



TANBead RT-LAMP SARS-CoV-2 detection kit

I. Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), has infected millions of people around the world. The outbreak caused by the novel coronavirus (SARS-CoV-2) poses a great health risk to the public. The current standard method for coronavirus detection is the reverse transcription-polymerase chain reaction (RT-PCR) method. However, laboratory-based RT-PCR test for SARS-CoV-2 detection needs complex facilities and elaborate training of operators, thus it is suffering from limited testing capacity and delayed results obtainment.

Therefore, a rapid and accurate diagnosis of the virus plays a crucial role in the clinical treatment of this disease. In overcoming the time-consuming RT-PCR method, loop-mediated isothermal amplification assay (LAMP) has been emerging as a great alternative. LAMP is a gene amplification technique for replicating nucleic acid under an isothermal condition, eliminating the time required for instrument heating and cooling that is continuously done during PCR cycles. TANBead RT-LAMP SARS-CoV-2 detection kit was designed based on this technique, serving as a rapid alternative to PCR-based diagnostic tools for CoV-2 gene detection.

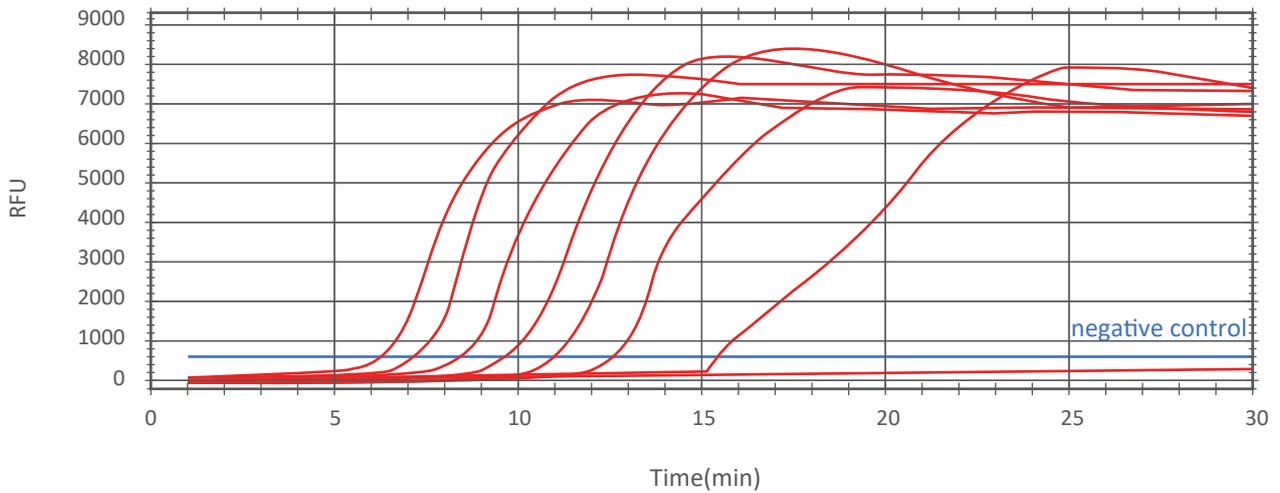
II. Advantages

- Provide highly sensitive nucleic acid detection within 30 minutes.
- Amplification is performed at a constant temperature by using simple and low-cost equipment.
- Provides a potentially larger diagnostic capacity while maintaining similar sensitivity and specificity.

III. Application data

Table 1. This kit is designed for Loop-mediated isothermal amplification (LAMP), which is a type of Nucleic Acid Amplification Tests (NAATs). The reaction utilizes a set of primers to rapidly amplify a specific DNA fragment at 65°C with reverse transcriptase and recombinant Bst DNA polymerase. This assay is very time-efficient and sensitive, in which strongly positive samples can generate results as soon as 10 minutes (Fig. 1). Even with varying RNA input amount (10^{-10} - 10^7), TANBead RT-LAMP could amplify the SARS-CoV-2 RNA in less than 20 minutes (Fig. 2). All in all, the process of gene amplification and detection using our kit could be done under 30 minutes.

