of_3_IFNg_IL2_TNF α	0	Placebo			0/11 = 0.00%	0/11 = 0.00%	
			H4:IC31			0/24 = 0.00%	0/24 = 0.00%	
			H56:IC31			0/22 = 0.00%	0/22 = 0.00%	
			BCG			0/24 = 0.00%	0/24 = 0.00%	
			14	Placebo		0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
				H4:IC31		0/22 = 0.00%	0/22 = 0.00%	0/22 = 0.00%
				H56:IC31		0/22 = 0.00%	0/22 = 0.00%	0/22 = 0.00%

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
				28	BCG	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					H56:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					BCG	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
					H56:IC31	0/21 = 0.00%	0/21 = 0.00%	0/21 = 0.00%
					BCG	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
Rv2660c	2_of_3_IFNg_IL2_TNF α	0	Placebo			0/11 = 0.00%	0/11 = 0.00%	
					H4:IC31	0/24 = 0.00%	0/24 = 0.00%	
					H56:IC31	0/22 = 0.00%	0/22 = 0.00%	
					BCG	0/24 = 0.00%	0/24 = 0.00%	
				14	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/22 = 0.00%	0/22 = 0.00%	0/22 = 0.00%
					H56:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
				28	BCG	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					H56:IC31	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%
					BCG	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
					H56:IC31	0/21 = 0.00%	0/21 = 0.00%	0/21 = 0.00%
					BCG	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
	TB 10.4	2_of_3_IFNg_IL2_TNF α		0	Placebo	0/11 = 0.00%	0/11 = 0.00%	
					H4:IC31	0/22 = 0.00%	0/22 = 0.00%	
					H56:IC31	0/20 = 0.00%	0/20 = 0.00%	
					BCG	0/23 = 0.00%	0/23 = 0.00%	
				14	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/22 = 0.00%	0/22 = 0.00%	0/22 = 0.00%
					H56:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
				28	BCG	0/20 = 0.00%	0/20 = 0.00%	0/20 = 0.00%

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
				70	Placebo	0/11 = 0.00%	0/11 = 0.00%	0/11 = 0.00%
					H4:IC31	0/19 = 0.00%	0/19 = 0.00%	0/19 = 0.00%
					H56:IC31	0/18 = 0.00%	0/18 = 0.00%	0/18 = 0.00%
					BCG	0/17 = 0.00%	0/17 = 0.00%	0/17 = 0.00%
				168	Placebo	0/10 = 0.00%	0/10 = 0.00%	0/10 = 0.00%
					H4:IC31	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
					H56:IC31	0/21 = 0.00%	0/21 = 0.00%	0/21 = 0.00%
					BCG	0/23 = 0.00%	0/23 = 0.00%	0/23 = 0.00%
CMV	2_of_3_IFNg_IL2_TNFa	0	Placebo			9/11 = 81.82%	9/11 = 81.82%	
			H4:IC31			18/22 = 81.82%	19/22 = 86.36%	
			H56:IC31			15/17 = 88.24%	17/17 = 100.0%	
			BCG			18/21 = 85.71%	19/21 = 90.48%	
				14	Placebo	10/10 = 100.0%	10/10 = 100.0%	5/10 = 50.00%
					H4:IC31	16/20 = 80.00%	18/20 = 90.00%	5/20 = 25.00%
					H56:IC31	22/22 = 100.0%	22/22 = 100.0%	2/22 = 9.09%
				28	BCG	16/18 = 88.89%	17/18 = 94.44%	2/18 = 11.11%

Unreliable samples are excluded.

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HVTN 602 / AERAS A-042: A randomized, placebo-controlled, partially blinded phase 1b clinical trial to evaluate the safety and immunogenicity of BCG revaccination, H4:IC31, and H56:IC31 in healthy, HIV-1-uninfected adolescent participants

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Table 2

Response Rates by Fisher's Exact Test, MIMOSA, and MIMOSA2

Lab	Tcell	Peptide	Cytokine	Day	Group	Fisher	MIMOSA	MIMOSA2
	70	Placebo		10/10 = 100.0%	10/10 = 100.0%	2/10 = 20.00%		
		H4:IC31		13/17 = 76.47%	15/17 = 88.24%	2/17 = 11.76%		
		H56:IC31		12/13 = 92.31%	12/13 = 92.31%	1/13 = 7.69%		
		BCG		13/16 = 81.25%	13/16 = 81.25%	2/16 = 12.50%		
	168	Placebo		9/ 9 = 100.0%	9/ 9 = 100.0%	5/ 9 = 55.56%		
		H4:IC31		15/16 = 93.75%	15/16 = 93.75%	4/16 = 25.00%		
		H56:IC31		12/12 = 100.0%	12/12 = 100.0%	1/12 = 8.33%		
		BCG		10/13 = 76.92%	12/13 = 92.31%	2/13 = 15.38%		

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Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
CH	CD4+	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0	Placebo	11	-0.008	0.214	0.041	0.029
					H4:IC31	23	-0.060	0.111	0.014	0.011
					H56:IC31	22	-0.071	0.399	0.055	0.010
					BCG	24	-0.062	0.144	0.024	0.008
				14	Placebo	10	-0.008	0.088	0.024	0.021
					H4:IC31	22	-0.041	0.063	0.009	0.005
					H56:IC31	22	-0.037	0.315	0.045	0.025
				28	BCG	20	-0.056	0.482	0.085	0.043
				70	Placebo	11	-0.020	0.074	0.018	0.014
					H4:IC31	20	-0.047	0.077	0.016	0.017
					H56:IC31	20	-0.007	0.367	0.070	0.045
					BCG	18	-0.037	0.508	0.107	0.041
				168	Placebo	10	-0.070	0.062	0.024	0.034
					H4:IC31	20	-0.009	0.046	0.016	0.014
					H56:IC31	20	-0.030	0.184	0.048	0.030
					BCG	18	-0.039	0.652	0.099	0.043
Ag85B		2_of_3_IFNg_IL2_TNFa		0	Placebo	11	-0.028	0.010	-0.007	-0.006

Unreliable samples are excluded.

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
					H4:IC31	24	-0.036	0.033	-0.006	-0.006
					H56:IC31	22	-0.048	0.060	-0.004	-0.002
					BCG	24	-0.072	0.013	-0.011	-0.004
				14	Placebo	11	-0.053	0.017	-0.007	-0.005
					H4:IC31	21	-0.023	0.068	0.015	0.007
					H56:IC31	23	-0.035	0.164	0.030	0.015
				28	BCG	20	-0.043	0.036	-0.003	-0.004
				70	Placebo	11	-0.075	0.007	-0.010	-0.002
					H4:IC31	20	-0.011	0.430	0.124	0.064
					H56:IC31	20	0.001	0.511	0.118	0.077
					BCG	18	-0.072	0.026	-0.005	-0.001
				168	Placebo	10	-0.022	0.009	-0.004	-0.002
					H4:IC31	23	-0.008	0.355	0.083	0.071
					H56:IC31	21	0.008	0.321	0.064	0.034
					BCG	23	-0.047	0.124	0.003	-0.005
ESAT-6	2_of_3_IFNg_IL2_TNF α	0	Placebo	11	-0.033	0.011	-0.009	-0.006		
			H4:IC31	24	-0.128	0.001	-0.017	-0.010		

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
					H56:IC31	22	-0.077	0.034	-0.012	-0.008
					BCG	24	-0.100	0.007	-0.018	-0.008
				14	Placebo	11	-0.041	0.001	-0.010	-0.002
					H4:IC31	22	-0.045	0.004	-0.018	-0.018
					H56:IC31	22	-0.060	0.087	-0.001	0.001
				28	BCG	20	-0.063	0.008	-0.014	-0.006
				70	Placebo	11	-0.088	0.011	-0.013	-0.003
					H4:IC31	20	-0.067	0.029	-0.014	-0.012
					H56:IC31	20	-0.029	0.086	0.025	0.016
					BCG	18	-0.057	0.013	-0.012	-0.007
				168	Placebo	10	-0.050	0.006	-0.007	-0.002
					H4:IC31	23	-0.048	0.068	-0.008	-0.008
					H56:IC31	21	-0.030	0.079	0.006	0.001
					BCG	23	-0.060	0.006	-0.012	-0.009
Rv2660c	2_of_3_IFNg_IL2_TNFa	0	Placebo	11	-0.039	0.007	-0.015	-0.016		
			H4:IC31	24	-0.121	0.004	-0.015	-0.008		
			H56:IC31	22	-0.065	0.029	-0.015	-0.012		

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
					BCG	24	-0.098	0.005	-0.021	-0.007
				14	Placebo	11	-0.052	0.006	-0.010	-0.007
					H4:IC31	22	-0.061	0.004	-0.019	-0.014
					H56:IC31	23	-0.126	0.020	-0.018	-0.008
				28	BCG	20	-0.069	0.014	-0.015	-0.007
				70	Placebo	11	-0.068	0.003	-0.012	-0.002
					H4:IC31	20	-0.046	0.008	-0.016	-0.013
					H56:IC31	20	-0.048	0.019	-0.003	0.001
					BCG	18	-0.059	0.008	-0.014	-0.010
				168	Placebo	10	-0.028	0.001	-0.007	-0.006
					H4:IC31	23	-0.041	0.009	-0.010	-0.007
					H56:IC31	21	-0.061	0.005	-0.011	-0.008
					BCG	23	-0.057	0.003	-0.017	-0.016
TB 10.4	2_of_3_IFNg_IL2_TNF α	0	Placebo	11	-0.032	0.038	0.002	0.002		
			H4:IC31	22	-0.153	0.006	-0.015	-0.007		
			H56:IC31	20	-0.064	0.170	0.012	-0.002		
			BCG	23	-0.096	0.129	-0.009	-0.005		

