



ARCIS
BIOTECHNOLOGY

One-Step Reagents for SARS-CoV-2 testing

*Products for simpler, safer, and scalable
sample collection and extraction*

Two products with One-Step chemistry accelerate PCR saliva testing



For use at point of collection:

One-Step Plus Extracting Transport Medium

- Virucidal transport medium eliminates heating and hazardous chemicals
- Stabilizes RNA, eliminates cold chain
- Extracts RNA before arrival in lab
- Liquifies saliva; facilitates automation



For use in lab or kits

One-Step Extraction Reagent

- Lyses virus, extracts RNA for direct RT-qPCR testing in 1 minute
- Eliminates need for heat or centrifugation
- Simplifies workflow and cuts consumables usage
- Non-hazardous

Reduce false negatives by > 33% while decreasing costs



One-Step Plus Extracting Transport Medium – RNA prepped at point of collection

How it works

One-Step Plus at point of collection

- One Step Plus dispensed into saliva sample when collected, or
- One Step Plus-pre-aliquoted into collection vessel before saliva-collected

Transport samples to lab

- Donor ships without cold chain or special packaging
- Stable for four days under ambient conditions

Analyse

- Samples liquified and ready for high-throughput qRT-PCR
- Prepped samples then stored for variant detection

Impact

- Viricidal assures safety at earliest point possible without heat or hazardous chemicals.
- Saliva requires little to no assistance to collect or send samples

- Lowest transport cost
- Samples in transit inactivated – safest for all in transit
- RNA extracted before arrival

- Reduce false negatives by 33%
- Reduce consumption of tips and tubes
- No heating or hazardous materials in lab



One-Step Extraction Reagent - 1-minute protocol for use in lab

How it works

One-Step Extraction Reagent added to saliva sample

- Liquifies saliva samples before automation
- RNA stable at ambient conditions during reaction preparation
- Samples prepped for RT-qPCR in one minute

Analyse

- 30% greater sensitivity
- Enables assay kits to test directly from saliva
- Widely compatible with RT-qPCR enzymes

Impact

- Eliminate heat step, chemicals, hazmat risks in lab
- Compatible with high-throughput testing
- Faster turnaround time

- Reduce false negatives by 33%
- Enables and optimize using less invasive sample type
- Integrates easily into existing workflows

Non-hazardous transport media completely inactivates virus

One-Step Plus delivers SARS-CoV-2 inactivation $\geq 99.99\%$

| Test Agent | Negative Control | Arcis |
|---|------------------|----------------------|
| Contact Time (minutes) | 0 | 30 |
| Average Log recovery \pm SD ($\text{Log}_{10}\text{TCID}_{50}\text{mL}^{-1}$) | 5.96 \pm 0.10 | $\leq 1.90 \pm 0.00$ |
| Average Log reduction \pm SD ($\text{Log}_{10}\text{TCID}_{50}\text{mL}^{-1}$) | N/A | $\geq 4.06 \pm 0.00$ |
| Percent reduction (%) | N/A | ≥ 99.99 |

Efficacy testing of Arcis demonstrated that no coronavirus was detected after a 30 minute exposure.

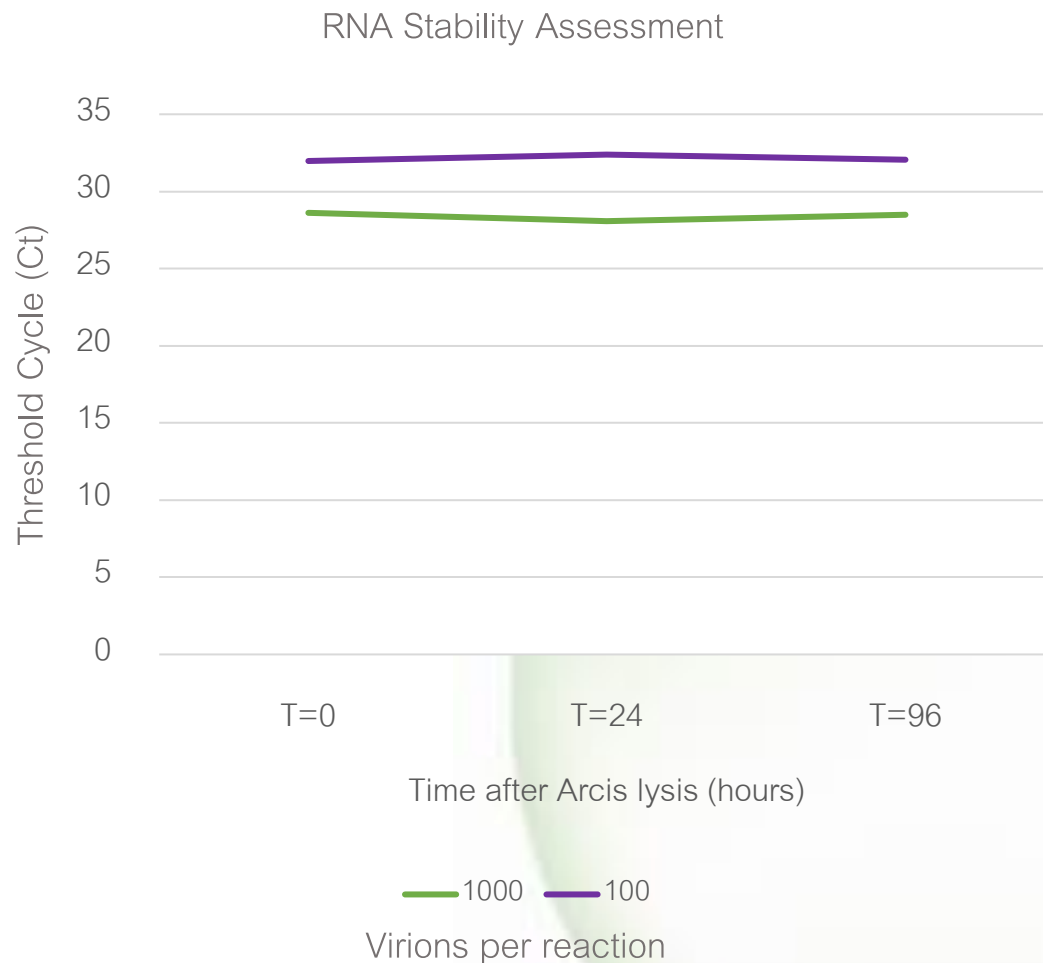
One-Step & One-Step Plus are non-hazardous based on the REACH standard

