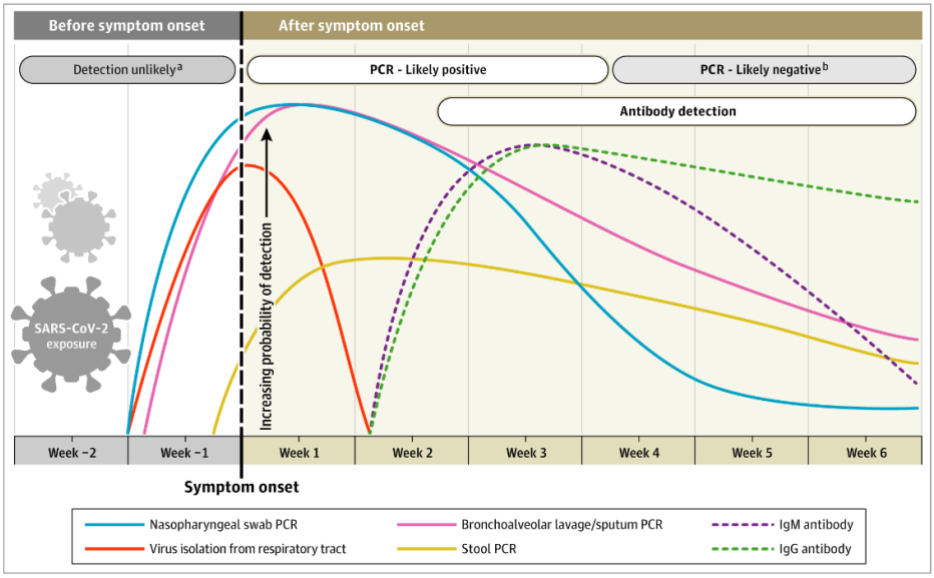
# Evolved value proposition of *OnSite* COVID-IgG/IgM Rapid Test

## Window for detection of SARS-COV-2 infection

SARS-COV-2 is a new virus, emergent to humans. Since its first report in December 2019, we have gained tremendous understanding of its transmission, virus replication in the human body, immunoresponse, pathogenesis, clinical symptoms, diagnosis and treatment.

Nandini Sethuraman et al[1] concluded a most comprehensive and sound laboratory testing window with different technologies based on all of the studies published.




It clearly promotes that detection sensitivity for SARS-COV-2 antibodies or NTA varies significantly from the time the specimens are taken. Often, we have seen specimens drawn far too early (i.e., less than two weeks after the onset of symptom) for a body's immune response to have released the minimum levels of antibodies that an antibody test would need to detect infection.

A review article suggests that Over the 4 days of infection before the typical time of symptom onset (day 5), the probability of a PCR false-negative result in an infected person was 100% on day 1 after infection before onset, and 68% on day 4 after infection before onset.[2] On the day of symptom onset, the median false-negative rate was 38%. This decreased to 20% on 3 days after symptom onset, then began to increase again, from 21% on day 9 to 66% on day 21.

CTK's *OnSite* COVID-19 IgG/IgM Rapid test was evaluated by The Doherty Institute's study, "Post-market validation of three serological assays for COVID-19" showing a curve in IgM and IgG detection similar to the one illustrated above.[3] The data showed an increase in IgM detection up to 20 days post-symptom onset, followed by a decrease, while IgG performance showed detection increase for up to 30 days.

In summary, the time of testing relative to the onset of symptoms is critical to achieve highest detection rate for any test.

***OnSite* COVID-IgG and IgM Rapid Test performance over time, after onset of symptoms**

The *OnSite* COVID- IgG/IgM is designed to specifically detect IgG or IgM antibodies in human serum, plasma and whole blood, as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior SCAR-COV-2 infection. The result does not provide an answer to whether the individual has an acute infection. A confirmative test is required to diagnose acute infection.

Both in-house and outside evaluation studies of the *OnSite* COVID-19 IgG and IgM rapid test were conducted in multiple countries, and they consistently show high antibody detection rate on specimens collected after 2-3 weeks from first demonstration of symptoms (see table 1 below).

| Country | Laboratory | IgG or IgM | | | Overall specificity | Recommendation |
|---|---|---|---|---|---|---|
| | | < 2 weeks | 2 -3 weeks | >3 weeks | | |
| **N/A** | **In house** | 85% | 80% | 98.2% | 97.8% | For adapt immunity |
| **Kuwait** March | Jaber Alahmad Hospital Laboratory Department | 88% on specimens collected after 2-3 days | | | 100% | Not for early diagnostic test, for late stage test |
| **Demark** March | Statens Serum Institute | 71.4% | 93.3% | 100% | 100% | N/A |
| **Norway** April | Norwegian Institute of Public Health | 40% (medium 5 days) | N/A | 87% (medium 30 days) | 92% - 100% | Detect past infection, not for diagnosis acute infection |
| **UK** May | Unilabs | 52.00% | 100% | | 100% | Suitable for use to detect COV-2 antibodies |
| **Australia** May | Doherty Institute | 31.0% | 77.8% | 86.0% | 95.6% | Recommend for population antibody test |

Table 1: Summary of results of multiple evaluation studies in different countries

These results are in agreement with USA FDA latest guidelines on the application of serological tests: identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

The *OnSite* Rapid Test features 1) a low complicity test method, that can be used by any health care provider with minimal training, 2) not need for instrument or electricity, 3) a 10-15 minutes time to results, 4) the possibility of using multiple specimen types, including fingertip capillary blood. Therefore, this test is suited for the following scenarios:

- Testing at clinics and labs for individual screening of patients who are suspected of COVID-19 exposure, or have shown symptoms
- Employees being tested before returning to work
- Screening given to professionals with close proximity to coworkers and customers, such as airline, restaurant, cruise or sea freight workers, or military personnel.
- Education system testing faculty, staff and students before returning to the classroom.

1. Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. Published online May 06, 2020. doi:10.1001/jama.2020.8259
2. Tollanes M.C, Bakken Kran A, Abildsnes E, Jenum P.A, Breivik A.C. and Sandberg S. Evaluation of eleven rapid tests for detection of antibodies against SARS-CoV-2. Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus). Published online April 24, 2020. https://www.noklus.no/media/ffkpk53g/report_1_covid19_rapidtests_noklus_2020.pdf
3. Bond K, Nicholson S, Hoang T, Catton M, Howden B and Williamson D. Post-market validation of three serological assays for COVID-19. Doherty Institute. Published online April 29, 2020 https://www.health.gov.au/sites/default/files/documents/2020/05/post-market-validation-of-three-serological-assays-for-covid-19-final-report.pdf