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Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
				14	Placebo	11	-0.052	0.016	-0.006	-0.005
					H4:IC31	22	-0.035	0.078	0.002	-0.002
					H56:IC31	23	-0.108	0.194	0.004	0.004
				28	BCG	20	-0.049	0.240	0.033	0.016
				70	Placebo	11	-0.045	0.043	-0.003	-0.004
					H4:IC31	19	-0.048	0.184	0.057	0.035
					H56:IC31	18	-0.022	0.068	0.013	0.003
					BCG	17	-0.046	0.183	0.023	0.015
				168	Placebo	10	-0.040	0.031	-0.001	-0.001
					H4:IC31	23	-0.047	0.240	0.040	0.023
					H56:IC31	21	-0.039	0.164	0.013	0.002
					BCG	23	-0.033	0.182	0.020	0.003
CMV		2_of_3_IFNg_IL2_TNF α	0	Placebo	11	0.022	0.786	0.191	0.127	
					H4:IC31	22	-0.080	0.506	0.075	0.049
					H56:IC31	17	0.007	0.357	0.096	0.051
					BCG	21	-0.006	3.595	0.369	0.126

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
				14	Placebo	10	0.010	0.511	0.119	0.094
					H4:IC31	20	-0.018	0.719	0.142	0.080
					H56:IC31	22	-0.050	0.401	0.095	0.077
				28	BCG	18	0.008	5.139	0.444	0.073
				70	Placebo	10	0.023	0.463	0.174	0.106
					H4:IC31	17	-0.011	0.492	0.082	0.048
					H56:IC31	13	0.020	0.441	0.113	0.055
					BCG	16	-0.004	1.493	0.244	0.097
				168	Placebo	9	0.025	0.884	0.206	0.078
					H4:IC31	16	0.011	0.710	0.166	0.097
					H56:IC31	12	0.013	0.689	0.151	0.074
					BCG	13	0.038	0.552	0.201	0.149
CD8+	BCG-Pasteur	2_of_3_IFNg_IL2_TNF α	0	Placebo	11	-0.007	0.033	0.010	0.009	
					H4:IC31	23	-0.048	0.056	0.013	0.010
					H56:IC31	22	-0.019	0.138	0.012	0.007
					BCG	24	-0.024	0.134	0.016	0.002
				14	Placebo	10	-0.004	0.004	0.001	0.002

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
					H4:IC31	22	-0.005	0.128	0.022	0.003
					H56:IC31	22	-0.006	0.108	0.011	0.004
				28	BCG	20	-0.014	0.063	0.014	0.012
				70	Placebo	11	-0.004	0.029	0.008	0.006
					H4:IC31	20	-0.009	0.084	0.018	0.009
					H56:IC31	20	-0.034	0.116	0.010	0.004
					BCG	18	-0.002	0.070	0.017	0.012
				168	Placebo	10	-0.007	0.008	0.000	0.000
					H4:IC31	20	-0.007	0.073	0.019	0.009
					H56:IC31	20	-0.008	0.058	0.008	0.005
					BCG	18	-0.014	0.042	0.007	0.002
Ag85B	2_of_3_IFNg_IL2_TNFa	0	Placebo			11	-0.003	0.009	0.001	0.000
			H4:IC31			24	-0.035	0.007	-0.002	0.000
			H56:IC31			22	-0.012	0.019	-0.002	-0.003
			BCG			24	-0.012	0.008	-0.003	-0.003
			14	Placebo		11	-0.007	0.020	0.001	0.001
				H4:IC31		21	-0.010	0.007	-0.001	-0.000

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
					H56:IC31	23	-0.023	0.009	-0.000	0.000
				28	BCG	20	-0.008	0.024	0.001	-0.000
				70	Placebo	11	-0.005	0.004	-0.000	0.000
					H4:IC31	20	-0.010	0.012	-0.001	-0.001
					H56:IC31	20	-0.016	0.007	-0.002	-0.001
					BCG	18	-0.007	0.003	-0.001	0.000
				168	Placebo	10	-0.006	0.003	-0.000	0.000
					H4:IC31	23	-0.042	0.006	-0.003	-0.000
					H56:IC31	21	-0.008	0.008	0.000	0.000
					BCG	23	-0.011	0.015	-0.001	-0.001
ESAT-6	2_of_3_IFNg_IL2_TNF α	0	Placebo			11	-0.004	0.003	0.000	-0.000
					H4:IC31	24	-0.047	0.006	-0.003	-0.001
					H56:IC31	22	-0.019	0.005	-0.003	-0.001
					BCG	24	-0.021	0.001	-0.004	-0.003
				14	Placebo	11	-0.006	0.007	-0.001	-0.000
					H4:IC31	22	-0.007	0.003	-0.002	-0.002
					H56:IC31	22	-0.031	0.006	-0.002	-0.000

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
				28	BCG	20	-0.012	0.011	-0.000	-0.000
				70	Placebo	11	-0.005	0.006	0.001	0.001
					H4:IC31	20	-0.005	0.006	-0.001	-0.002
					H56:IC31	20	-0.037	0.003	-0.004	-0.000
					BCG	18	-0.011	0.008	-0.001	-0.001
				168	Placebo	10	-0.003	0.003	0.000	0.000
					H4:IC31	23	-0.095	0.005	-0.006	-0.002
					H56:IC31	21	-0.008	0.011	0.001	0.000
					BCG	23	-0.017	0.008	-0.001	-0.000
Rv2660c	2_of_3_IFNg_IL2_TNFa	0	Placebo	11	-0.008	0.004	-0.002	-0.000		
			H4:IC31	24	-0.055	0.007	-0.004	-0.001		
			H56:IC31	22	-0.015	0.005	-0.002	-0.001		
			BCG	24	-0.017	0.003	-0.004	-0.003		
			14	Placebo	11	-0.007	0.008	-0.001	0.000	
				H4:IC31	22	-0.009	0.003	-0.003	-0.003	
				H56:IC31	23	-0.031	0.008	-0.003	-0.000	

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Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
				28	BCG	20	-0.011	0.008	-0.000	-0.000
				70	Placebo	11	-0.005	0.007	-0.000	-0.001
					H4:IC31	20	-0.011	0.003	-0.002	-0.000
					H56:IC31	20	-0.013	0.003	-0.002	-0.001
					BCG	18	-0.011	0.006	-0.001	0.000
				168	Placebo	10	-0.004	0.005	0.000	0.000
					H4:IC31	23	-0.064	0.013	-0.003	-0.000
					H56:IC31	21	-0.008	0.012	-0.000	0.000
					BCG	23	-0.009	0.006	-0.001	-0.000
	TB 10.4	2_of_3_IFNg_IL2_TNF α		0	Placebo	11	-0.010	0.004	-0.001	0.000
					H4:IC31	22	-0.060	0.004	-0.005	-0.002
					H56:IC31	20	-0.019	0.007	-0.003	-0.002
					BCG	23	-0.016	0.017	-0.003	-0.002
				14	Placebo	11	-0.006	0.007	-0.002	-0.003
					H4:IC31	22	-0.010	0.005	-0.002	-0.001
					H56:IC31	23	-0.031	0.004	-0.003	-0.000
				28	BCG	20	-0.012	0.007	-0.001	-0.000

Unreliable samples are excluded.

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
				70	Placebo	11	-0.005	0.003	-0.002	-0.001
					H4:IC31	19	-0.012	0.008	-0.003	-0.003
					H56:IC31	18	-0.018	0.001	-0.003	-0.000
					BCG	17	-0.008	0.005	-0.001	-0.001
				168	Placebo	10	-0.006	0.004	-0.000	0.000
					H4:IC31	23	-0.072	0.008	-0.004	-0.001
					H56:IC31	21	-0.008	0.009	-0.000	0.000
					BCG	23	-0.014	0.010	-0.001	0.000
CMV	2_of_3_IFNg_IL2_TNFa	0	Placebo	11	-0.000	3.996	1.567	1.364		
			H4:IC31	22	-0.005	2.503	0.596	0.344		
			H56:IC31	17	0.050	2.498	0.875	0.624		
			BCG	21	-0.007	4.488	1.390	0.953		
			Placebo	10	0.036	3.490	1.561	1.199		
			H4:IC31	20	0.006	2.583	0.670	0.405		
			H56:IC31	22	0.091	3.729	1.271	0.812		
			BCG	18	0.013	3.394	1.001	0.806		

Unreliable samples are excluded.

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Lab PT Report

Data as of February 5, 2018

Table 3

Descriptive Statistics by T-cell subset, visit, and treatment arm

Lab	Tcell	Peptide Pool	Cytokine	Day	Treatment	n	Min	Max	Mean	Median
				70	Placebo	10	0.032	4.111	1.749	1.324
					H4:IC31	17	0.003	2.410	0.613	0.352
					H56:IC31	13	0.023	3.881	1.156	0.713
					BCG	16	0.003	3.372	1.241	0.831
				168	Placebo	9	0.681	3.149	1.944	1.740
					H4:IC31	16	0.013	3.823	0.959	0.490
					H56:IC31	12	0.070	5.171	1.462	0.730
					BCG	13	0.022	4.464	1.037	0.668

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj	
CH	BCG	042002	CD4+	28	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.137	0.033	0.104	
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.124	0.044	0.079	
		042005	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.136	0.002	0.134	
				28	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.049	0.004	0.045	
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.039	0.000	0.039	
			CD4+	28	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.063	0.028	0.035	
				CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.075	0.012	0.063
			042016	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.075	0.005	0.070	
				CD4+	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.045	0.008	0.038
				CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.042	0.001	0.040
			042022	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.038	0.001	0.037	
				CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.110	0.048	0.062
				28	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.212	0.025	0.187	
			042026	168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.134	0.026	0.108	
				CD4+	28	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.125	0.014	0.111
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.050	0.006	0.044	
			042027	168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.690	0.038	0.652	
				CD4+	28	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.110	0.028	0.081
			042031	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.033	0.000	0.033
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.120	0.035	0.085	
			042035	CD8+	28	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.077	0.014	0.063

