



## **Rapid and reliable mass-testing solutions by ender diagnostics provide a novel approach for an effective management of the COVID-19 pandemic**

The current pandemic management strategy of testing symptomatic people and the issue of infectious but asymptomatic carriers spreading the virus

In December 2019 the world was hit by the ongoing coronavirus pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The rapidly spreading disease created a global need for diagnostic solutions for the newly emerged challenges.

An infection with SARS-CoV-2 can produce respiratory symptoms and high viral loads (VL) in infected individuals with exponential growth of virus, leading to a peak viral load and infectiousness, and ending with declining viral levels and clearance. Infectiousness was shown to peak at two days before to one day after symptom onset (Xi He et al. Aug 2020). Current strategies for pandemic management are based on testing symptomatic people, with a positive test result leading to ordered isolation or placement in medical custody depending on severity.

Such strategies of selective testing do not account for asymptomatic but infectious carriers, thus allowing SARS-CoV-2 to spread quickly and unmonitored resulting in infection chains not being adequately traceable (Zhiru Gao et al. May 2020). This barely controlled spread of the virus increases the risk for additional lockdowns, school closures and consequential macroeconomic losses.

Distinguishing between infectious versus non-infectious individuals

Over the course of the pandemic, knowledge of epidemiological processes has increased rapidly and the critical viral load has now been described in studies (Jeroen J.A. van Kampen et al. June 2020, Wölfel et al. April 2020). The key questions to consider are the duration and determinants of infectious viral shedding.

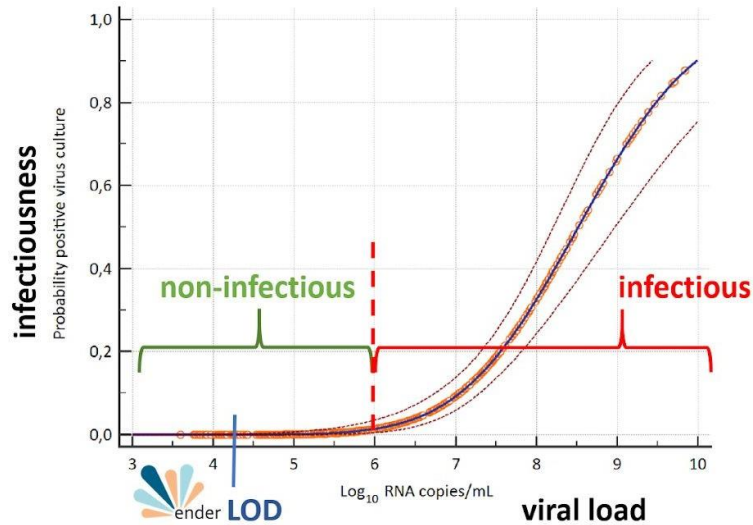


Figure 1: Graph showing the correlation between infectiousness and viral load. It is important to note that the limit of detection (LOD) of the ender test falls within the range of viral loads in which individuals are considered to be non-infectious. Adapted from Jeroen J.A. van Kampen et al. June 2020

Looking at the data presented in the graph above, it is paramount to distinguish between individuals falling in the range of either “infectious” or “non-infectious” and subsequently taking the required measures. This distinction allows for scientific data-driven decisions on where to decree local lockdowns and rules of conduct.

A study published in June 2020 by Daniel B. Larremore demonstrated that given the pattern of viral load kinetics (Figure 2) effective surveillance, including time to first detection and outbreak control, depends largely on frequency of testing and the speed of reporting, and is only marginally improved by high test sensitivity.

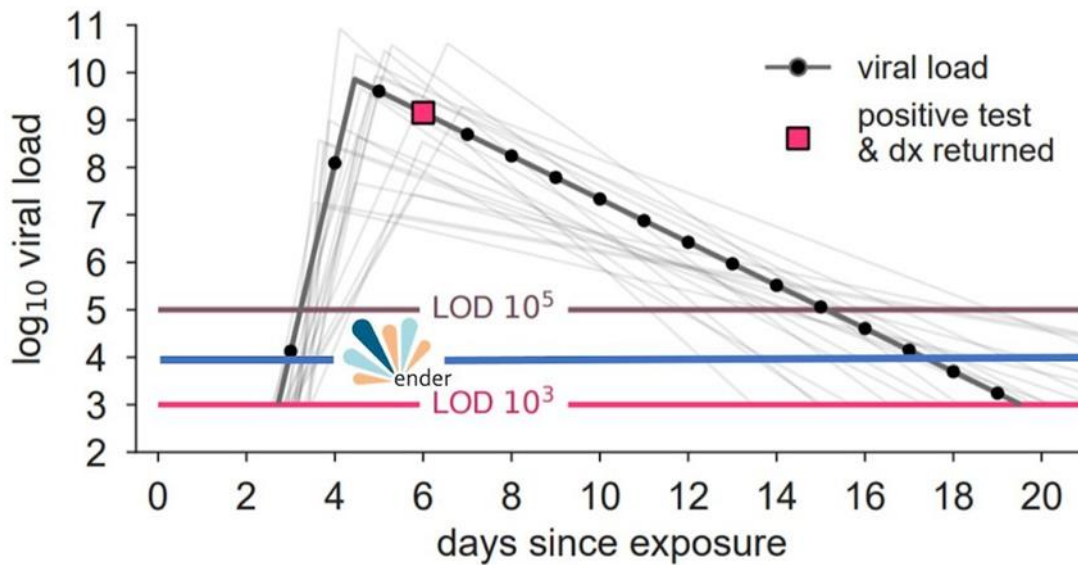


Figure 2: The Figure shows minimal differences in effective surveillance using viral detection tests of different sensitivities, such as RT-qPCR with a limit of detection (LOD) at  $10^3$  cp/ml compared to often cheaper or faster assays with higher limits of detection (i.e., around  $10^5$  cp/ml) or the LOD of ender diagnostics test kits ( $10^4$  cp/ml). Adapted from Daniel B. Larremore et al June 2020.

