



Saliva CnP™

Single Step Rapid Saliva Collection and Processing at the Point of Collection & Care Suitable for Molecular testing by RT-PCR or RT-LAMP

Saliva collection is non-invasive when compared with the use of nasopharyngeal swabs for sample collection. Furthermore, nasopharyngeal swab increases the chances of nosocomial spread of virus.

Saliva CnP™ is designed for collection of saliva samples in convenient and secure manner to eliminate the spread of contamination from donor during collection, transportation, or handling. Saliva samples collected in this device may be used for extraction of DNA or RNA by any traditional extraction method. However, the USA, FDA has approved methods where SARS-CoV-2 detection may be performed without the extraction of RNA from saliva samples. The direct use of saliva in detection techniques eliminates the risks associated with lengthy procedure of RNA extraction. Saliva CnP™ device may be use for collection of saliva for molecular testing of respiratory viruses, both DNA and RNA virus, present in saliva samples.

Saliva CnP™ device is provided with lysis buffer and optimized concentration of Proteinase-K in immobilized form, secured behind a perforated barrier. As soon as saliva is collected, saliva migrates across the barrier and meets with optimized concentration of viral lysis buffer containing Proteinase-K. Lysis buffer and Proteinase-K immediately begins to act; lyse the viral particles, denature RNases and DNases, inactivates saliva born inhibitors, liquefies saliva. Saliva is stabilized and preserved for later use. Before testing Saliva CnP device is heated for 10 minutes and it is ready for molecular testing, either by RT-PCR or RT-LAMP. (Patents Pending)

Example: Saliva samples have been successfully subjected to both RT-PCR and RT-LAMP.

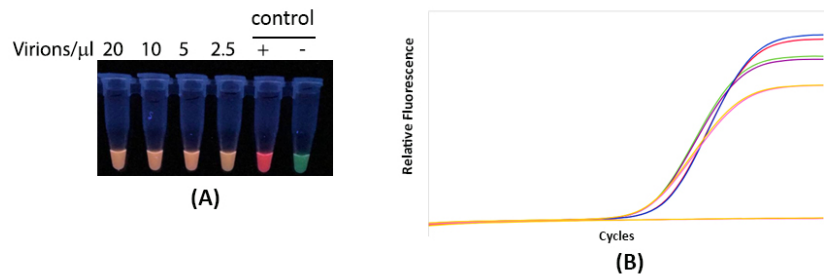


Fig 1 (A):RT-LAMP Assay for Covid-19 virus (SARS-CoV-2). Covid-19 positive shows red, orange or yellow fluorescence. Covid -19 negative sample shows green fluorescence. (B) Real-time RT-PCR for Covid-19 virus using SARS-Cov2 specific primers.



FEATURES

- Suitable for one-step direct use of saliva in detection technique such as RT-PCR or RT-LAMP
- Suitable for RNA/DNA extraction based molecular testing.
- Compatible with most RNA/DNA extraction protocols such as G-Biosciences GET™ Viral Nucleic Acid, GET™ Viral Nucleic Acid-Mag, GET™ Total RNA-Mag and Applied Biosystems MagMAX Viral/pathogen kits (RUO)
- Suitable for Thermo Scientific King Fisher Purification systems, Applied Biosystems MagMAX Viral/pathogen kits (RUO) and Applied Biosystems TaqCheck SARS-Cov-2 Fast PCR Assay (RUO) and TaqMan Applied Biosystems TaqMan Assays (RUO).
- 6 ml standardized polypropylene tube with cap which is compatible with automation rack for decapping downstream analysis for less manual, labor-intensive saliva pipetting using liquid handler.
- Provided with lysis buffer and optimized concentration of Proteinase-K
- Immobilized reagents separated and secured behind a barrier
- Supplied with a detachable funnel for convenient self-collection of saliva and identification label included
- Device is stable at ambient room temperature for 12 months
- Saliva collected in the device, may be stored at room temperature for 7 days. Refrigerator (2-8°C) for 21 days. Frozen at -20°C for 1 month. For long term storage (90 days) use -80°C.

APPLICATIONS

- Collection, preservation, transportation, and storage of saliva specimen
- Saliva collection for in-vitro testing of respiratory virus
- Suitable for SARS-CoV-2 and other DNA & RNA virus
- Suitable for other molecular detection based on DNA & RNA
- Design of the device allow it to fit in automation racks and thus allow automated high-throughput detection of viral nucleic acid in saliva samples.

SALIVA CnP™ STORAGE CONDITIONS

Saliva CnP™ devices, stored in its original packing at ambient room temperature for 6 months or 12 months in refrigerators.

SALIVA COLLECTION

Follow the instructions provided in kit.

SALIVA STORAGE AND TRANSPORTATION

Saliva collected in the device, may be stored at room temperature for 7 days. Refrigerator (2-8° C) for 21 days. Frozen at -20° C for 1 month. For long term storage (90 days) use -80° C.

INSTRUCTION FOR TESTING LABS

Remove the saliva sample containing Saliva CnP™ device from the zip-log bag. Make sure tube is tightly closed. Follow recording and documentation process as per lab recommendations.

1. Gently and intermittently flick the tube the tube for 2-3 times. OPTIONAL- a mechanical roller-mixer may be used for mixing.
2. Place the saliva tube in heat-block, incubator or boiling water set at 90°C for 10-15 minutes. Do not remove the cap while heating.
3. After heating the saliva sample, it is ready for testing. Allow the tube to cool down to room temperature.
4. Open the cap and retrieve a sample for testing by reaching into tube using a regular lab pipettor or using multi pipette or high throughput liquid handler robot. For high throughput the tubes may be positioned on test racks or platform.
5. After testing the leftover saliva with Saliva CnP™ device should be discarded in a biohazard disposal container