HomeScreen Saliva collection CEIVD kit

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Introduction

Currently, SARS-Cov-2 detection is based on nasopharyngeal (NP) samples which requires collection by a healthcare professional at a hospital or laboratory. This process is not convenient for large-scale testing and causes patient discomfort. We developed a device for sputum/saliva collection with RNA preservation and virus inactivation that could be used by anyone at home. The device is supplied with a unique QR-code that enables data entry through web-application and the data can be retrieved through diagnostic laboratories.

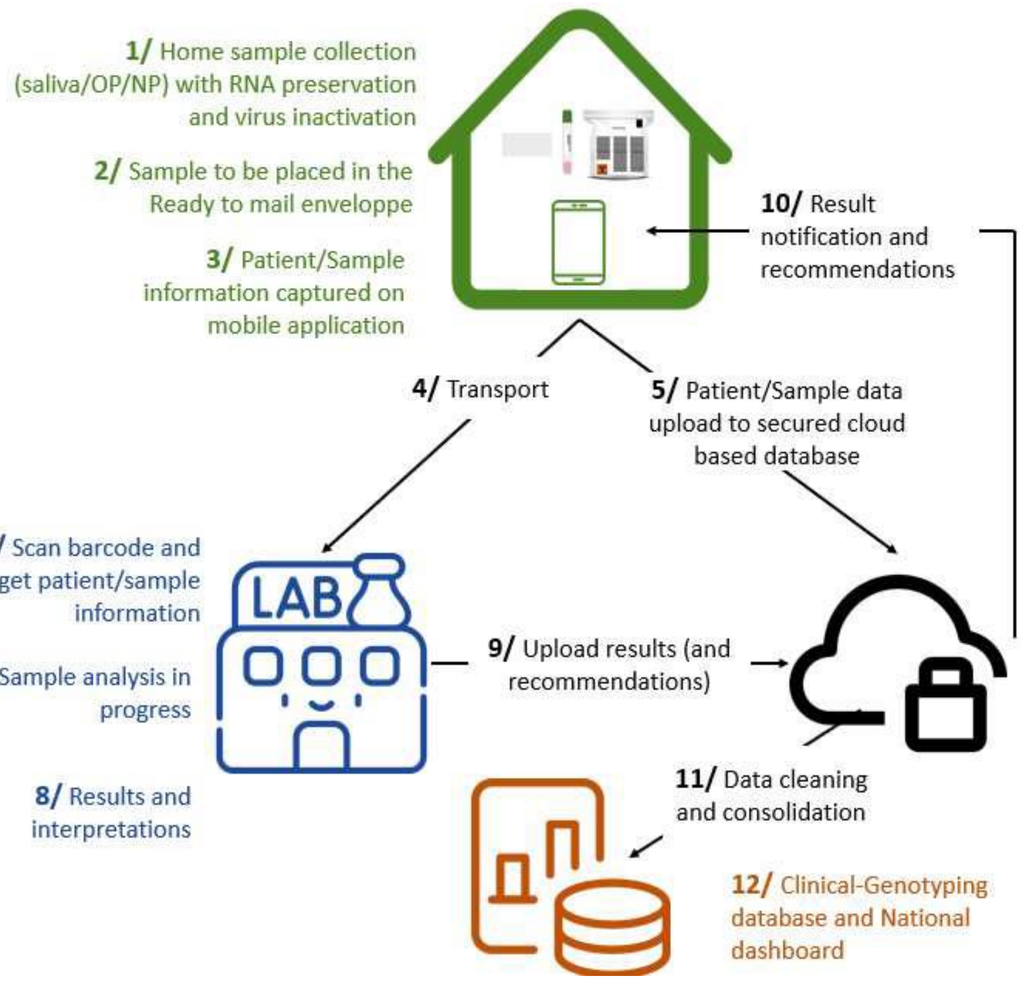

Fig. 1: proposed workflow for HomeScreening sample collection.

Methods

Saliva samples were collected at the Luxembourg Laboratoire national de santé (LNS) in parallel with NP samples from the same patient. NP samples were processed by LNS routine analysis for SARS-CoV-2 using Seegene Allplex kit. We used the ABL UltraGene SARS-CoV-2 Universalis kit to test the saliva samples. The samples were pre-treated with proteinase K to reduce viscosity. Data from the saliva samples were shared with LNS for comparison with NP samples.