A. Amplification curve with TANBead LAMP Kit



B. Amplification curve with D-brand RT-PCR-based Kit

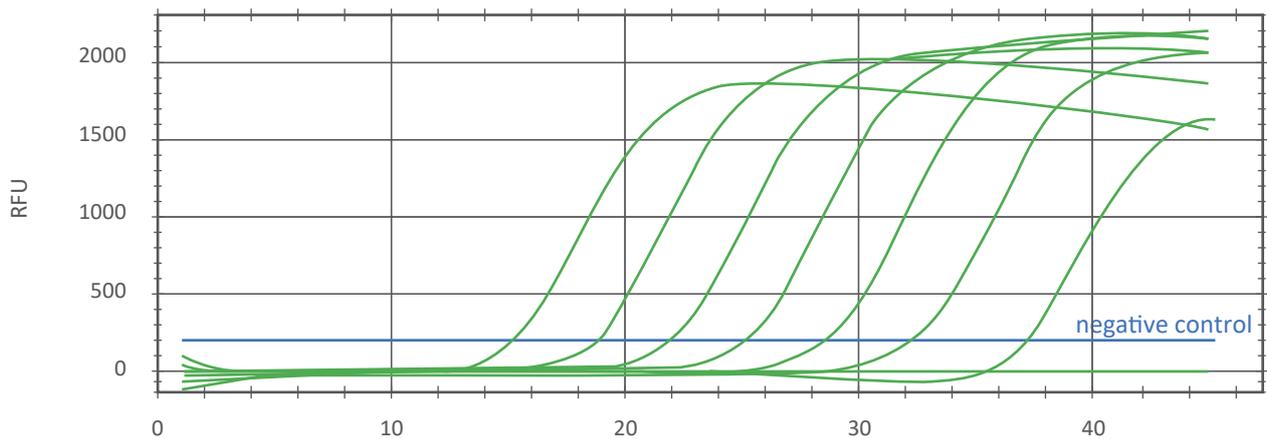


Figure 1. Comparison of RT-LAMP and RT-qPCR kits for the detection of SARS-CoV-2 RNA samples, both performed on CFX96™ Real-Time PCR Detection System. Ten-fold serial dilutions of SARS-CoV-2 RNA (10^7 - 10 copies/reaction) were prepared then amplified with (A) TANBead® RT-LAMP reagents or (B) DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit. The relative fluorescence units (RFU) indicated the presence of SARS-CoV-2 N gene nucleic acid in samples. The Ct values of each dilutant (containing 10^7 to 10 copies) and negative control were 15.06, 18.61, 21.85, 25.06, 28.46, 21.18, 36.97, and ND (not detected), respectively.

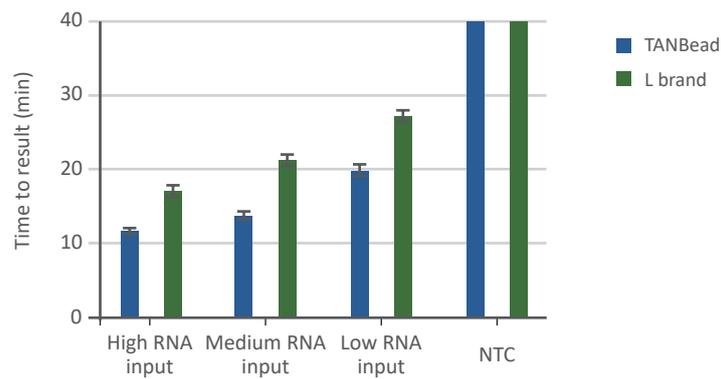


Figure 2. Detection of SARS-CoV-2 RNA via real-time RT-LAMP. Blue bars represent TANBead’s detection kit, while the green bars represent competitor L brand’s kit. Clinical SARS-CoV-2 RNA samples previously calculated with RT-qPCR were prepared and categorized as low (10^3), medium (10^5), and high (10^7) RNA input to demonstrate the effect of RNA amount to detection time (each $n = 4$), expressed as time-to-result (min). No template control (NTC) signal indicated no SARS-CoV-2 RNA was detected even after 40 minutes of assay.

IV. Specifications

| Specification | |
|----------------|--------------------------|
| Samples | Purified nucleic acids |
| Time-to-result | 30 minutes |
| Reagent kits | TANBead® RT-LAMP kit |
| System | Real-time PCR instrument |
| Applications | For SARS-CoV-2 detection |

V. Conclusion

TANBead RT-LAMP SARS-CoV-2 detection kit is designed for rapid detection of purified nucleic acids of the SARS-CoV-2 virus. The purified nucleic acids can be obtained from swabs, saliva, serum, and urine specimens previously treated with TANBead Nucleic acids extraction kits. The presence of SARS-CoV-2 RNA is indicated by fluorescent signal to support real-time detection.