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042038	CD4+	042038	BCG-Pasteur	28	2_of_3_IFNg_IL2_TNFa	0.167	0.046	0.120	
				70	2_of_3_IFNg_IL2_TNFa	0.127	0.027	0.100	
042043	CD4+	042043	BCG-Pasteur	0	2_of_3_IFNg_IL2_TNFa	0.166	0.022	0.144	
				70	2_of_3_IFNg_IL2_TNFa	0.387	0.016	0.371	
				168	2_of_3_IFNg_IL2_TNFa	0.353	0.026	0.327	
042053	CD4+	042053	BCG-Pasteur	0	2_of_3_IFNg_IL2_TNFa	0.159	0.016	0.144	
				28	2_of_3_IFNg_IL2_TNFa	0.531	0.048	0.482	
				70	2_of_3_IFNg_IL2_TNFa	0.526	0.018	0.508	
				168	2_of_3_IFNg_IL2_TNFa	0.301	0.056	0.246	
042058	CD4+	042058	BCG-Pasteur	70	2_of_3_IFNg_IL2_TNFa	0.076	0.018	0.057	
042063	CD4+	042063	BCG-Pasteur	28	2_of_3_IFNg_IL2_TNFa	0.138	0.043	0.095	
				70	2_of_3_IFNg_IL2_TNFa	0.285	0.052	0.232	
		042063	BCG-Pasteur	0	2_of_3_IFNg_IL2_TNFa	0.050	0.006	0.043	
				70	2_of_3_IFNg_IL2_TNFa	0.044	0.005	0.039	
042065	CD4+	042065	BCG-Pasteur	0	2_of_3_IFNg_IL2_TNFa	0.044	0.009	0.035	
				28	2_of_3_IFNg_IL2_TNFa	0.119	0.019	0.100	
				168	2_of_3_IFNg_IL2_TNFa	0.074	0.005	0.070	
042066	CD4+	042066	BCG-Pasteur	28	2_of_3_IFNg_IL2_TNFa	0.292	0.026	0.266	
				70	2_of_3_IFNg_IL2_TNFa	0.246	0.060	0.186	
042077	CD4+	042077	BCG-Pasteur	0	2_of_3_IFNg_IL2_TNFa	0.199	0.062	0.137	
				70	2_of_3_IFNg_IL2_TNFa	0.323	0.124	0.199	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
H4:IC31	CD4+	042084	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.115	0.025	0.090
		042004	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.032	0.002	0.030
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.044	0.010	0.033
	CD4+			168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.034	0.003	0.031
		042008	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.065	0.018	0.047
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.061	0.015	0.046
	CD8+			0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.051	0.000	0.051
				14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.131	0.003	0.128
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.044	0.004	0.039
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.078	0.008	0.070
	CD8+	042012	CD8+	14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.060	0.007	0.053
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.078	0.006	0.073
	CD8+	042018	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.022	0.000	0.022
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.036	0.000	0.036
	CD4+	042021	CD4+	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.125	0.064	0.061
				CD8+	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.040	0.004
	CD8+	042025	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.048	0.001	0.047
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.085	0.001	0.084
	CD8+	042032	CD8+	14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.097	0.006	0.091
	CD4+	042036	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.161	0.050	0.111
	CD4+	042037	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.078	0.018	0.060

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042052	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.036	0.008	0.029		
		CD8+	14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.122	0.005	0.117	
		70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.059	0.003	0.057		
042055	CD4+	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.083	0.027	0.056		
042074	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.095	0.029	0.066		
		14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.072	0.009	0.063		
		70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.120	0.043	0.077		
	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.059	0.003	0.056		
		14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.046	0.000	0.046		
		168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.047	0.000	0.047		
	CD8+	168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.049	0.004	0.045		
H56:IC31	042013	CD4+	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.070	0.011	0.059	
	042014	CD8+	14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.062	0.003	0.058	
	042024	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.071	0.014	0.057	
			14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.145	0.019	0.126	
			70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.074	0.010	0.065	
	042028	CD4+	14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.077	0.017	0.060	
			70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.122	0.041	0.082	
			168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.068	0.012	0.056	
	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.035	0.002	0.033		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
		042039	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.091	0.001	0.090
		042042	CD4+	14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.114	0.048	0.066
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.196	0.074	0.121
		042048	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.436	0.058	0.378
				14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.334	0.019	0.315
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.293	0.055	0.237
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.208	0.030	0.178
		042061	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.194	0.015	0.179
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.189	0.036	0.153
		042068	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.142	0.004	0.138
				14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.108	0.000	0.108
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.116	0.000	0.116
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.058	0.000	0.058
		042071	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.074	0.030	0.044
				14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.206	0.025	0.180
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.071	0.015	0.056
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.183	0.016	0.167
		042073	CD4+	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.180	0.090	0.090
		042079	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.122	0.024	0.098
		042080	CD4+	70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.054	0.013	0.041
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.083	0.022	0.061

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
Placebo	CD4+	042081	CD4+	168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.064	0.027	0.037
		042083	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.416	0.018	0.399
				14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.115	0.025	0.090
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.382	0.015	0.367
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.211	0.026	0.184
	CD4+	042019	CD4+	14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.095	0.007	0.088
				168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.084	0.022	0.062
	CD8+	042029	CD8+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.035	0.001	0.033
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.032	0.002	0.029
	CD4+	042033	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.053	0.008	0.045
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.052	0.010	0.042
		042045	CD4+	168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.065	0.023	0.042
		042070	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.276	0.062	0.214
BCG	CD4+	042072	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.059	0.005	0.054
				14	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.059	0.009	0.049
				70	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.080	0.006	0.074
	CD4+			168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.071	0.014	0.057
		042075	CD4+	0	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.113	0.037	0.076
	CD4+			168	BCG-Pasteur	2_of_3_IFNg_IL2_TNFa	0.064	0.011	0.054
		042005	CD4+	28	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.082	0.028	0.054
	042016	CD4+	168	Ag85B		2_of_3_IFNg_IL2_TNFa	0.149	0.056	0.093

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj		
042022	CD4+	042022	CD4+	28	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.198	0.025	0.174		
				168	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.101	0.026	0.076		
042027	CD4+	042027	Ag85B	168	2_of_3_IFNg_IL2_TNFa	0.163	0.038	0.124			
					TB 10.4	2_of_3_IFNg_IL2_TNFa	0.133	0.038	0.095		
042053	CD4+	042053	CD4+	0	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.145	0.016	0.129		
				28	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.289	0.048	0.240		
				70	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.201	0.018	0.183		
					168	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.238	0.056	0.182	
					042058	CD4+	70	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.072	0.018
H4:IC31	042006	042006	CD4+	14	Ag85B	2_of_3_IFNg_IL2_TNFa	0.132	0.064	0.068		
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.132	0.050	0.081		
	042008	042008	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.143	0.015	0.128		
					TB 10.4	2_of_3_IFNg_IL2_TNFa	0.180	0.015	0.165		
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.120	0.048	0.071		
					TB 10.4	2_of_3_IFNg_IL2_TNFa	0.135	0.048	0.087		
					042012	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.247	0.041
	042018	042018	CD4+	168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.123	0.031	0.092		
					TB 10.4	2_of_3_IFNg_IL2_TNFa	0.098	0.031	0.067		
					042018	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.093	0.033

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042021	CD4+	168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.168	0.033	0.134		
			Ag85B	2_of_3_IFNg_IL2_TNFa	0.290	0.064	0.226		
		TB 10.4	2_of_3_IFNg_IL2_TNFa	0.248	0.064	0.184			
	CD4+	168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.187	0.061	0.127		
		TB 10.4	2_of_3_IFNg_IL2_TNFa	0.153	0.061	0.092			
		70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.257	0.011	0.246		
042025	CD4+	168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.127	0.011	0.116		
			Ag85B	2_of_3_IFNg_IL2_TNFa	0.170	0.023	0.147		
		70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.496	0.065	0.430		
	CD4+	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.236	0.065	0.171			
		168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.376	0.020	0.355		
		TB 10.4	2_of_3_IFNg_IL2_TNFa	0.187	0.020	0.167			
042032	CD4+	168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.093	0.031	0.062		
042037	CD4+	168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.100	0.027	0.072		
042047	CD4+	14	Ag85B	2_of_3_IFNg_IL2_TNFa	0.096	0.035	0.061		
			Ag85B	2_of_3_IFNg_IL2_TNFa	0.110	0.035	0.075		
		168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.091	0.018	0.073		
	CD4+	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.070	0.018	0.052			
		70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.094	0.016	0.077		
		TB 10.4	2_of_3_IFNg_IL2_TNFa	0.068	0.016	0.051			
042050	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.067	0.016	0.051		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042055	CD4+	042055	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.301	0.027	0.274
				TB 10.4	2_of_3_IFNg_IL2_TNFa	0.147	0.027	0.120	
		168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.156	0.015	0.140		
	CD4+	042059	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.105	0.015	0.090		
				2_of_3_IFNg_IL2_TNFa	0.152	0.074	0.078		
				Ag85B	2_of_3_IFNg_IL2_TNFa	0.098	0.029	0.069	
042074	CD4+	042074	CD4+	70	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.197	0.029	0.168
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.075	0.025	0.051
				ESAT-6	2_of_3_IFNg_IL2_TNFa	0.092	0.025	0.068	
	CD4+	042076	CD4+	14	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.265	0.025	0.240
				70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.075	0.009	0.066
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.204	0.043	0.161
H56:IC31	CD4+	042076	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.129	0.016	0.113
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.342	0.057	0.284
				Ag85B	2_of_3_IFNg_IL2_TNFa	0.232	0.028	0.204	
	CD4+	042082	CD4+	168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.067	0.021	0.046
				042013	Ag85B	2_of_3_IFNg_IL2_TNFa	0.157	0.011	0.146
				042014	Ag85B	2_of_3_IFNg_IL2_TNFa	0.037	0.011	0.027
	CD4+	042082	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.086	0.017	0.069
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.083	0.017	0.066
				ESAT-6	2_of_3_IFNg_IL2_TNFa	0.047	0.007	0.040	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj	
		042015	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.104	0.030	0.074	
		042023	CD4+	0	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.070	0.015	0.055	
				14	TB 10.4	2_of_3_IFNg_IL2_TNFa	0.072	0.016	0.056	
				70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.135	0.011	0.124	
					TB 10.4	2_of_3_IFNg_IL2_TNFa	0.073	0.011	0.062	
					168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.094	0.025	0.069
		042024	CD4+	14	ESAT-6	2_of_3_IFNg_IL2_TNFa	0.106	0.019	0.087	
				70	ESAT-6	2_of_3_IFNg_IL2_TNFa	0.060	0.010	0.051	
		042028	CD4+	14	Ag85B	2_of_3_IFNg_IL2_TNFa	0.051	0.017	0.034	
				70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.145	0.041	0.104	
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.057	0.012	0.046	
		042039	CD4+	0	Ag85B	2_of_3_IFNg_IL2_TNFa	0.062	0.001	0.060	
					ESAT-6	2_of_3_IFNg_IL2_TNFa	0.035	0.001	0.034	
					TB 10.4	2_of_3_IFNg_IL2_TNFa	0.046	0.001	0.045	
				70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.254	0.048	0.207	
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.226	0.085	0.141	
		042042	CD4+	14	Ag85B	2_of_3_IFNg_IL2_TNFa	0.172	0.048	0.124	
				70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.426	0.074	0.352	
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.292	0.059	0.233	
		042044	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.071	0.010	0.061	
				168	Ag85B	2_of_3_IFNg_IL2_TNFa	0.055	0.013	0.042	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042048	CD4+	0	TB	10.4	2_of_3_IFNg_IL2_TNFa	0.228	0.058	0.170	
			Ag85B	14	2_of_3_IFNg_IL2_TNFa	0.102	0.019	0.083	
		168	TB	10.4	2_of_3_IFNg_IL2_TNFa	0.213	0.019	0.194	
			Ag85B	2_of_3_IFNg_IL2_TNFa	0.123	0.030	0.093		
			TB	10.4	2_of_3_IFNg_IL2_TNFa	0.194	0.030	0.164	
042061	CD4+	0	TB	10.4	2_of_3_IFNg_IL2_TNFa	0.069	0.015	0.054	
			Ag85B	70	2_of_3_IFNg_IL2_TNFa	0.253	0.036	0.217	
		168	TB	10.4	2_of_3_IFNg_IL2_TNFa	0.098	0.036	0.062	
			Ag85B	2_of_3_IFNg_IL2_TNFa	0.098	0.004	0.094		
042068	CD4+	70	Ag85B	2_of_3_IFNg_IL2_TNFa	0.136	0.015	0.121		
			Ag85B	168	2_of_3_IFNg_IL2_TNFa	0.078	0.016	0.063	
		168	ESAT-6	2_of_3_IFNg_IL2_TNFa	0.140	0.061	0.079		
042079	CD4+	0	TB	10.4	2_of_3_IFNg_IL2_TNFa	0.138	0.061	0.077	
			TB	10.4	2_of_3_IFNg_IL2_TNFa	0.103	0.024	0.078	
		70	2_of_3_IFNg_IL2_TNFa	0.086	0.017	0.068			
			Ag85B	70	2_of_3_IFNg_IL2_TNFa	0.095	0.031	0.064	
042080	CD4+	14	Ag85B	2_of_3_IFNg_IL2_TNFa	0.088	0.013	0.076		
			Ag85B	70	2_of_3_IFNg_IL2_TNFa	0.189	0.025	0.164	
		14	Ag85B	2_of_3_IFNg_IL2_TNFa	0.525	0.015	0.511		
			Ag85B	70	2_of_3_IFNg_IL2_TNFa	0.081	0.015	0.066	
042083	CD4+	168	ESAT-6	2_of_3_IFNg_IL2_TNFa	0.348	0.026	0.321		
		168	Ag85B	2_of_3_IFNg_IL2_TNFa					