We present three examples where broad testing with sensitive and specific methods is highly beneficial:

**Medical staff** is facing extremely high exposure with varying degrees of equipment for personal protection available. If the people who are taking care of the most vulnerable are asymptomatic spreaders themselves, the patients in their care are at high risk for infection.

**School environment** poses a high risk for infection, with an exceptionally high amount of people in a confined space, as well as social distancing rules being difficult to enforce. Teachers with underlying diseases are at increased risk for severe COVID-19.

**Duration of quarantine** of previously positive tested individuals, their relatives and travellers from high-risk geographical regions can be reduced by consequent testing. Studies examining the duration of infectious viral shedding show that case by case



testing is required to re-assess the individual duration of the currently standardized quarantine lasting 10 days (Jeroen J.A. van Kampen et al. June 2020).

Considering the cases where extensive testing is key to manage the pandemic, decision-makers need to focus on innovative solutions available to make rigorous testing a reality.

The test solutions of ender diagnostics enable the detection of infectious but asymptomatic individuals posing a threat to the health of the many

ender diagnostics is a Swiss company specialized in molecular diagnostic tests for the reliable and rapid detection of COVID-19 infections. Since the onset of the pandemic, ender diagnostics has launched two CE-marked rapid tests. The sensitivity and specificity of the products match the specifications of routinely used rtPCR diagnostics. The limit of detection of the ender tests falling in the non-infectious range guarantees a positive test result for every infectious carrier (Figure 1). Due to the simplified sample preparation not requiring a conventional RNA extraction, the time to result is drastically reduced and allows for higher sample throughput.

With increased testing capacities and simplified assay procedure, the ender testing solutions allow for accurate evaluation of prevalence of infectious asymptomatic individuals to detect superspreaders early and bring the chain of infection to a halt.

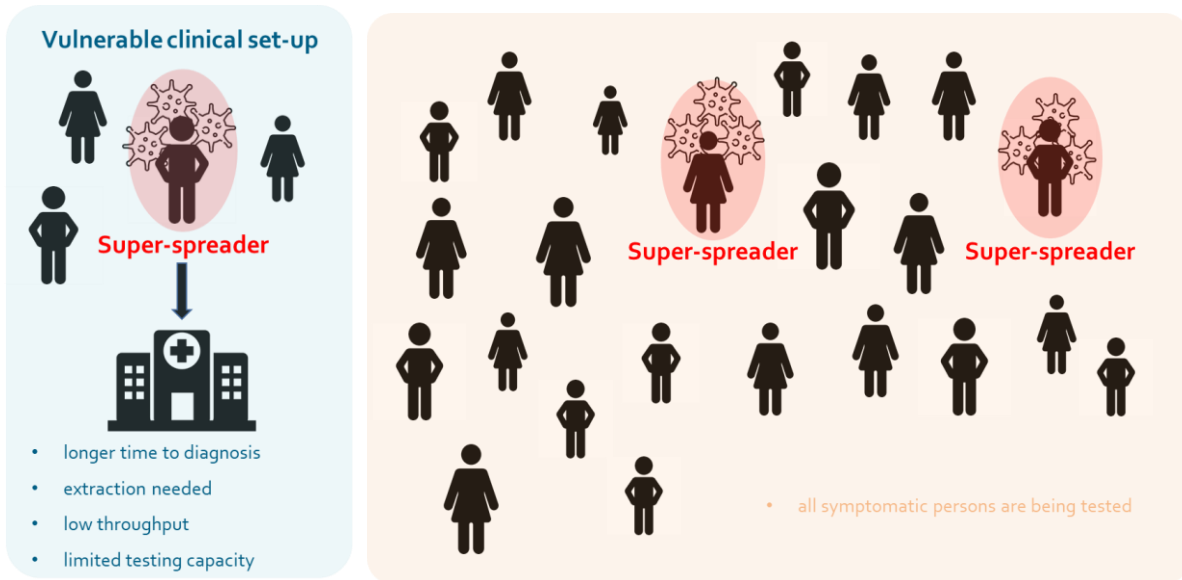


Figure 3: The figure above exemplifies how testing solutions with a massive increase in throughput, such as the testing provided by ender diagnostics, can complement the conventional testing procedures based on rtPCR.

How do we proceed?

By observing the pandemic spread globally, establishing routine diagnostic procedures and contact tracing measures, the world has settled into a new “normality.” To mitigate risks in daily life, currently applied testing schemes need to be re-evaluated. Looking at the newest epidemiologic data, special focus needs to lie on quickly identifying infectious but asymptomatic people spreading the virus. The gold standard of current testing capacities is far from testing large numbers of asymptomatic carriers and therefore novel strategies are required. With ender testing solutions we offer shorter times to result, higher sample throughput at uncompromised sensitivity and specificity supporting efforts to evaluate the prevalence of infectious asymptomatic individuals and breaking the infection chain.

**Let’s return to normal!**

## References

Xi He et al Aug 2020; Temporal dynamics in viral shedding and transmissibility of COVID-19  
Zhiru Gao et al May 2020; A systematic review of asymptomatic infections with COVID-19

Jeroen J.A. van Kampen et al June 2020; Shedding of infectious virus in hospitalized patients with coronavirus disease-2019 (COVID-19): duration and key determinants

Wölfel et al. April 202; Virological assessment of hospitalized patients with COVID-2019

Daniel B. Larremore et al June 2020;; Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance