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## Introduction

The emergence of the SARS-CoV-2 pandemic resulted in the urgent need for fast, sensitive and non-laborious diagnosis. The current state-of-the-art for diagnosis is nucleic acid detection with qPCR kits. These kits are produced in solutions that need to be mixed to prepare the reaction. Also, the kit's reagents are thermolabile, requiring frozen shipment. We developed a highly sensitive lyophilized qPCR kit that can be shipped at ambient temperatures, doesn't need prior preparation as the sample can be added directly to the reaction

## Methods

We designed primers and probes targeting 2 conserved genes (N and rdrp) in the SARS-CoV-2 genome based on all emergent variants. We developed our formula of all qPCR components in a single master mix that was lyophilized directly in qPCR tubes. We tested the 15 clinical samples with both PrimeCheck and standard qPCR kit.



Fig. 1: 8-tube strip with lyophilized master mix for direct qPCR set up

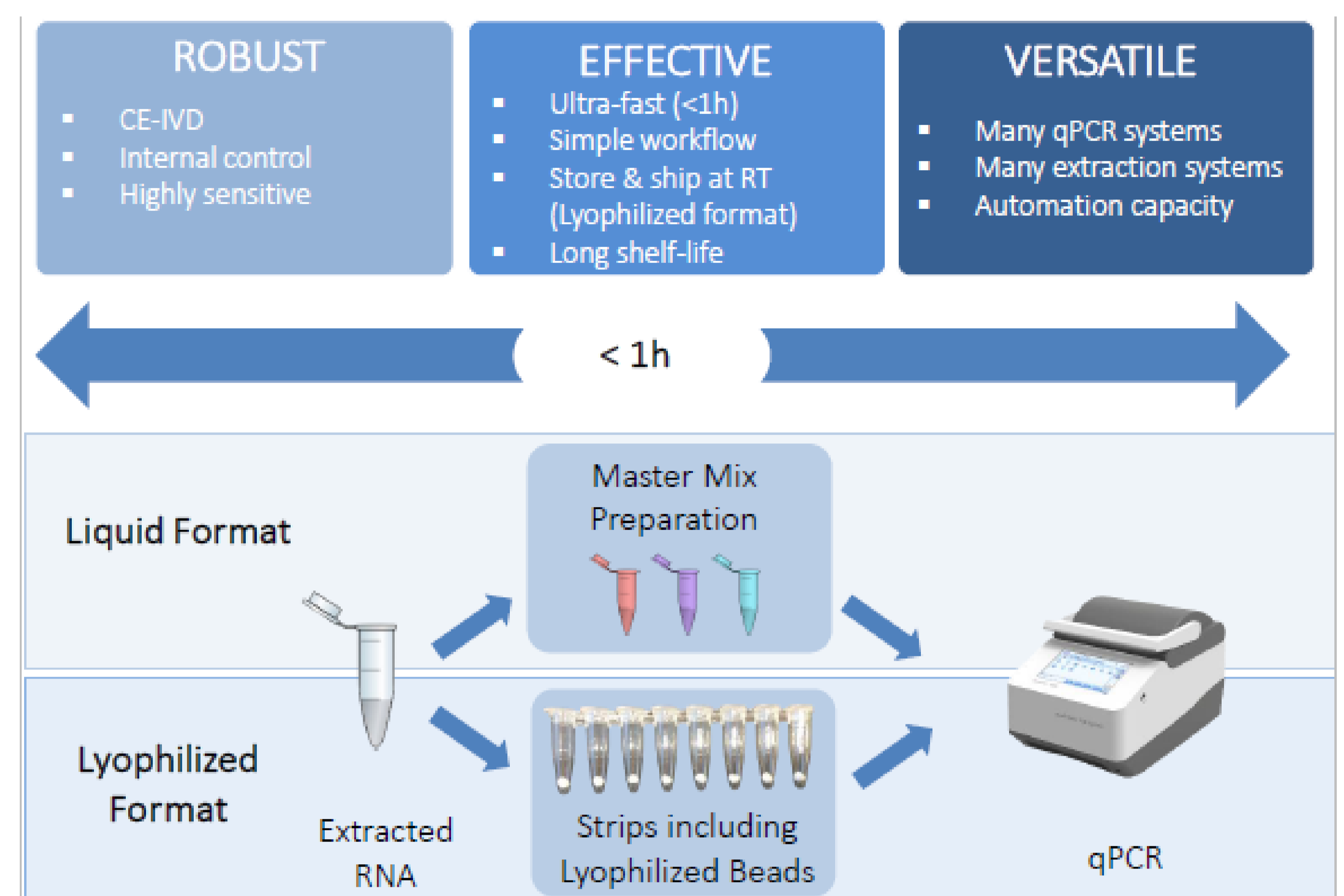


Fig. 2: PrimeCheck is available in two formats, liquid and premixed lyophilized. The kit is robust, effective and versatile

## Results

It took almost 115 minutes for reaction setup and qPCR run for standard qPCR kit while it took 60 minutes using PrimeCheck reducing workflow by half. Moreover, Ct values were better using PrimeCheck where the N and rdrp targets were detected 3 and 1.6 cycles earlier than standard qPCR.

## Discussion

PrimeCheck is an easy-to-use and highly sensitive qPCR CE-IVD kit that can be shipped and stored at ambient temperature. The kit offers fast and easy qPCR setup eliminating human error in reaction mixing and save time by almost half. Finally, it can be shipped at ambient temperature reducing the shipping cost and the risk of reagents degradation during long shipment.