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
BCG	042002 CD8+	0	CMV	ESAT-6	2_of_3_IFNg_IL2_TNFa	0.089	0.026	0.062	
				28	2_of_3_IFNg_IL2_TNFa	0.585	0.002	0.583	
				70	2_of_3_IFNg_IL2_TNFa	0.389	0.004	0.385	
	042005 CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.658	0.000	0.658		
				28	2_of_3_IFNg_IL2_TNFa	0.374	0.026	0.349	
				70	2_of_3_IFNg_IL2_TNFa	0.528	0.028	0.500	
				168	2_of_3_IFNg_IL2_TNFa	0.519	0.032	0.488	
				168	2_of_3_IFNg_IL2_TNFa	0.572	0.020	0.552	
	CD8+	28	CMV	2_of_3_IFNg_IL2_TNFa	0.025	0.000	0.025		
				168	2_of_3_IFNg_IL2_TNFa	0.037	0.002	0.035	
042016	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.117	0.014	0.103		
				28	2_of_3_IFNg_IL2_TNFa	0.166	0.041	0.125	
				70	2_of_3_IFNg_IL2_TNFa	0.096	0.008	0.088	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.689	0.001	0.688		
				28	2_of_3_IFNg_IL2_TNFa	0.778	0.006	0.772	
				70	2_of_3_IFNg_IL2_TNFa	0.872	0.001	0.871	
	042022 CD4+	28	CMV	2_of_3_IFNg_IL2_TNFa	0.096	0.025	0.072		
				168	2_of_3_IFNg_IL2_TNFa	0.097	0.026	0.072	
		CD8+	0	2_of_3_IFNg_IL2_TNFa	0.787	0.003	0.785		
				28	2_of_3_IFNg_IL2_TNFa	0.689	0.000	0.689	
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.441	0.004	0.437		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042026	CD4+	0	CMV	28	2_of_3_IFNg_IL2_TNFa	0.084	0.021	0.063	
				70	2_of_3_IFNg_IL2_TNFa	0.039	0.014	0.026	
				28	2_of_3_IFNg_IL2_TNFa	0.072	0.006	0.065	
	CD8+	0	CMV	2.923	2_of_3_IFNg_IL2_TNFa	2.923	0.003	2.920	
				1.237	2_of_3_IFNg_IL2_TNFa	1.237	0.005	1.233	
				2.767	2_of_3_IFNg_IL2_TNFa	2.767	0.004	2.762	
	CD4+	0	CMV	0.054	2_of_3_IFNg_IL2_TNFa	0.054	0.020	0.034	
				0.029	2_of_3_IFNg_IL2_TNFa	0.029	0.002	0.027	
				0.050	2_of_3_IFNg_IL2_TNFa	0.050	0.009	0.040	
042030	CD4+	0	CMV	28	2_of_3_IFNg_IL2_TNFa	0.150	0.025	0.126	
				0.091	2_of_3_IFNg_IL2_TNFa	0.091	0.028	0.063	
				0.082	2_of_3_IFNg_IL2_TNFa	0.082	0.041	0.041	
	CD8+	0	CMV	168	2_of_3_IFNg_IL2_TNFa	0.142	0.062	0.079	
				2.465	2_of_3_IFNg_IL2_TNFa	2.465	0.027	2.437	
				1.533	2_of_3_IFNg_IL2_TNFa	1.533	0.009	1.523	
	CD4+	0	CMV	70	2_of_3_IFNg_IL2_TNFa	1.070	0.010	1.059	
				1.513	2_of_3_IFNg_IL2_TNFa	1.513	0.010	1.503	
				0.371	2_of_3_IFNg_IL2_TNFa	0.371	0.020	0.351	
042031	CD8+	0	CMV	70	2_of_3_IFNg_IL2_TNFa	0.489	0.036	0.454	
				0.497	2_of_3_IFNg_IL2_TNFa	0.497	0.000	0.497	
	CD4+	0	CMV	70	2_of_3_IFNg_IL2_TNFa	0.630	0.006	0.624	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042035	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.215	0.054	0.161		
				28	2_of_3_IFNg_IL2_TNFa	0.148	0.090	0.058	
				70	2_of_3_IFNg_IL2_TNFa	0.135	0.035	0.100	
				168	2_of_3_IFNg_IL2_TNFa	0.169	0.049	0.120	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	4.488	0.000	4.488		
				28	2_of_3_IFNg_IL2_TNFa	3.408	0.014	3.394	
				70	2_of_3_IFNg_IL2_TNFa	3.314	0.006	3.307	
				168	2_of_3_IFNg_IL2_TNFa	4.467	0.003	4.464	
042038	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	1.234	0.034	1.200		
				70	2_of_3_IFNg_IL2_TNFa	1.520	0.027	1.493	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.956	0.002	0.953		
				70	2_of_3_IFNg_IL2_TNFa	0.838	0.000	0.838	
042043	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.391	0.022	0.369		
				70	2_of_3_IFNg_IL2_TNFa	0.371	0.016	0.355	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	3.992	0.005	3.987		
				70	2_of_3_IFNg_IL2_TNFa	3.374	0.002	3.372	
042051	CD4+	28	CMV	2_of_3_IFNg_IL2_TNFa	0.780	0.028	0.752		
				168	2_of_3_IFNg_IL2_TNFa	0.551	0.018	0.534	
	CD8+	28	CMV	2_of_3_IFNg_IL2_TNFa	0.618	0.002	0.616		
				168	2_of_3_IFNg_IL2_TNFa	0.668	0.000	0.668	
042053	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.071	0.016	0.055		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj	
042056	CD8+	0	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.105	0.048	0.057	
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.070	0.018	0.052	
		0		28	CMV	2_of_3_IFNg_IL2_TNFa	0.048	0.008	0.040	
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.076	0.014	0.062	
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.054	0.001	0.053	
	CD4+	70	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.223	0.087	0.136	
		168	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.233	0.076	0.157	
		CD8+	70	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	1.914	0.004	1.910
		168	CMV	70	CMV	2_of_3_IFNg_IL2_TNFa	2.746	0.003	2.743	
		168	CMV	168	CMV	2_of_3_IFNg_IL2_TNFa	2.042	0.014	2.028	
042058	CD4+	0	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.211	0.019	0.193	
		70	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.112	0.018	0.094	
	CD8+	0	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.979	0.004	0.975	
		70	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.826	0.002	0.824	
		168	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.099	0.048	0.051	
042062	CD4+	168	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.108	0.029	0.079	
		168	CMV	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.352	0.007	0.345
	CD4+	0	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.383	0.002	0.381	
		70	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.337	0.000	0.337	
		168	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.412	0.000	0.412	
	CD4+	70	CMV	28	CMV	2_of_3_IFNg_IL2_TNFa	0.123	0.052	0.071	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042065	CD8+	28	CMV	2_of_3_IFNg_IL2_TNFa	1.704	0.003	1.701		
			70	CMV	2_of_3_IFNg_IL2_TNFa	2.350	0.005	2.345	
		0	CMV	2_of_3_IFNg_IL2_TNFa	0.089	0.009	0.080		
	CD4+	28	CMV	2_of_3_IFNg_IL2_TNFa	0.094	0.019	0.075		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.074	0.005	0.069		
		0	CMV	2_of_3_IFNg_IL2_TNFa	0.990	0.004	0.986		
	CD8+	28	CMV	2_of_3_IFNg_IL2_TNFa	1.315	0.002	1.314		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.695	0.004	0.691		
		0	CMV	2_of_3_IFNg_IL2_TNFa	0.221	0.063	0.157		
042066	CD4+	28	CMV	2_of_3_IFNg_IL2_TNFa	0.266	0.026	0.240		
		70	CMV	2_of_3_IFNg_IL2_TNFa	0.263	0.060	0.204		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.276	0.039	0.238		
	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.509	0.014	0.495		
		28	CMV	2_of_3_IFNg_IL2_TNFa	0.302	0.013	0.289		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.312	0.020	0.292		
042067	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	3.302	0.009	3.293		
		28	CMV	2_of_3_IFNg_IL2_TNFa	1.760	0.000	1.760		
		168	CMV	2_of_3_IFNg_IL2_TNFa	1.644	0.000	1.644		
	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.073	0.009	0.063		
		28	CMV	2_of_3_IFNg_IL2_TNFa	0.101	0.007	0.093		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.155	0.007	0.149		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042077	CD8+	0	CMV	28	2_of_3_IFNg_IL2_TNFa	1.046	0.006	1.039	
				168	2_of_3_IFNg_IL2_TNFa	1.323	0.003	1.321	
				CD4+	2_of_3_IFNg_IL2_TNFa	1.491	0.002	1.489	
	CD4+	0	CMV	0	2_of_3_IFNg_IL2_TNFa	3.658	0.062	3.595	
				28	2_of_3_IFNg_IL2_TNFa	5.197	0.058	5.139	
		CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.683	0.003	0.680	
042078	CD8+	28	CMV	28	2_of_3_IFNg_IL2_TNFa	0.842	0.002	0.840	
				70	2_of_3_IFNg_IL2_TNFa	0.456	0.103	0.353	
				168	2_of_3_IFNg_IL2_TNFa	0.313	0.082	0.231	
	CD4+	0	CMV	168	2_of_3_IFNg_IL2_TNFa	0.314	0.073	0.241	
				CD8+	2_of_3_IFNg_IL2_TNFa	2.392	0.007	2.385	
				28	2_of_3_IFNg_IL2_TNFa	0.084	0.009	0.076	
042084	CD4+	0	CMV	168	2_of_3_IFNg_IL2_TNFa	0.054	0.006	0.047	
				CD8+	2_of_3_IFNg_IL2_TNFa	0.270	0.025	0.245	
				0	2_of_3_IFNg_IL2_TNFa	2.121	0.044	2.078	
	H4:IC31	042003	CD4+	168	CMV	2_of_3_IFNg_IL2_TNFa	0.062	0.026	0.037
				CD8+	2_of_3_IFNg_IL2_TNFa	2.568	0.004	2.564	
		042004	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.103	0.021	0.081
042003	H4:IC31	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.115	0.019	0.096	
				70	2_of_3_IFNg_IL2_TNFa	0.197	0.056	0.141	
		CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.207	0.011	0.197	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0	2.504	0.002	2.503		
				14	1.944	0.010	1.934		
				70	2.420	0.010	2.410		
				168	3.826	0.003	3.823		
042006	CD8+	CMV	2_of_3_IFNg_IL2_TNFa	0	0.540	0.015	0.525		
				14	0.412	0.008	0.404		
				70	0.634	0.011	0.624		
				168	0.594	0.010	0.584		
042007	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	2.066	0.069	1.998		
042008	CD4+	70	CMV	2_of_3_IFNg_IL2_TNFa	0.064	0.015	0.049		
				0	0.044	0.000	0.044		
				14	0.113	0.003	0.110		
				70	0.104	0.004	0.099		
042011	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.130	0.020	0.110		
				70	0.093	0.045	0.048		
				CD8+	0.061	0.004	0.058		
				70	0.047	0.008	0.039		
042012	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.109	0.031	0.078		
				14	0.109	0.027	0.082		
				168	0.185	0.031	0.155		
042018	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.334	0.000	0.334		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042021	CD4+	0	CMV	14	2_of_3_IFNg_IL2_TNFa	0.996	0.007	0.990	
				70	2_of_3_IFNg_IL2_TNFa	0.352	0.000	0.352	
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.141	0.043	0.098		
				14	2_of_3_IFNg_IL2_TNFa	0.163	0.050	0.113	
				70	2_of_3_IFNg_IL2_TNFa	0.139	0.064	0.075	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.040	0.002	0.037		
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.043	0.002	0.040		
		0	CMV	2_of_3_IFNg_IL2_TNFa	0.060	0.010	0.050		
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.077	0.024	0.053		
		70	CMV	2_of_3_IFNg_IL2_TNFa	0.108	0.011	0.097		
042025	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.175	0.001	0.174		
				14	2_of_3_IFNg_IL2_TNFa	0.151	0.007	0.144	
				70	2_of_3_IFNg_IL2_TNFa	0.187	0.001	0.185	
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.785	0.003	0.782		
				70	2_of_3_IFNg_IL2_TNFa	0.983	0.006	0.977	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.664	0.009	0.655		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.828	0.003	0.825		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.069	0.031	0.038		
		0	CMV	2_of_3_IFNg_IL2_TNFa	0.307	0.004	0.303		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.290	0.005	0.285		
042037	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.453	0.041	0.412		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042041	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.825	0.000	0.825		
				14	2_of_3_IFNg_IL2_TNFa	2.588	0.005	2.583	
				70	2_of_3_IFNg_IL2_TNFa	1.000	0.013	0.987	
	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.069	0.024	0.045		
				14	2_of_3_IFNg_IL2_TNFa	0.112	0.057	0.055	
				168	2_of_3_IFNg_IL2_TNFa	0.137	0.033	0.104	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.311	0.003	0.308		
				14	2_of_3_IFNg_IL2_TNFa	0.459	0.011	0.448	
				168	2_of_3_IFNg_IL2_TNFa	0.722	0.005	0.717	
042047	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.754	0.035	0.719		
				168	2_of_3_IFNg_IL2_TNFa	0.526	0.018	0.508	
	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.049	0.006	0.043		
				168	2_of_3_IFNg_IL2_TNFa	0.057	0.002	0.055	
	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.526	0.020	0.506		
				14	2_of_3_IFNg_IL2_TNFa	0.460	0.055	0.405	
				70	2_of_3_IFNg_IL2_TNFa	0.509	0.016	0.492	
				168	2_of_3_IFNg_IL2_TNFa	0.757	0.048	0.710	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	1.248	0.000	1.248		
				14	2_of_3_IFNg_IL2_TNFa	1.046	0.000	1.046	
				70	2_of_3_IFNg_IL2_TNFa	1.293	0.002	1.291	
				168	2_of_3_IFNg_IL2_TNFa	1.670	0.000	1.670	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042050	CD4+	042050	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.085	0.023	0.062
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.115	0.012	0.103
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.074	0.016	0.059
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.069	0.009	0.060
	CD8+	042052	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.354	0.000	0.354
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.377	0.000	0.377
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.320	0.000	0.320
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.219	0.000	0.219
	CD4+	042055	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.149	0.008	0.141
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.338	0.026	0.312
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.147	0.014	0.133
				0	CMV	2_of_3_IFNg_IL2_TNFa	0.438	0.007	0.431
042052	CD8+	042055	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.837	0.005	0.832
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.397	0.000	0.397
				0	CMV	2_of_3_IFNg_IL2_TNFa	0.244	0.039	0.205
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.302	0.087	0.215
	CD4+	042055	CD4+	70	CMV	2_of_3_IFNg_IL2_TNFa	0.293	0.027	0.266
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.425	0.015	0.410
				0	CMV	2_of_3_IFNg_IL2_TNFa	0.786	0.005	0.781
				14	CMV	2_of_3_IFNg_IL2_TNFa	1.287	0.000	1.287
				70	CMV	2_of_3_IFNg_IL2_TNFa	1.517	0.000	1.517

