Inactivation/Transport

PCR DIRECT inactivates ≥ 99.99% coronavirus

Test Agent	Negative Control	PCR DIRECT
Contact Time (minutes)	0	30
Average Log recovery ±SD ($Log_{10}TCID_{50}mL^{-1}$)	5.96 ±0.10	≤1.90 ±0.00
Average Log reduction ±SD ($Log_{10}TCID_{50}mL^{-1}$)	N/A	≥4.06 ±0.00
Percent reduction (%)	N/A	≥99.99

PCR DIRECT ETM protects RNA for up to 4 days at ambient temperature

PCR DIRECT ETM lyses virus and donor cells, protects released RNA and DNA, and inhibits nucleases at ambient temperatures. To measure RNA stability, heat inactivated virus (BEI) was spiked into raw saliva and tested over four days by RT-qPCR. This stabilized samples can be transported without cold-chain to laboratories, where samples can safely reside within automated liquid handlers while RT-qPCR tests are assembled.

Improve automated liquid handling of saliva by removing viscosity

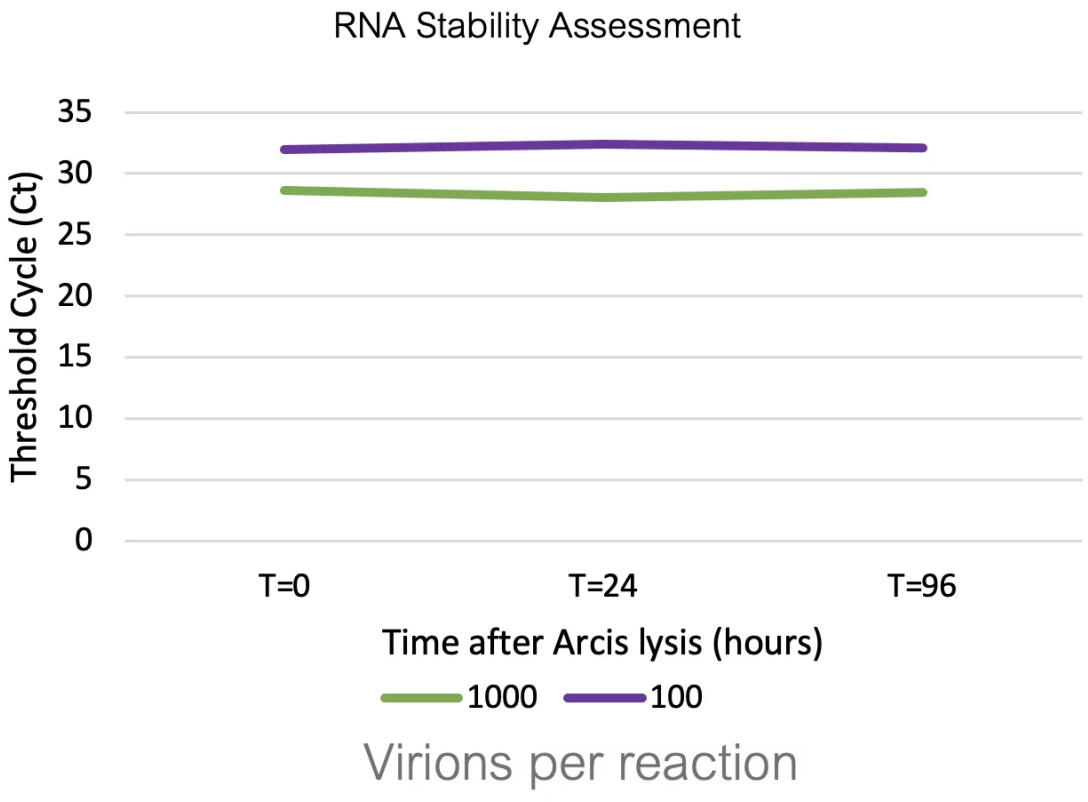
An automated liquid handler (OT-2, Opentrons) attempts to aspirate saliva that was freshly collected via spitting. Before the addition of PCR DIRECT, long filaments remain attached to the pipette tips. After the addition of PCR DIRECT, the automated pipettors easily aspirate the liquified saliva.