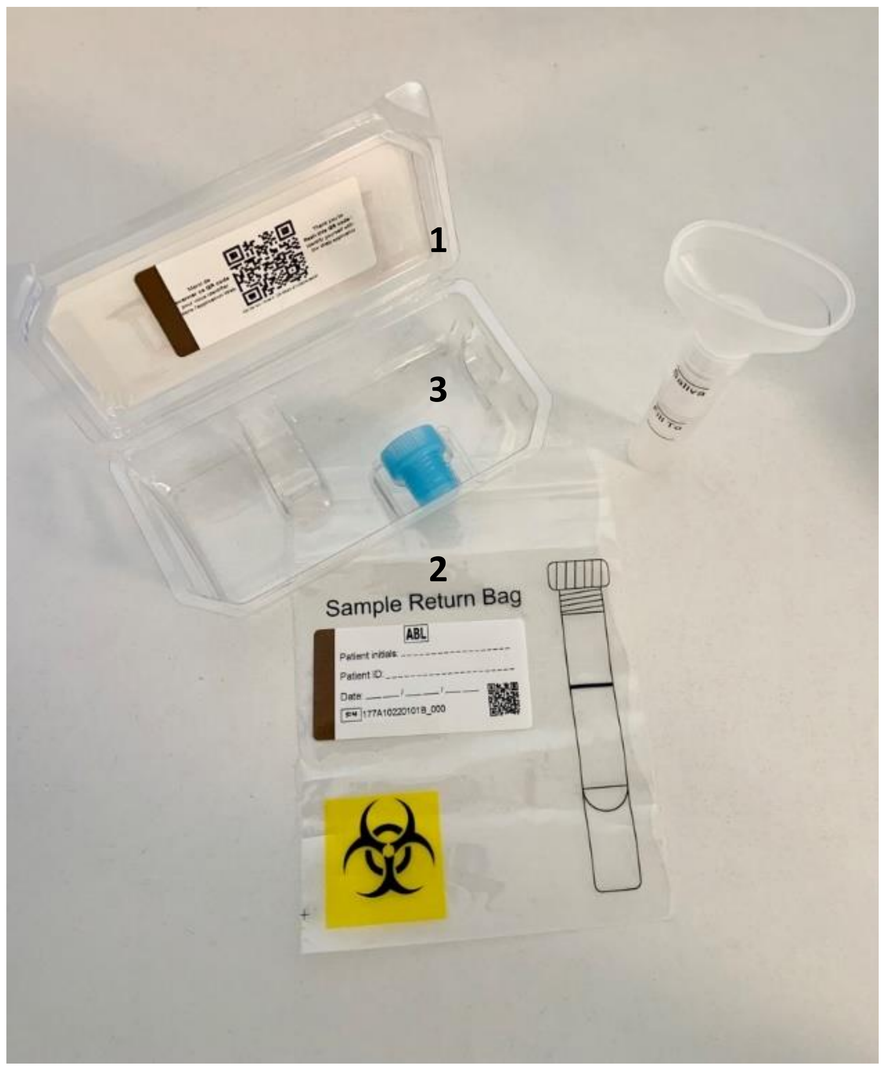

Fig. 2: Saliva collection kit components 1) Saliva collection tube filled with Inactivation and Preservation Solution and equipped with a screwed saliva collection funnel 2) Sample bag biohazard for specimen mailing packing 3)Blue screw cap to safely covered the receptacle filled with the oral fluid mixed with the viral inactivation and preservation solution

Results

In total, 89 clinical saliva and their respective NP samples were collected. There was good detection rate agreement between saliva and NP samples 95% and 93.1% for positive and negative samples respectively. There was high variation in ΔCt between NP and saliva samples - 8.6±5.8 with high standard deviation

		NP	
		POS	NEG
Saliva	POS	57	2
	NEG	3	27
		60	29

Positive samples: (57/60, 95% CI: 86.1% - 99.0%)
Negative samples: (27/29, 95% CI: 77.2% - 99.2%)

Discussion

We have developed an easy to use and convenient device for saliva sample collection. Clinical evaluation for SARS-CoV-2 testing showed good agreement with NP samples (95%). The high ΔCt between NP and saliva samples could be due to individual variations in samples collection. Nevertheless, it did not highly impact the detection rate