Protocol: ORA-CoV-2-01 12 Dec 2023

Listings 16.2.8.5 Serum Immunogenicity

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
01-001	1st Vaccination	14 Dec 2021	2.2 AU/mL Abnormal NCS NCS	Non reactive Normal
01-001	2nd Vaccination	04 Jan 2022	1 AU/mL Abnormal NCS ncs	Non reactive Normal
01-001	Week 6	25 Jan 2022	1 AU/mL Normal	Non-Reactive Normal
01-001	Week 10	25 Feb 2022	1.4 AU/mL Abnormal NCS ncs	Non reactive Normal
01-001	Week 14	25 Mar 2022	0.8 AU/mL Normal	Non-reative Normal
01-001	Week 18	13 Apr 2022	0	non reactive
01-002	Week 6	10 Mar 2022	3325.5 AU/mL Abnormal NCS NCS	reactive Normal
01-002	Week 10	22 Mar 2022	2821 AU/mL Abnormal NCS NCS	Reactive Normal
01-002	Week 14	21 Apr 2022	2456.5 AU/mL Abnormal NCS NCS	Reactive Normal
01-002	Week 18	13 May 2022	2556.2 AU/mL Abnormal NCS ncs	Reactive Normal
01-002	Week 24/ET	23 Jun 2022	2220.1 AU/mL Abnormal NCS NCS	Reactive Normal
01-005	2nd Vaccination	01 Feb 2022	1940.6 AU/mL Abnormal NCS NCS	Reactive Normal
01-005	Week 6	22 Feb 2022	1955.8 AU/mL Abnormal NCS NCS	Reactive Normal
01-005	Week 10	18 Mar 2022	1894 AU/ML Abnormal NCS NCS	reactive Normal

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
01-005	Week 14	20 Apr 2022	1688.2 AU/mL Abnormal NCS NCS	Reactive Normal
01-005	Week 18	16 May 2022	1605.7 reactive Abnormal NCS ncs	reactive Normal
01-005	Week 24/ET	27 Jun 2022	1703.9 AU/mL Abnormal NCS NCS	Reactive Normal
01-022	2nd Vaccination	21 Jun 2022	0 AU/mL Normal	Non-reactive Normal
01-022	Week 6	12 Jul 2022	1.1 AU/mL Normal	Non-reactive Normal
01-022	Week 10	10 Aug 2022	0 AU/mL Normal	Non-reactive Normal
01-022	Week 14	07 Sep 2022	0 AU/mL Normal	Non reactive Normal
01-022	Week 18	05 Oct 2022	0 AU/mL Normal	Non reactive Normal
01-022	Week 24/ET	16 Nov 2022	0.7 AU/mL Normal	Non reactive Normal
01-023	Week 14	07 Sep 2022	727.5 AU/mL Normal	reactive Normal
01-024	2nd Vaccination	21 Jun 2022	82.7 AU/mL Abnormal NCS NCS	reactive Normal
01-024	Week 6	13 Jul 2022	73.2 AU/mL Abnormal NCS ncs	Reactive Normal
01-024	Week 10	10 Aug 2022	77.2 AU/mL Normal	Reactive Normal
01-024	Week 18	05 Oct 2022	68.3 AU/mL Abnormal NCS NCS	Reactive Normal
01-024	Week 24/ET	16 Nov 2022	58.3 AU/mL Abnormal NCS ncs	reactive Normal
01-025	2nd Vaccination	21 Jun 2022	1133.6 AU/mL Abnormal NCS	Reactive Normal

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
01-025	Week 6	12 Jul 2022	1120.6 AU/mL Abnormal NCS NCS	reactive Normal
01-025	Week 10	10 Aug 2022	1103.5 AU/mL Normal	Reactive Normal
01-025	Week 14	07 Sep 2022	927.5 AU/mL Abnormal NCS NCS	Reactive Normal
01-025	Week 18	05 Oct 2022	854.8 AU/mL Abnormal NCS NCS	Reactive Normal
01-025	Week 24/ET	18 Nov 2022	857.5 AU/mL Normal	Reactive Normal
01-027	2nd Vaccination	29 Jun 2022	133.3 AU/mL Abnormal NCS NCS	Reactive Normal
01-027	Week 6	20 Jul 2022	140.3 AU/mL Abnormal NCS NCS	Reactive Normal
01-027	Week 10	18 Aug 2022	144.4 AU/mL Abnormal NCS NCS	Reactive Normal
01-027	Week 14	15 Sep 2022	153.3 AU/mL Abnormal NCS ncs	Reactive Normal
01-027	Week 18	13 Oct 2022	133.9 AU/mL Abnormal NCS ncs	Reactive Normal
01-027	Week 24/ET	18 Nov 2022	131.6 AU/mL Abnormal CS ncs	Reactive Normal
01-029	2nd Vaccination	29 Jun 2022	443.6 AU/mL Abnormal NCS NCS	Reactive Normal
01-029	Week 6	20 Jul 2022	479.6 AU/mL Abnormal NCS ncs	Reactive Normal
01-029	Week 10	18 Aug 2022	489.6 AU/mL Abnormal NCS NCS	Reactive Normal
01-029	Week 14	15 Sep 2022	437.4 AU/mL Abnormal NCS ncs	reactive Normal