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042057	CD4+	0	CMV	168	CMV	2_of_3_IFNg_IL2_TNFa	2.119	0.002	2.117
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.094	0.040	0.054
	CD8+	168	CMV	2_of_3_IFNg_IL2_TNFa	0.058	0.025	0.033		
042059	CD4+	0	CMV	168	CMV	2_of_3_IFNg_IL2_TNFa	1.744	0.006	1.738
				14	CMV	2_of_3_IFNg_IL2_TNFa	1.512	0.004	1.508
	CD8+	70	CMV	2_of_3_IFNg_IL2_TNFa	1.342	0.007	1.335		
042074	CD4+	14	CMV	168	CMV	2_of_3_IFNg_IL2_TNFa	1.462	0.007	1.455
				0	CMV	2_of_3_IFNg_IL2_TNFa	0.033	0.009	0.024
	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.399	0.003	0.396		
042076	CD4+	0	CMV	14	CMV	2_of_3_IFNg_IL2_TNFa	0.407	0.000	0.407
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.370	0.002	0.368
	CD8+	168	CMV	2_of_3_IFNg_IL2_TNFa	0.373	0.000	0.373		
042082	CD4+	14	CMV	0	CMV	2_of_3_IFNg_IL2_TNFa	0.057	0.016	0.041
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.078	0.022	0.056
	CD8+	168	CMV	2_of_3_IFNg_IL2_TNFa	0.113	0.057	0.056		
042082	CD4+	0	CMV	14	CMV	2_of_3_IFNg_IL2_TNFa	0.117	0.028	0.089
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.059	0.008	0.050
	CD8+	168	CMV	2_of_3_IFNg_IL2_TNFa	0.075	0.010	0.065		
	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.063	0.004	0.060		
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.099	0.027	0.072		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj		
H56:IC31	CD8+	042001	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.101	0.022	0.079		
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.132	0.021	0.111		
				0	CMV	2_of_3_IFNg_IL2_TNFa	0.250	0.007	0.242		
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.207	0.002	0.205		
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.166	0.012	0.153		
		042010	CD4+	168	CMV	2_of_3_IFNg_IL2_TNFa	0.197	0.007	0.190		
				0	CMV	2_of_3_IFNg_IL2_TNFa	1.484	0.000	1.484		
				14	CMV	2_of_3_IFNg_IL2_TNFa	1.425	0.004	1.421		
	042013			14	CMV	2_of_3_IFNg_IL2_TNFa	0.028	0.001	0.027		
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.033	0.003	0.030		
	CD8+		0	CMV	2_of_3_IFNg_IL2_TNFa	0.987	0.000	0.987			
			14	CMV	2_of_3_IFNg_IL2_TNFa	0.781	0.000	0.781			
			70	CMV	2_of_3_IFNg_IL2_TNFa	1.035	0.008	1.028			
	CD4+	0	0	CMV	2_of_3_IFNg_IL2_TNFa	0.240	0.016	0.224			
			14	CMV	2_of_3_IFNg_IL2_TNFa	0.406	0.005	0.401			
			70	CMV	2_of_3_IFNg_IL2_TNFa	0.452	0.011	0.441			
			168	CMV	2_of_3_IFNg_IL2_TNFa	0.295	0.008	0.286			
	CD8+	0	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	2.506	0.007	2.498		
				14	CMV	2_of_3_IFNg_IL2_TNFa	2.988	0.000	2.988		
				70	CMV	2_of_3_IFNg_IL2_TNFa	3.073	0.006	3.068		
				168	CMV	2_of_3_IFNg_IL2_TNFa	2.123	0.000	2.123		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042014	CD4+	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.202	0.011	0.191	
			168	CMV	2_of_3_IFNg_IL2_TNFa	0.306	0.007	0.299	
	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	3.412	0.003	3.409		
		168	CMV	2_of_3_IFNg_IL2_TNFa	5.174	0.003	5.171		
042015	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.126	0.045	0.081		
		70	CMV	2_of_3_IFNg_IL2_TNFa	0.085	0.030	0.055		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.134	0.041	0.093		
	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.508	0.003	0.505		
		70	CMV	2_of_3_IFNg_IL2_TNFa	0.713	0.000	0.713		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.638	0.005	0.633		
042020	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.190	0.019	0.171		
		CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.500	0.010	0.491	
	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.154	0.015	0.140		
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.114	0.016	0.098		
042023	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	1.919	0.002	1.917		
		14	CMV	2_of_3_IFNg_IL2_TNFa	1.887	0.004	1.883		
	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.139	0.014	0.125		
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.282	0.019	0.263		
042024	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.443	0.009	0.435		
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.515	0.010	0.506		
	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.089	0.017	0.072		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.058	0.012	0.046
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa			0.538	0.002	0.536
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.480	0.004	0.476
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.425	0.002	0.423
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.489	0.000	0.489
042034	CD4+	70	CMV			2_of_3_IFNg_IL2_TNFa	0.026	0.006	0.020
	CD8+	0	CMV			2_of_3_IFNg_IL2_TNFa	0.115	0.000	0.115
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.522	0.004	0.517
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.440	0.010	0.431
042039	CD4+	0	CMV			2_of_3_IFNg_IL2_TNFa	0.114	0.001	0.112
	CD8+	0	CMV			2_of_3_IFNg_IL2_TNFa	0.394	0.000	0.394
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.296	0.013	0.283
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.233	0.000	0.233
042040	CD8+	0	CMV			2_of_3_IFNg_IL2_TNFa	0.118	0.011	0.107
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.105	0.014	0.091
042042	CD4+	14	CMV			2_of_3_IFNg_IL2_TNFa	0.324	0.048	0.276
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.748	0.059	0.689
	CD8+	14	CMV			2_of_3_IFNg_IL2_TNFa	0.211	0.017	0.193
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.330	0.010	0.320
042044	CD4+	0	CMV			2_of_3_IFNg_IL2_TNFa	0.365	0.007	0.357
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.318	0.010	0.308