To quantify the impact on accurate pipetting, the volume of aspirated saliva and saliva treated with PCR DIRECT was measured by increasing volumetric aspirations with a micro pipettor. This was then converted into percentage of target volume pipetted and in shown

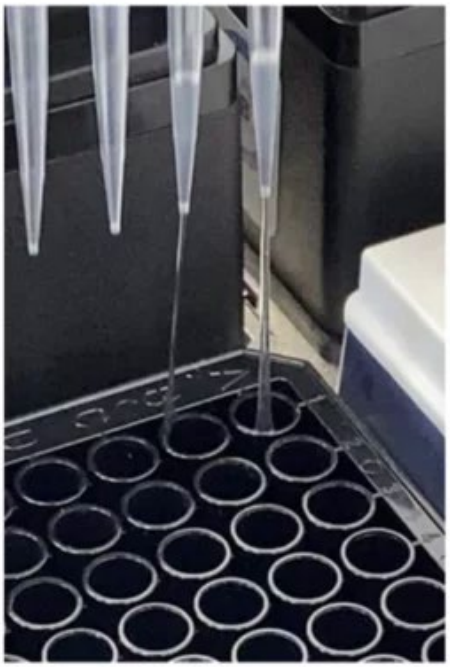
in the chart to the below. Without treating raw saliva, there is an approximately 30% reduction in aspirated versus target volume of saliva. This significant reduction in aspirated saliva would result in under sampling and subsequent losses in sensitivity.

Assessment of PCR DIRECT ETM against Human coronavirus 229E was performed by incubation at room temperature for 30 minutes. Following contact time, the suspensions were purified, and ten-fold serial dilutions (in triplicate) were evaluated for virucidal activity using TCID50.

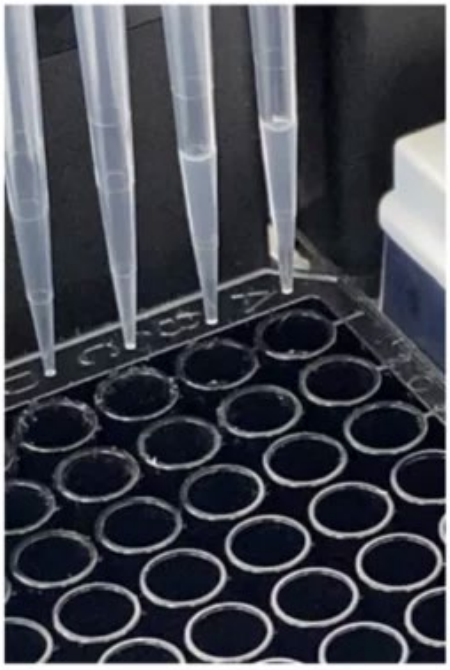
In negative control samples, following 0 minutes incubation, an average of 5.96 ± 0.10 Log10TCID50mL-1 coronavirus 229E was observed. Following a 30-minute exposure, an average 1.90 ± 0.00 Log10TCID50mL-1 coronavirus 229E was observed. An average Log reduction of 4.06 ± 0.00 Log10TCID50mL-1 and an average percentage reduction of 99.99% was observed.



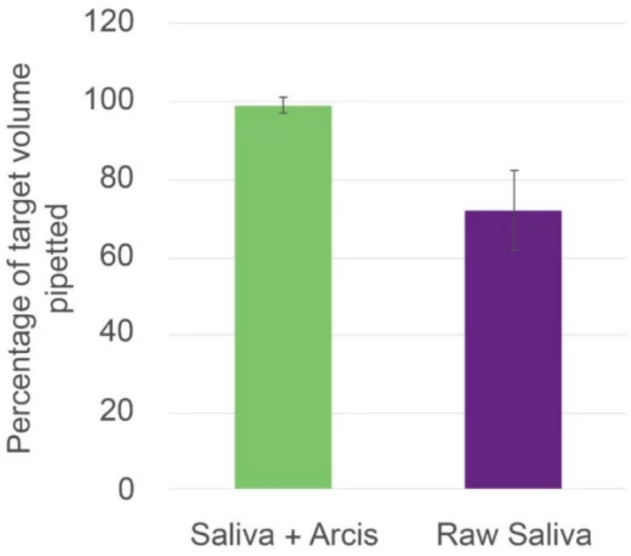
Before PCR DIRECT



After PCR DIRECT



Improved saliva pipetting accuracy



The volume transferred was measured relative to the target volume. Results are averages of 32 replicates for saliva mixed with Arcis reagent and 8 replicates for raw saliva.

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