## **Supplemental Material**

Table S1. Summary of performance characteristics as compared to the claims in the instructions for use (IFU) where \*sensitivity is derived from IFU data for samples collected from subjects within two weeks of PCR confirmed SARS-CoV-2 infection. The total number samples, false-positive (FP), and false-negative (FN) results are shown for each NEG CTRL, PCR POS, CPD, VD, and HSCT recipients. Sensitivity in PCR POS patient samples is shown for patients presenting within two weeks of symptom onset (1-2w SYMP) or since first PCR positive (1-2w PCR); all CPD; and VD at D2+4,D2+12 and D2+22 weeks; as well as at D2 and D2+4 weeks for HSCT recipients. Note: the IFU for the EP methods do not state the time since PCR positivity for the sensitivity claims and is therefore not available (N/A), \*borderline results have been excluded for EP and EU methods.

	AB IgG	AB IgM	DS IgG	*EP IgG	*EP IgM	*EU IgG	*EU IgA	RN TOT	RS TOT
NEG CTRL, total n (FP)	59 (0)	55 (0)	75 (5)	55 (4)	57 (0)	57 (1)	52 (8)	88 (0)	59 (0)
Specificity	100%	100%	93%	93%	100%	98%	85%	100%	100%
PCR POS, total n	131	74	81	113	114	67	67	160	137
1-2w SYMP (FN),	81 (46)	41 (19)	54 (40)	69 (27)	68 (35)	28 (11)	29 (2)	95 (59)	86 (43)
Sensitivity	43%	54%	26%	61%	49%	61%	93%	38%	50%
1-2w PCR (FN),	124 (54)	69 (25)	76 (44)	105 (34)	103 (47)	61 (19)	60 (5)	150 (70)	131 (52)
Sensitivity	56%	64%	42%	68%	54%	69%	92%	53%	60%
CPD, total n (FN)	28 (0)	26 (6)	14 (0)	17 (1)	18 (18)	20 (0)	18 (1)	107 (1)	100 (0)
Sensitivity	100%	77%	100%	94%	0%	100%	94%	99%	100%
VD, total n	-	-	-	-	-	-	-	168	168
D2+4, n (FN)									26 (0)
D2+12, n (FN)									26 (0)
D2+22, n (FN)									16 (0)
Sensitivity									100%
HSCT, total n (FN)	-	-	-	-	-	-	-	29	29 (10)
Sensitivity									66%
Specificity (IFU)	99.4%	99%	98.2%	99.8%	99.8%	98.6%	92.5%	99.8%	100%
*Sensitivity (IFU)	61.8%	63.8%	59.1%	N/A	N/A	29.1%	66.7%	73.1%	88.1%
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Table S2. Median (IQR) RS TOT concentration (U/mL) for vaccinated donors (VD) receiving Moderna (M) and Pfizer (P) vaccination series, as compared to hematopoietic stem cell transplant (HSCT) recipients and convalescent plasma donors (CPD) with neutralizing antibody titers ID50>100 (Figure 6). Statistically significant differences (p<0.0001) in antibody concentrations were observed between donors receiving Moderna and Pfizer vaccinations for all timepoints (shown in weeks) beyond the initial dose. HSCT recipients demonstrated significantly lower antibody responses (p<0.0001) from healthy VD (Moderna and Pfizer combined). *Note: not all timepoints were available for all VDs.* 

	D1+2	D2	D2+4	D2+12	D2+22	CPD
VD M	76	363	6642	3205	1491	-
(n=16)	(32-177)	(201-386)	(4586-8146)	(2010-4717)	(1167-3142)	
VD P	23	57	1781	1408	1000	-
(n=11)	(8-39)	(45-101)	(1057-2284)	(748-1556)	(670-1225)	
HSCT		1.0	204	-	-	-
(n=10)	-	(0.4-8)	(1.4-1704)			
CPD	-	-	-	-	-	368
(n=100)						(186-783)