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
01-029	Week 18	13 Oct 2022	413.2 AU/mL Abnormal NCS ncs	Reactive Normal
01-029	Week 24/ET	18 Nov 2022	2895.3 AU/mL Abnormal NCS NCS	Reactive
01-030	2nd Vaccination	30 Jun 2022	101.2 AU/mL Normal	reactive Normal
01-030	Week 6	20 Jul 2022	96.3 AU/mL Normal	reactive Normal
01-030	Week 10	18 Aug 2022	85.6 AU/mL Normal	reactive Normal
01-030	Week 14	15 Sep 2022	85.1 AU/mL Normal	reactive Normal
01-030	Week 18	13 Oct 2022	83.5 AU/mL Normal	Reactive Normal
01-030	Week 24/ET	23 Nov 2022	95.8 AU/mL Normal	Reactive Normal
02-001	1st Vaccination	23 Jun 2022	1546.9 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-001	2nd Vaccination	14 Jul 2022	1446.8 AU/mL Abnormal NCS Confirmed not clinically significant	Reactive
02-001	Week 6	04 Aug 2022	1245.9 AU/mL Abnormal NCS Confirmed not clinically significant	Reactive
02-001	Week 10	01 Sep 2022	1249.1 AU/mL Abnormal NCS confirmed not clinically significant	Reactive Normal
02-001	Week 14	29 Sep 2022	1237 AU/mL Abnormal NCS confifrmed not clinically significant	Reactive
02-001	Week 18	27 Oct 2022	1366.8 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-001	Week 24/ET	08 Dec 2022	1180.3 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-002	1st Vaccination	23 Jun 2022	17.3 AU/mL Normal	non-reactive

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
02-002	2nd Vaccination	14 Jul 2022	16.9 AU/mL Normal	non-reactive
02-002	Week 6	04 Aug 2022	11.7 AU/mL	non reactive
02-002	Week 10	01 Sep 2022	10.4 AU/mL Normal	non-reactive
02-002	Week 14	29 Sep 2022	2546.5 AU/mL Abnormal NCS Confirmed not clinically significant	Reactive
02-002	Week 18	27 Oct 2022	1908.6 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-002	Week 24/ET	08 Dec 2022	1196.1 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-003	1st Vaccination	23 Jun 2022	953 AU/mL Abnormal NCS confirmed not clinically significant	Reactive Normal
02-003	2nd Vaccination	14 Jul 2022	914 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-003	Week 6	04 Aug 2022	812 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-003	Week 10	01 Sep 2022	786.9 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-003	Week 14	29 Sep 2022	716.6 AU/mL Abnormal NCS confirmed not clinical significant	Reactive
02-005	1st Vaccination	12 Aug 2022	47.2 AU/mL Normal	Non reactive
02-005	2nd Vaccination	02 Sep 2022	45.9 AU/mL Normal	non-reactive
02-005	Week 6	23 Sep 2022	41.3 AU/mL Normal	non-reactive
02-005	Week 10	21 Oct 2022	38.4 AU/mL Normal	Non reactive
02-005	Week 14	18 Nov 2022	2145.1 AU/mL Abnormal NCS confirmed not clinically significant	Reactive

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
02-005	Week 18	15 Dec 2022	1060.4 AU/mL Abnormal NCS Confirmed not clinically significant	reactive
02-005	Week 24/ET	26 Jan 2023	690.7 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-008	1st Vaccination	17 Aug 2022	NA	
02-008	2nd Vaccination	07 Sep 2022	NA	
02-008	Week 6	28 Sep 2022	177.5 AU/mL Abnormal CS confirmed not clinically significant	reactive
02-008	Week 10	26 Oct 2022	197.8 AU/mL Abnormal NCS Confirmed not clinically significant	reactive
02-008	Week 14	23 Nov 2022	186.5 AU/mL Abnormal NCS Confirmed not clinically significant	reactive
02-008	Week 18	21 Dec 2022	184.2 AU/mL Abnormal NCS Confirmed not clinically significant	reactive
02-008	Week 24/ET	01 Feb 2023	180.3 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-011	1st Vaccination	31 Aug 2022	377.4 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-011	2nd Vaccination	21 Sep 2022	358.2 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-011	Week 6	12 Oct 2022	321.9 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-011	Week 10	09 Nov 2022	335.6 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-011	Week 14	07 Dec 2022	298.7 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-011	Week 18	06 Jan 2023	296.9 AU/mL Abnormal NCS confirmed not clinically significant	reactive

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
02-011	Week 24/ET	15 Feb 2023	329.2 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-015	1st Vaccination	01 Sep 2022	86.2 AU/mL Normal	non-reactive
02-015	2nd Vaccination	22 Sep 2022	127 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-015	Week 6	13 Oct 2022	73.5 AU/mL Abnormal NCS Confirmed not clinically significant	reactive
02-015	Week 10	10 Nov 2022	72.6 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-015	Week 14	08 Dec 2022	72.1 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-015	Week 18	05 Jan 2023	79.4 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-015	Week 24/ET	16 Feb 2023	75.5 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-016	1st Vaccination	01 Sep 2022	584.6 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-016	2nd Vaccination	22 Sep 2022	494.5 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-016	Week 6	13 Oct 2022	551.7 AU/mL Abnormal CS confirmed not clinically significant	reactive
02-016	Week 10	10 Nov 2022	555.4 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-016	Week 14	08 Dec 2022	534.3 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-016	Week 18	05 Jan 2023	481.6 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-016	Week 24/ET	16 Feb 2023	517.5 AU/mL Abnormal NCS confirmed not clinically significant	reactive

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
02-017	1st Vaccination	22 Sep 2022	NA	
02-017	2nd Vaccination	13 Oct 2022	46.3 AU/mL Normal	non-reactive
02-017	Week 6	03 Nov 2022	43.4 AU/mL Normal	non reactive
02-017	Week 10	01 Dec 2022	41.1 AU/mL Normal	non reactive
02-017	Week 14	05 Jan 2023	40.6 AU/mL Normal	non-reactive
02-017	Week 18	26 Jan 2023	36.7 AU/mL Normal	non-reactive
02-017	Week 24/ET	09 Mar 2023	44.2 AU/mL Normal	non-reacive
02-019	1st Vaccination	22 Sep 2022	760.7 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-019	2nd Vaccination	13 Oct 2022	2881.2 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-019	Week 6	03 Nov 2022	2190 AU/mL Abnormal NA confirmed not clinically significant	reactive
02-019	Unscheduled 1	07 Nov 2022	NA	NA NA
02-019	Week 10	01 Dec 2022	1589.1 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-019	Week 14	05 Jan 2023	1229 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-019	Week 18	26 Jan 2023	1031.8 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-019	Week 24/ET	09 Mar 2023	1113.2 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-023	1st Vaccination	22 Sep 2022	54.9 AU/mL Abnormal NCS confirmed not clinically significant	reactive

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
02-023	2nd Vaccination	13 Oct 2022	51.3 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-023	Week 6	03 Nov 2022	41.7 AU/mL Normal	non-reactive
02-023	Week 10	01 Dec 2022	40.3 AU/mL Normal	non-reactive
02-023	Week 14	05 Jan 2023	39.6 AU/mL Normal	Non-reactive
02-023	Week 18	26 Jan 2023	577.5 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-023	Week 24/ET	09 Mar 2023	225.7 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-028	1st Vaccination	20 Oct 2022	937.7 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-028	2nd Vaccination	10 Nov 2022	5278.8 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-028	Week 6	01 Dec 2022	4001.1 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-028	Week 10	03 Jan 2023	9708 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-028	Week 14	26 Jan 2023	5001.8 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-028	Week 18	23 Feb 2023	3506.4 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-028	Week 24/ET	06 Apr 2023	3068.6 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-030	1st Vaccination	20 Oct 2022	78 Abnormal NCS confirmed not clinically significant	reactive
02-030	2nd Vaccination	10 Nov 2022	76.3 AU/mL Abnormal NCS confirmed not clinically significant	reactive

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
02-030	Week 6	01 Dec 2022	3134.2 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-030	Week 10	03 Jan 2023	1063.4 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-030	Week 14	26 Jan 2023	549.2 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-030	Week 18	23 Feb 2023	480.8 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-030	Week 24/ET	06 Apr 2023	484.7 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-033	1st Vaccination	03 Nov 2022	9.9 AU/mL Normal	non-reactive
02-033	2nd Vaccination	24 Nov 2022	526.5 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-033	Week 6	15 Dec 2022	331.6 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-033	Week 10	12 Jan 2023	173 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-033	Week 14	09 Feb 2023	103.2 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-033	Week 18	09 Mar 2023	86.7 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-033	Week 24/ET	20 Apr 2023	65.8 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-037	1st Vaccination	15 Dec 2022	140.3 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-037	2nd Vaccination	05 Jan 2023	146 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-037	Week 6	26 Jan 2023	125.2 AU/mL Abnormal NCS confirmed not clinically significant	Reactive

Subject ID	Visit	Date	SARS-CoV-2 IgG S Quant	SARS-CoV-2 IgG S Abbott
02-037	Week 10	23 Feb 2023	126.4 AU/mL Abnormal NCS confirmed not clinically significant	Reactive
02-037	Week 14	23 Mar 2023	NA	
02-037	Week 18	20 Apr 2023	120.5 AU/mL Abnormal NCS confirmed not clinically significant	reactive
02-037	Week 24/ET	31 May 2023	156.9 AU/mL Abnormal NCS confirmed not clinically significant	reactive