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj	
042046	CD4+	042046	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.117	0.000	0.117	
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.080	0.000	0.080	
			CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.102	0.019	0.083	
	CD8+	042048		70	CMV	2_of_3_IFNg_IL2_TNFa	0.064	0.014	0.050	
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.088	0.025	0.063	
			CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.966	0.010	0.956	
		042061		14	CMV	2_of_3_IFNg_IL2_TNFa	1.136	0.000	1.136	
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.576	0.000	0.576	
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.826	0.000	0.826	
042068	CD4+	042068	CD4+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.184	0.019	0.165	
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.134	0.055	0.078	
			CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	3.732	0.003	3.729	
	CD8+	042061		70	CMV	2_of_3_IFNg_IL2_TNFa	3.891	0.010	3.881	
				0	CMV	2_of_3_IFNg_IL2_TNFa	0.066	0.015	0.051	
				0	CMV	2_of_3_IFNg_IL2_TNFa	0.625	0.001	0.624	
		042068		14	CMV	2_of_3_IFNg_IL2_TNFa	0.590	0.004	0.585	
	CD4+			0	CMV	2_of_3_IFNg_IL2_TNFa	0.102	0.028	0.074	
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.133	0.018	0.115	
				70	CMV	2_of_3_IFNg_IL2_TNFa	0.167	0.004	0.163	
	CD8+	042068		168	CMV	2_of_3_IFNg_IL2_TNFa	0.113	0.028	0.085	
				0	CMV	2_of_3_IFNg_IL2_TNFa	1.039	0.004	1.035	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042071	CD4+	0	CMV	14	2_of_3_IFNg_IL2_TNFa	0.842	0.000	0.842	
				70	2_of_3_IFNg_IL2_TNFa	1.440	0.000	1.440	
				168	2_of_3_IFNg_IL2_TNFa	0.587	0.000	0.587	
				14	2_of_3_IFNg_IL2_TNFa	0.213	0.030	0.183	
				70	2_of_3_IFNg_IL2_TNFa	0.214	0.025	0.189	
	CD8+	0	CMV	168	2_of_3_IFNg_IL2_TNFa	0.152	0.015	0.137	
				14	2_of_3_IFNg_IL2_TNFa	0.184	0.016	0.168	
				168	2_of_3_IFNg_IL2_TNFa	0.050	0.000	0.050	
				14	2_of_3_IFNg_IL2_TNFa	0.097	0.003	0.094	
				168	2_of_3_IFNg_IL2_TNFa	0.070	0.000	0.070	
042073	CD8+	14	CMV	14	2_of_3_IFNg_IL2_TNFa	2.122	0.000	2.122	
				168	2_of_3_IFNg_IL2_TNFa	2.660	0.007	2.653	
		0	CMV	14	2_of_3_IFNg_IL2_TNFa	1.257	0.001	1.256	
				70	2_of_3_IFNg_IL2_TNFa	1.184	0.003	1.181	
042079	CD8+	0	CMV	168	2_of_3_IFNg_IL2_TNFa	1.383	0.002	1.381	
				14	2_of_3_IFNg_IL2_TNFa	2.080	0.004	2.076	
				168	2_of_3_IFNg_IL2_TNFa	0.199	0.031	0.168	
		14	CMV	70	2_of_3_IFNg_IL2_TNFa	0.110	0.013	0.097	
				70	2_of_3_IFNg_IL2_TNFa	3.019	0.008	3.012	
042080	CD4+	14	CMV	14	2_of_3_IFNg_IL2_TNFa	1.749	0.002	1.747	
				168	2_of_3_IFNg_IL2_TNFa	0.060	0.027	0.033	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042083	CD8+	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.527	0.009	0.518	
				168	CMV	2_of_3_IFNg_IL2_TNFa	0.596	0.002	0.594
		CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	1.876	0.006	1.869	
			14	CMV	2_of_3_IFNg_IL2_TNFa	1.701	0.006	1.695	
	Placebo	CD8+	168	CMV	2_of_3_IFNg_IL2_TNFa	2.001	0.004	1.997	
			14	CMV	2_of_3_IFNg_IL2_TNFa	0.908	0.004	0.905	
		CD8+	168	CMV	2_of_3_IFNg_IL2_TNFa	1.276	0.006	1.270	
			0	CMV	2_of_3_IFNg_IL2_TNFa	0.847	0.062	0.786	
042017	CD4+	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.529	0.018	0.511	
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.500	0.038	0.463
		CD4+	70	CMV	2_of_3_IFNg_IL2_TNFa	0.416	0.017	0.399	
			168	CMV	2_of_3_IFNg_IL2_TNFa	3.996	0.000	3.996	
	CD8+	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	3.348	0.000	3.348	
			14	CMV	2_of_3_IFNg_IL2_TNFa	3.497	0.000	3.497	
		CD8+	70	CMV	2_of_3_IFNg_IL2_TNFa	2.894	0.000	2.894	
			168	CMV	2_of_3_IFNg_IL2_TNFa	0.152	0.025	0.127	
042019	CD4+	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.119	0.007	0.111	
				14	CMV	2_of_3_IFNg_IL2_TNFa	0.146	0.035	0.110
		CD8+	70	CMV	2_of_3_IFNg_IL2_TNFa	1.369	0.004	1.364	
			14	CMV	2_of_3_IFNg_IL2_TNFa	0.818	0.000	0.818	
	CD8+	CD8+	70	CMV	2_of_3_IFNg_IL2_TNFa	1.099	0.005	1.093	
			0	CMV	2_of_3_IFNg_IL2_TNFa	0.000	0.000	0.000	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042029	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.158	0.062	0.095		
				2_of_3_IFNg_IL2_TNFa	0.154	0.043	0.111		
				2_of_3_IFNg_IL2_TNFa	0.140	0.038	0.102		
	CD8+	14	CMV	2_of_3_IFNg_IL2_TNFa	0.041	0.005	0.036		
		70		2_of_3_IFNg_IL2_TNFa	0.034	0.002	0.032		
		168		2_of_3_IFNg_IL2_TNFa	2.311	0.007	2.304		
042033	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	2.735	0.001	2.734		
		14		2_of_3_IFNg_IL2_TNFa	2.654	0.003	2.651		
		70		2_of_3_IFNg_IL2_TNFa	2.413	0.004	2.409		
	CD4+	168	CMV	2_of_3_IFNg_IL2_TNFa	0.086	0.023	0.063		
		0		2_of_3_IFNg_IL2_TNFa	0.798	0.010	0.788		
		14		2_of_3_IFNg_IL2_TNFa	1.103	0.008	1.094		
042045	CD8+	70	CMV	2_of_3_IFNg_IL2_TNFa	0.678	0.004	0.674		
		168		2_of_3_IFNg_IL2_TNFa	1.740	0.000	1.740		
		0	CMV	2_of_3_IFNg_IL2_TNFa	0.113	0.031	0.082		
	CD4+	14		2_of_3_IFNg_IL2_TNFa	0.191	0.114	0.077		
		168		2_of_3_IFNg_IL2_TNFa	0.121	0.043	0.078		
		0	CMV	2_of_3_IFNg_IL2_TNFa	1.772	0.003	1.768		
042054	CD8+	14		2_of_3_IFNg_IL2_TNFa	1.395	0.006	1.389		
		70		2_of_3_IFNg_IL2_TNFa	1.437	0.006	1.431		
		168		2_of_3_IFNg_IL2_TNFa	1.129	0.000	1.129		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042060	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.196	0.014	0.182		
				14	2_of_3_IFNg_IL2_TNFa	0.158	0.012	0.146	
				70	2_of_3_IFNg_IL2_TNFa	0.354	0.010	0.344	
				168	2_of_3_IFNg_IL2_TNFa	0.247	0.012	0.236	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.378	0.000	0.378		
				14	2_of_3_IFNg_IL2_TNFa	0.491	0.000	0.491	
				70	2_of_3_IFNg_IL2_TNFa	0.665	0.005	0.661	
				168	2_of_3_IFNg_IL2_TNFa	0.681	0.000	0.681	
042064	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.527	0.028	0.499		
				70	2_of_3_IFNg_IL2_TNFa	0.503	0.066	0.436	
				168	2_of_3_IFNg_IL2_TNFa	0.968	0.083	0.884	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	2.014	0.000	2.014		
				70	2_of_3_IFNg_IL2_TNFa	2.125	0.000	2.125	
				168	2_of_3_IFNg_IL2_TNFa	3.156	0.007	3.149	
	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.190	0.062	0.128		
042070	CD4+	0	CMV	2_of_3_IFNg_IL2_TNFa	0.029	0.005	0.024		
				70	2_of_3_IFNg_IL2_TNFa	0.038	0.006	0.032	
				168	2_of_3_IFNg_IL2_TNFa	0.048	0.014	0.034	
	CD8+	0	CMV	2_of_3_IFNg_IL2_TNFa	1.076	0.003	1.073		
				14	2_of_3_IFNg_IL2_TNFa	1.311	0.006	1.305	
				70	2_of_3_IFNg_IL2_TNFa	1.220	0.003	1.217	

