

Application note

Comparative performance review of the ReadyGo Sampler™ sample collection device vs traditional sample collection techniques in SARS-CoV-2 testing.

- Sampler demonstrated excellent concordance with both the FlowFlex™ standard protocol and RT-qPCR.
- Provides a viable alternative for sample collection and processing in a single, easy-to-use disposable.
- Conducted independently by a European institution, registered and experienced in research and experimental development.
- Simple sample collection device with scope for use with multiple sample types, in various industries.

Introduction

The SARS-CoV-2 pandemic continues to greatly influence healthcare provision across the globe¹². The move to point-of-need testing has seen people all over the world, become familiar with the sampling and processing of lateral flow tests. This increased public exposure to the testing process has been a source of high-quality feedback and has highlighted a need for simpler and more environmentally friendly approaches to testing³⁴⁵.

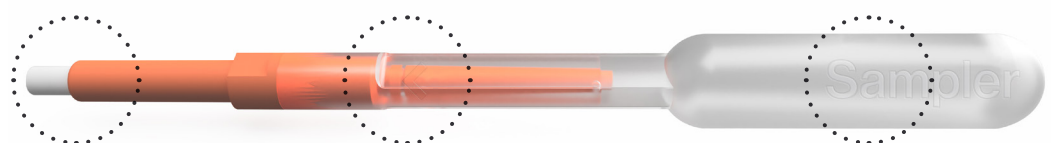
In response to this need ReadyGo has developed Sampler, a novel sample collection device which could vastly improve convenience, reduce user error and be more sustainable.

Sampler facilitates simple sample collection by cleverly combining a sampling nib and pre-filled buffer bulb into one disposable component. In three simple steps, users can sample, release buffer, and dispense onto the diagnostic assay of choice – Sample, Snap, Squeeze.

Hospital Carlos III (Madrid, Spain), evaluated Sampler in September 2021, reviewing ease of use and sample suitability for testing. The testing platform used for the evaluation was the FlowFlex™ SARS-CoV-2 lateral flow device. The results were compared against standard testing protocols and RT-qPCR testing data.

Convenience and reproducibility

Compatible with Lateral Flow, Nucleic Acid Tests and other biochemical assays.



Sampler nib

Engineered material
Absorbs a defined volume of sample
Incorporates pre-treated reagents that can instantaneously lyse viral and bacterial cells
Human safe for oral collection

Snap valve

Simple user operation

Sampler buffer

Defined volumes from 50µl to 500µl in a single squeeze. Allows accurate dilution for biochemistry assays.

Objectives

The primary objective of the study was to assess whether the ReadyGo Sampler sample collection device was suitable for use with lateral flow devices without a loss of analytical performance when compared to the standard swab and buffer.

Materials & Method

The study used retrospective clinical samples (N=60, 30 positive and 30 negative) and included individuals across ages 18 to 65+ years and Ct values of <30. Upon collection samples were assessed using the TaqPath® COVID-19 CE-IVD RT-PCR high sensitivity molecular test, verified as SARS-CoV-2 positive or negative, and then stored frozen.

On the day of analysis, the samples (saliva, nasal swab, and nasopharyngeal swab (NP)) were removed from the freezer and allowed to equilibrate at room temperature.

A Sampler, containing ReadyGo buffer was used in place of the swab and buffer provided with the FlowFlex lateral flow device (LFD). The Sampler nib was immersed into the saliva sample to allow absorption, once complete the valve was broken to release the buffer and the bulb squeezed to dispense the sample/buffer mix onto the FlowFlex LFD.

Two comparator methods were utilised:

- FlowFlex LFD with a nasal swab and kit provided components, processed according to the FlowFlex instructions for use.
- TaqPath® COVID-19 CE-IVD RT-PCR Kit with a NP swab and extraction using the Maxwell® RSC Buccal Swab RNA Kit and generating three amplification plots for the ORF 1ab, N and S gene targets.

The lateral flow devices were observed according to the timeframe defined by FlowFlex and the presence of a control and test line were monitored. Results were scored by a trained scientist and comparative photos of both methods were captured.

ReadyGo Sampler FlowFlex Swab



Excerpt from study photos showing LFD result using ReadyGo Sampler (R) and FlowFlex Swab (S)

Results - Sampler

SARS CoV-2	#Test	#(+)	#(-)	Sensitivity
+	30	30	0	100%
SARS CoV-2	#Test	#(+)	#(-)	Specificity
-	30	0	30	100%

Table 1: Test results summary

Method	Status	# Samples	# (+)	# (-)
Sampler	(+) Positive	30	30	0
	(-) Negative	30	0	30
FlowFlex	(+) Positive	30	30	0
	(-) Negative	30	0	30
RT-qPCR	(+) Positive	30	30	0
	(-) Negative	30	0	30

Conclusion

The results show strong concordance with both the standard swab and buffer system, and with RT-qPCR testing. The technicians carrying out the study also reported that the ReadyGo device was simpler, easier, and faster to use than the standard swab and buffer components.

The success of this study supports use of a single disposable for sampling and processing, offering a more sustainable method with less plastic waste compared to other products.

Further studies will continue to assess the breadth of samples that Sampler can support and there is a wealth of possibilities for its use in other diagnostic assays.

References

1. The COVID-19 pandemic in 2023: far from over. Editorial (2023). Lancet. Volume 401, Issue 10371, p79.
[https://doi.org/10.1016/S0140-6736\(23\)00050-8](https://doi.org/10.1016/S0140-6736(23)00050-8)
2. Considerations for implementing and adjusting public health and social measures in the context of COVID-19. World Health Organisation. Interim guidance – 30 March 2023
<https://www.who.int/publications/i/item/who-2019-ncov-adjusting-ph-measures-2023.1>
3. Budd, J., Miller, B.S., Weckman, N.E. et al. Lateral flow test engineering and lessons learned from COVID-19. Nat Rev Bioeng 1, 13–31 (2023).
<https://doi.org/10.1038/s44222-022-00007-3>
4. How to make lateral flow tests more sustainable? Medical Device Network, Miller, A. 17 June 2023.
<https://www.medicaldevice-network.com/features/lfts-plastic-waste-sustainability/>
5. Ongaro, A., Ndlovu, Z., Sollier, E., et al. Engineering a sustainable future for point-of-care diagnostics and single-use microfluidic devices. Lab Chip, 2022, 22, 3122
<https://pubs.rsc.org/en/content/articlepdf/2022/lc/d2lc00380e>

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