One-Step & One-Step Plus are **guanidine thiocyanate free**, and compatible with bleach and acid-based cleaning procedures such as Hologic's.

Eliminate risk of burns, caustic exposure and hazardous waste disposal cost.



Enable transportation and liquid handling without cold chain



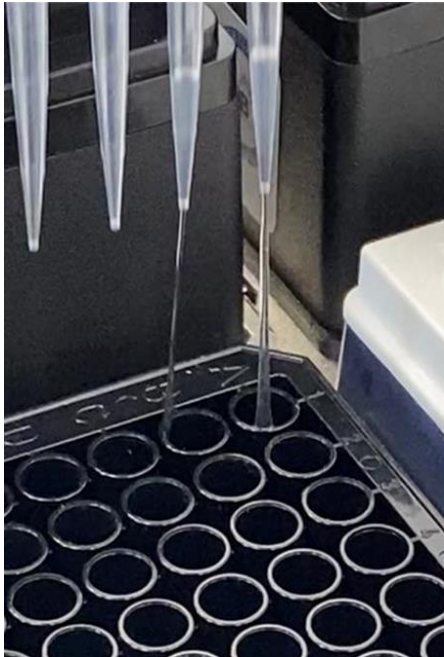
One-Step Plus protects RNA for up to 4 days at ambient temperature ensuring:

- Stabilized samples and inactivate virus at site of collection
- Transport at ambient conditions
- Maintain sample stability on liquid handlers as reactions are assembled