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 4

Listing of Positive ICS Responses Using MIMOSA

Lab	Group	Pub ID	T cell	Day	Peptide Pool	Cytokine	% Cytokine Response	% Response Neg Ctrl	% Response Bkgd Adj
042075	CD4+	0	CMV	168	2_of_3_IFNg_IL2_TNFa	1.097	0.005	1.093	
		14	CMV	2_of_3_IFNg_IL2_TNFa	0.165	0.037	0.128		
	CD8+	70	CMV	2_of_3_IFNg_IL2_TNFa	0.181	0.019	0.162		
		168	CMV	2_of_3_IFNg_IL2_TNFa	0.208	0.027	0.181		
		0	CMV	2_of_3_IFNg_IL2_TNFa	0.120	0.011	0.109		
				14	2_of_3_IFNg_IL2_TNFa	3.556	0.007	3.549	
		70	CMV	2_of_3_IFNg_IL2_TNFa	3.490	0.000	3.490		
		168	CMV	2_of_3_IFNg_IL2_TNFa	4.115	0.004	4.111		

Unreliable samples are excluded.

Records are excluded if the number of T-cell subsets is < 1,000

These criteria are applied separately to CD4+ and CD8+ subsets.

Lab PT Report

Data as of February 5, 2018

Table 5

Comparison of Response Rates at Day 0 vs. Day 14 (BCG Day 28)

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes		McNemar's Test p-values	
				Day 0	Day 14/28	Unadjusted	Adjusted
2_of_3_IFNg_IL2_TNF α	CD4+	BCG-Pasteur	Placebo	11	10	1.0000	1.0000
			H4:IC31	23	22	0.1250	1.0000
			H56:IC31	22	22	0.6250	1.0000
			BCG	24	20	0.0703	0.7031
	Ag85B		Placebo	11	11	.	.
			H4:IC31	24	21	0.2500	1.0000
			H56:IC31	22	23	0.2188	1.0000
			BCG	24	20	.	.
	ESAT-6		Placebo	11	11	.	.
			H4:IC31	24	22	.	.
			H56:IC31	22	22	1.0000	1.0000
			BCG	24	20	.	.
	Rv2660c		Placebo	11	11	.	.
			H4:IC31	24	22	.	.
			H56:IC31	22	23	.	.
			BCG	24	20	.	.
	TB 10.4		Placebo	11	11	.	.
			H4:IC31	22	22	1.0000	1.0000
			H56:IC31	20	23	0.2500	1.0000
			BCG	23	20	0.2500	1.0000

Missing: Not applicable; responses all positive or all negative.

There is no data for BCG at day 14. BCG responses are compared between day 0 and 28.

Positive responses are calculated using MIMOSA.

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 5

Comparison of Response Rates at Day 0 vs. Day 14 (BCG Day 28)

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes		McNemar's Test p-values	
				Day 0	Day 14/28	Unadjusted	Adjusted
CD8+	BCG-Pasteur	Placebo	Placebo	11	10	1.0000	1.0000
			H4:IC31	23	22	1.0000	.
			H56:IC31	22	22	1.0000	1.0000
			BCG	24	20	0.3750	1.0000
	Ag85B	Placebo	Placebo	11	11	.	.
			H4:IC31	24	21	.	.
			H56:IC31	22	23	.	.
			BCG	24	20	.	.
	ESAT-6	Placebo	Placebo	11	11	.	.
			H4:IC31	24	22	.	.
			H56:IC31	22	22	.	.
			BCG	24	20	.	.
	Rv2660c	Placebo	Placebo	11	11	.	.
			H4:IC31	24	22	.	.
			H56:IC31	22	23	.	.
			BCG	24	20	.	.
	TB 10.4	Placebo	Placebo	11	11	.	.
			H4:IC31	22	22	.	.
			H56:IC31	20	23	.	.
			BCG	23	20	.	.

Missing: Not applicable; responses all positive or all negative.

There is no data for BCG at day 14. BCG responses are compared between day 0 and 28.

Positive responses are calculated using MIMOSA.

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 6
Comparison of Response Magnitudes at Day 0 vs. Day 14 (BCG Day 28)

Cytokine	Tcell	Peptide	Treatment Group	Day 0 or 14/28	Wilcoxon Sign Rank Sample Sizes p-values	
					Unadjusted	Adjusted
2_of_3_IFNg_IL2_TNF α	CD4+	BCG-Pasteur	Placebo	12	1.0000	1.0000
			H4:IC31	24	0.2253	1.0000
			H56:IC31	24	0.8176	1.0000
			BCG	24	0.0010	0.0164
	Ag85B	Placebo	12	1.0000	1.0000	
		H4:IC31	24	0.0002	0.0031	
		H56:IC31	24	0.0008	0.0151	
		BCG	24	0.1641	1.0000	
	ESAT-6	Placebo	12	0.1875	1.0000	
		H4:IC31	24	0.5000	1.0000	
		H56:IC31	24	0.0522	0.8359	
		BCG	24	0.6875	1.0000	
	Rv2660c	Placebo	12	0.2500	1.0000	
		H4:IC31	24	1.0000	1.0000	
		H56:IC31	24	0.9375	1.0000	
		BCG	24	1.0000	1.0000	
	TB 10.4	Placebo	12	0.3125	1.0000	
		H4:IC31	24	0.1099	1.0000	
		H56:IC31	24	0.8926	1.0000	

Positive responses are calculated using MIMOSA.

There is no data for BCG at day 14. BCG responses are compared between day 0 and 28.

ICS response magnitudes are censored at 0.01%

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 6
Comparison of Response Magnitudes at Day 0 vs. Day 14 (BCG Day 28)

Cytokine	Tcell	Peptide	Treatment Group	Day 0 or 14/28	Wilcoxon Sign Rank p-values	
					Sample Sizes	p-values
CD8+	BCG-Pasteur	H4:IC31	BCG	24	0.0002	0.0046
			Placebo	12	0.0781	1.0000
			H56:IC31	24	0.9843	1.0000
			BCG	24	0.2413	1.0000
	Ag85B	H56:IC31	BCG	24	0.9217	1.0000
			Placebo	12	0.0781	1.0000
			H4:IC31	24	0.9780	1.0000
			BCG	24	0.7615	1.0000
	ESAT-6	H56:IC31	BCG	24	0.1602	1.0000
			Placebo	12	0.6875	1.0000
			H4:IC31	24	0.0977	1.0000
			BCG	24	0.3828	1.0000
Rv2660c	H56:IC31	TB 10.4	BCG	24	0.0234	0.4688
			Placebo	12	0.8438	1.0000
			H4:IC31	24	0.2324	1.0000
	TB 10.4	H4:IC31	BCG	24	0.7910	1.0000
			BCG	24	0.0645	1.0000
			Placebo	12	0.6250	1.0000

Positive responses are calculated using MIMOSA.

There is no data for BCG at day 14. BCG responses are compared between day 0 and 28.

ICS response magnitudes are censored at 0.01%

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 6

Comparison of Response Magnitudes at Day 0 vs. Day 14 (BCG Day 28)

Cytokine	Tcell	Peptide	Treatment Group	Day 0 or 14/28	Wilcoxon Sign Rank Sizes p-values	
					Unadjusted	Adjusted
		H56:IC31		24	0.4258	1.0000
		BCG		24	1.0000	1.0000

Positive responses are calculated using MIMOSA.

There is no data for BCG at day 14. BCG responses are compared between day 0 and 28.

