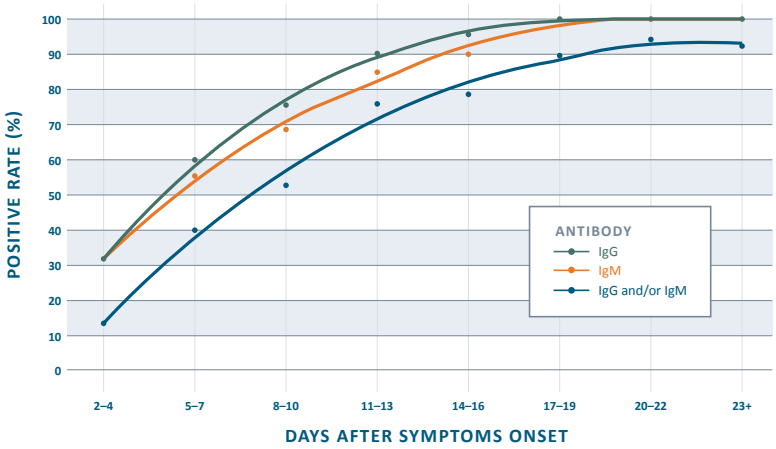
SARS-CoV-2 Total Antibody (IgM + IgG) Test

In patients infected with SARS-CoV-2, specific antibody production is detectable by days 2-4 (post-symptoms-onset). IgM and IgG antibodies are detectable at essentially the same time post-symptoms-onset, with blood levels of Total Antibody (IgM + IgG), or IgG alone, both exceeding the level of IgM antibody *(see Graph #1 below)*.

Initial studies have shown that, **within the first 7 days post-symptoms-onset, COMBINED TESTING with polymerase chain reaction (PCR) nucleic acid testing AND antibody testing, produces a Detection Sensitivity of almost 99%.** PCR-alone-testing, during this period, shows a 50-70% Detection Sensitivity, although this rate should improve with use of high-sensitivity PCR tests, such as the one developed and used at HealthTrackRx *(see HealthTrackRx' FDA EUA Study in Reference Section below)*.

Antibody-alone-testing during this period, shows a Detection Sensitivity of about 40-60%. During the second week (days 7-14 post-symptoms-onset), PCR Detection Sensitivity is generally 50-60%, with Antibody Test Detection Sensitivity increasing to about 90% *(see Graph #2 below)*.

After the first 14 days (post-symptoms-onset), PCR Detection Sensitivity continually declines, while Total Antibody Test Detection Sensitivity improves to 95-99%.



* DAYS	2–4 (N=22)	5–7 (N=45)	8–10 (N=70)	11–13 (N=79)	14–16 (N=70)	17–19 (N=47)	20–22 (N=17)	23+ (N=13)
IgG	7	25	48	67	63	47	17	13
IgM	3	18	37	60	55	42	16	12
IgG and/or IgM	7	27	53	71	67	47	17	13

** Number of serum samples with positive results*

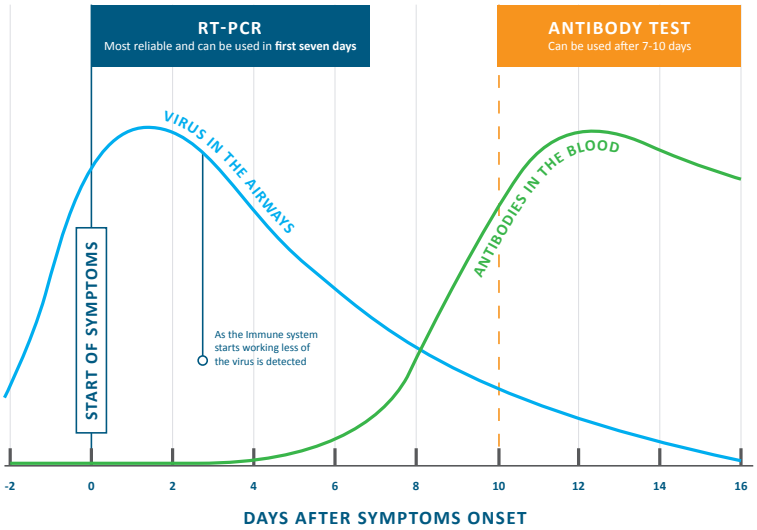
GRAPH #1: Quan-Xin Long et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nature Medicine (2020) https://doi.org/10.1038/s41591-020-0897-1

HealthTrackRx has selected a SARS-CoV-2 specific Total (IgM + IgG) Antibody Assay, which targets the S1 Receptor Binding Domain (S1-RBD) region of the SARS-CoV-2 Spike Protein. This target was selected, as it is the most specific target for SARS-CoV-2 and, to date, no cross-reactivity to SARS-CoV-1 virus, other Coronaviruses, or to other commonly encountered viruses, has been reported, with use of this Total Antibody Assay. Initial studies have shown that the main neutralizing antibodies (produced during natural recovery phase post-infection, or as a result of vaccination) target the Spike protein generally, and specifically the S1-RBD region. Vaccine producers are mainly targeting the Spike protein or the S1-RBD region, and Total Antibody Assays utilizing the S1-RBD target, are expected to be valuable in determining whether an adequate patient-specific antibody response is produced post-vaccination.

Post-infection-recovery-phase antibody testing is invaluable, in identifying individuals with higher levels of neutralizing antibodies. These individuals are potentially excellent candidates for plasma donation. Their plasma contains life-saving antibodies, of particular use in the elderly and other 'immunosuppressed' patients, who cannot mount an adequate natural or vaccine-induced immunity. The elderly (>65 years old), on average, mount an adequate post-vaccine immune response in only 30-50% of cases. This contrasts with younger patients, who on average, produce an adequate post-vaccine immune response in about 75-95% of cases (both age groups' response rates vary by specific administered vaccine).

Summary of Uses for the HealthTrackRx SARS-CoV-2 Total (IgM + IgG) Antibody Assay:

1. Combine with PCR testing, during early and mid-phase infections, to increase Detection Sensitivity.
2. Use in Late-phase infection, to assess "Natural Immunity", and to identify those individuals with higher levels of potentially life-saving plasma antibodies.
3. Potentially useful in patient-specific SARS-CoV-2 vaccination; initial baseline level, followed by post-vaccination antibody level assessment.



GRAPH #1: UKRI (United Kingdom Research and Innovation). What is the purpose of testing for COVID-19? (April 14, 2020) https://coronavirusexplained.ukri.org/en/article/vdt0006/

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Notes:

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