ICS response magnitudes are censored at 0.01%

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 7
Comparison of Response Rates at Day 0 vs. Day 70

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes		McNemar's Test p-values	
				Day 0	Day 70	Unadjusted	Adjusted
2_of_3_IFNg_IL2_TNF α	CD4+	BCG-Pasteur	Placebo	11	11	1.0000	1.0000
			H4:IC31	23	20	1.0000	1.0000
			H56:IC31	22	20	0.6875	1.0000
			BCG	24	18	0.0156	0.1250
	Ag85B		Placebo	11	11	.	.
			H4:IC31	24	20	0.0005	0.0049
			H56:IC31	22	20	0.0010	0.0088
			BCG	24	18	.	.
	ESAT-6		Placebo	11	11	.	.
			H4:IC31	24	20	.	.
			H56:IC31	22	20	0.6250	1.0000
			BCG	24	18	.	.
	Rv2660c		Placebo	11	11	.	.
			H4:IC31	24	20	.	.
			H56:IC31	22	20	.	.
			BCG	24	18	.	.
	TB 10.4		Placebo	11	11	.	.
			H4:IC31	22	19	0.0156	0.1250
			H56:IC31	20	18	0.5000	1.0000
			BCG	23	17	1.0000	1.0000

Missing: Not applicable; responses all positive or all negative.

Positive responses are calculated using MIMOSA.

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 7
Comparison of Response Rates at Day 0 vs. Day 70

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes		McNemar's Test p-values	
				Day 0	Day 70	Unadjusted	Adjusted
CD8+	BCG-Pasteur	Placebo	Placebo	11	11	.	.
			H4:IC31	23	20	1.0000	1.0000
			H56:IC31	22	20	1.0000	1.0000
			BCG	24	18	1.0000	1.0000
	Ag85B	Placebo	Placebo	11	11	.	.
			H4:IC31	24	20	.	.
			H56:IC31	22	20	.	.
			BCG	24	18	.	.
	ESAT-6	Placebo	Placebo	11	11	.	.
			H4:IC31	24	20	.	.
			H56:IC31	22	20	.	.
			BCG	24	18	.	.
	Rv2660c	Placebo	Placebo	11	11	.	.
			H4:IC31	24	20	.	.
			H56:IC31	22	20	.	.
			BCG	24	18	.	.
	TB 10.4	Placebo	Placebo	11	11	.	.
			H4:IC31	22	19	.	.
			H56:IC31	20	18	.	.
			BCG	23	17	.	.

Missing: Not applicable; responses all positive or all negative.

Positive responses are calculated using MIMOSA.

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 8
Comparison of Response Magnitudes at Day 0 vs. Day 70

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes	Wilcoxon Sign Rank p-values	
				Day 0 or 70	Unadjusted	Adjusted
2_of_3_IFNg_IL2_TNF α	CD4+	BCG-Pasteur	Placebo	12	0.8203	1.0000
			H4:IC31	23	0.5509	1.0000
			H56:IC31	23	0.6777	1.0000
			BCG	24	<.0001	0.0008
	Ag85B		Placebo	12	1.0000	1.0000
			H4:IC31	24	<.0001	0.0001
			H56:IC31	23	<.0001	<.0001
			BCG	24	0.1055	1.0000
	ESAT-6		Placebo	12	1.0000	1.0000
			H4:IC31	24	0.0938	1.0000
			H56:IC31	23	0.0013	0.0197
			BCG	24	0.3125	1.0000
	Rv2660c		Placebo	12	1.0000	1.0000
			H4:IC31	24	0.5000	1.0000
			H56:IC31	23	0.1272	1.0000
			BCG	24	0.6875	1.0000
	TB 10.4		Placebo	12	1.0000	1.0000
			H4:IC31	23	0.0002	0.0039
			H56:IC31	21	0.6772	1.0000
			BCG	23	0.0001	0.0021

Positive responses are calculated using MIMOSA.

ICS response magnitudes are censored at 0.01%

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 8
Comparison of Response Magnitudes at Day 0 vs. Day 70

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes	Wilcoxon Sign Rank p-values	
				Day 0 or 70	Unadjusted	Adjusted
CD8+	BCG-Pasteur	Placebo	Placebo	12	0.2500	1.0000
			H4:IC31	23	0.9843	1.0000
			H56:IC31	23	0.0987	1.0000
			BCG	24	0.6095	1.0000
	Ag85B	Placebo	Placebo	12	0.9375	1.0000
			H4:IC31	24	0.9032	1.0000
			H56:IC31	23	0.5469	1.0000
			BCG	24	0.6250	1.0000
	ESAT-6	Placebo	Placebo	12	0.2188	1.0000
			H4:IC31	24	0.9697	1.0000
			H56:IC31	23	0.9375	1.0000
			BCG	24	0.0273	0.5469
Rv2660c	Placebo	Placebo	Placebo	12	0.2500	1.0000
			H4:IC31	24	0.2661	1.0000
			H56:IC31	23	0.8438	1.0000
			BCG	24	0.1934	1.0000
	TB 10.4	Placebo	Placebo	12	0.8438	1.0000
			H4:IC31	23	0.3203	1.0000
			H56:IC31	21	0.4375	1.0000
			BCG	23	0.7344	1.0000

Positive responses are calculated using MIMOSA.

ICS response magnitudes are censored at 0.01%

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 9

Comparison of Response Rates at Day 0 vs. Day 168

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes		McNemar's Test p-values	
				Day 0	Day 168	Unadjusted	Adjusted
2_of_3_IFNg_IL2_TNF α	CD4+	BCG-Pasteur	Placebo	11	10	1.0000	1.0000
			H4:IC31	23	20	0.1250	1.0000
			H56:IC31	22	20	1.0000	1.0000
			BCG	24	18	0.5000	1.0000
	Ag85B		Placebo	11	10	.	.
			H4:IC31	24	23	<.0001	0.0007
			H56:IC31	22	21	0.0156	0.1719
			BCG	24	23	0.5000	1.0000
	ESAT-6		Placebo	11	10	.	.
			H4:IC31	24	23	1.0000	1.0000
			H56:IC31	22	21	1.0000	1.0000
			BCG	24	23	.	.
	Rv2660c		Placebo	11	10	.	.
			H4:IC31	24	23	.	.
			H56:IC31	22	21	.	.
			BCG	24	23	.	.
	TB 10.4		Placebo	11	10	.	.
			H4:IC31	22	23	0.0313	0.3125
			H56:IC31	20	21	0.1250	1.0000
			BCG	23	23	0.2500	1.0000

Missing: Not applicable; responses all positive or all negative.

Positive responses are calculated using MIMOSA.

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 9

Comparison of Response Rates at Day 0 vs. Day 168

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes		McNemar's Test p-values	
				Day 0	Day 168	Unadjusted	Adjusted
CD8+	BCG-Pasteur	Placebo	Placebo	11	10	.	.
			H4:IC31	23	20	1.0000	1.0000
			H56:IC31	22	20	1.0000	1.0000
			BCG	24	18	0.1250	0.3750
	Ag85B	Placebo	Placebo	11	10	.	.
			H4:IC31	24	23	.	.
			H56:IC31	22	21	.	.
			BCG	24	23	.	.
	ESAT-6	Placebo	Placebo	11	10	.	.
			H4:IC31	24	23	.	.
			H56:IC31	22	21	.	.
			BCG	24	23	.	.
	Rv2660c	Placebo	Placebo	11	10	.	.
			H4:IC31	24	23	.	.
			H56:IC31	22	21	.	.
			BCG	24	23	.	.
	TB 10.4	Placebo	Placebo	11	10	.	.
			H4:IC31	22	23	.	.
			H56:IC31	20	21	.	.
			BCG	23	23	.	.

Missing: Not applicable; responses all positive or all negative.

Positive responses are calculated using MIMOSA.

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 10
Comparison of Response Magnitudes at Day 0 vs. Day 168

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes	Wilcoxon Sign Rank p-values	
				Day 0 or 168	Unadjusted	Adjusted
2_of_3_IFNg_IL2_TNF α	CD4+	BCG-Pasteur	Placebo	12	0.3828	1.0000
			H4:IC31	24	0.9323	1.0000
			H56:IC31	24	0.8904	1.0000
			BCG	24	<.0001	0.0008
	Ag85B		Placebo	12	1.0000	1.0000
			H4:IC31	24	<.0001	<.0001
			H56:IC31	24	<.0001	0.0001
			BCG	24	0.7334	1.0000
	ESAT-6		Placebo	12	0.9375	1.0000
			H4:IC31	24	0.1250	1.0000
			H56:IC31	24	0.1514	1.0000
			BCG	24	1.0000	1.0000
	Rv2660c		Placebo	12	0.2500	1.0000
			H4:IC31	24	0.1641	1.0000
			H56:IC31	24	1.0000	1.0000
			BCG	24	0.3125	1.0000
	TB 10.4		Placebo	12	0.6250	1.0000
			H4:IC31	24	<.0001	0.0004
			H56:IC31	24	0.1531	1.0000
			BCG	24	0.0003	0.0046

Positive responses are calculated using MIMOSA.

ICS response magnitudes are censored at 0.01%

P-values are adjusted using the Holm method within groups of cell subset and cytokine.

Lab PT Report

Data as of February 5, 2018

Table 10
Comparison of Response Magnitudes at Day 0 vs. Day 168

Cytokine	Tcell	Peptide	Treatment Group	Sample Sizes	Wilcoxon Sign Rank p-values	
				Day 0 or 168	Unadjusted	Adjusted
CD8+	BCG-Pasteur	Placebo	Placebo	12	0.1094	1.0000
			H4:IC31	24	0.9265	1.0000
			H56:IC31	24	0.2247	1.0000
			BCG	24	0.2979	1.0000
	Ag85B	Placebo	Placebo	12	0.8438	1.0000
			H4:IC31	24	0.0574	1.0000
			H56:IC31	24	0.5771	1.0000
			BCG	24	0.6953	1.0000
	ESAT-6	Placebo	Placebo	12	0.6875	1.0000
			H4:IC31	24	0.3652	1.0000
			H56:IC31	24	0.0391	0.7813
			BCG	24	0.0840	1.0000
Rv2660c	Placebo	Placebo	Placebo	12	0.8125	1.0000
			H4:IC31	24	1.0000	1.0000
			H56:IC31	24	0.5469	1.0000
			BCG	24	0.3652	1.0000
	TB 10.4	Placebo	Placebo	12	0.5625	1.0000
			H4:IC31	24	0.4631	1.0000
			H56:IC31	24	0.1484	1.0000
			BCG	24	1.0000	1.0000

Positive responses are calculated using MIMOSA.

ICS response magnitudes are censored at 0.01%

P-values are adjusted using the Holm method within groups of cell subset and cytokine.