One-Step chemistry overcomes saliva viscosity

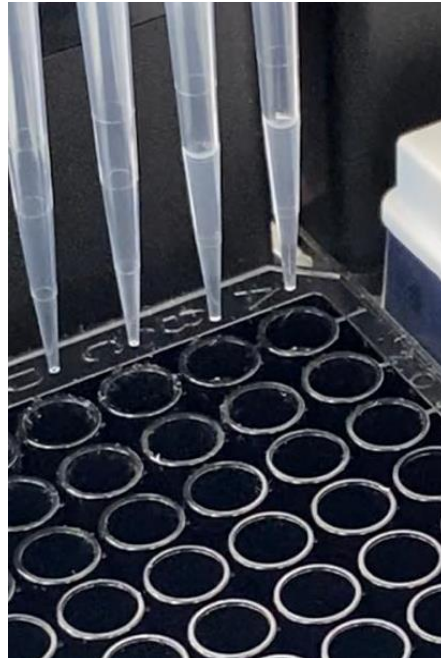
Before One-Step

Viscous sample – Difficult pipetting
Adheres to tube - Filamentous



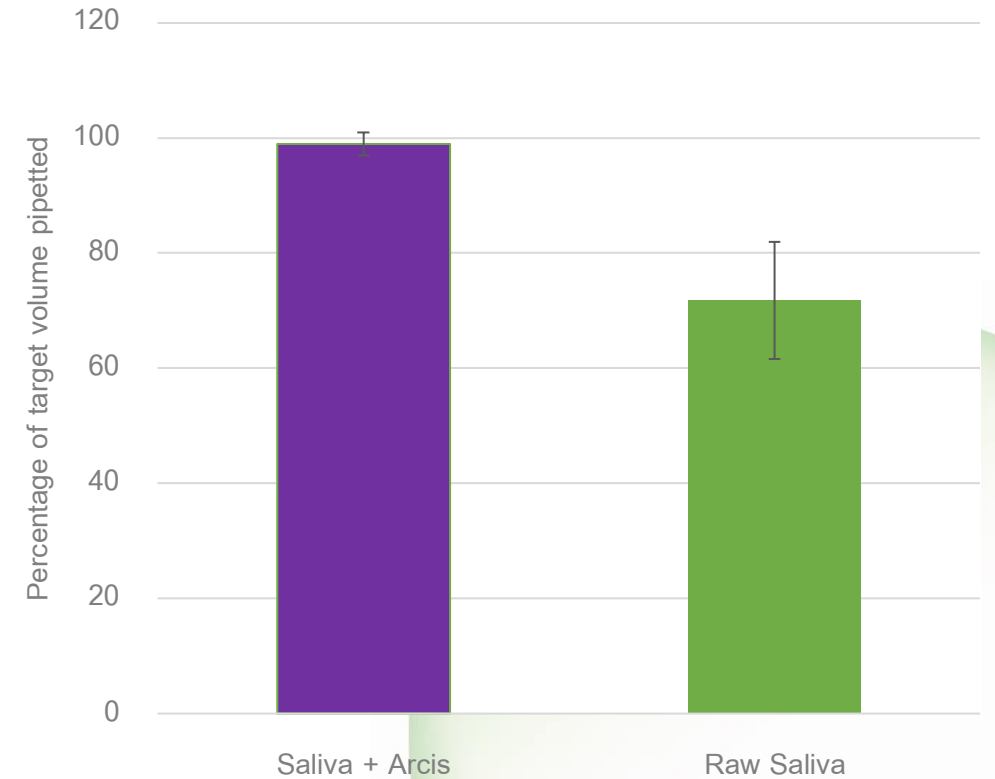
After One-Step

Good fluidity – Easy pipetting
Low adherence - No filaments



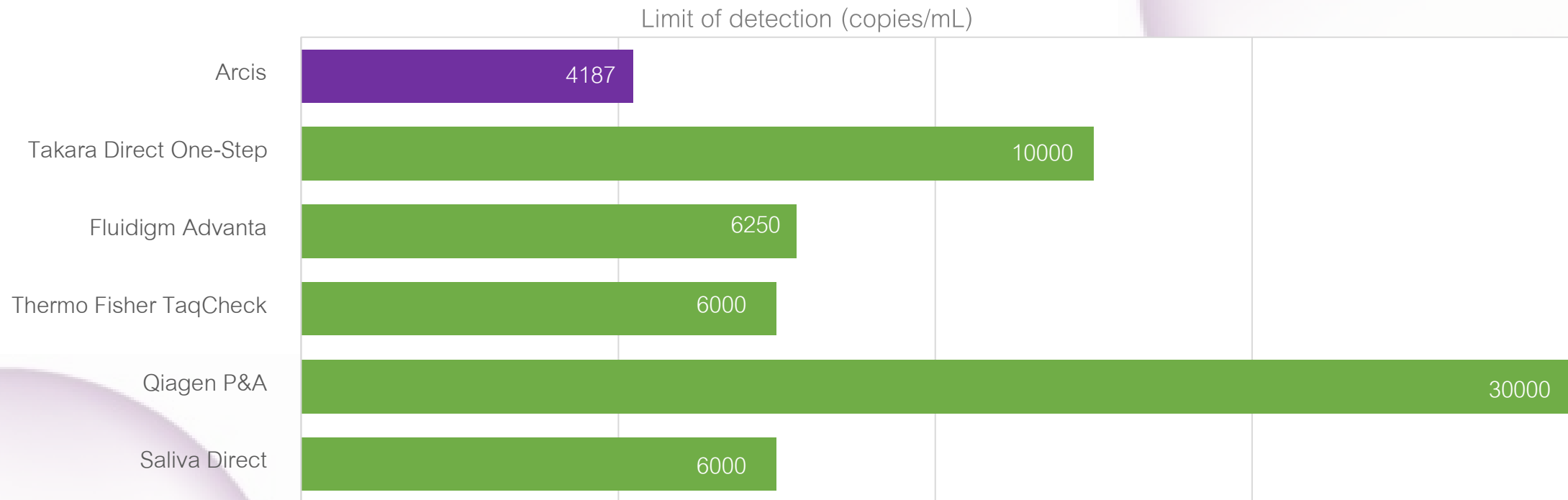
Saliva samples were mixed by pipetting a ratio of 100 μ l saliva to 235 μ l Arcis.

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.

Industry-leading sensitivity reduces false negatives by 33%



Limit of detection was established using heat-inactivated SARS-CoV-2 (BEI) spiked into raw saliva and extracted with Arcis reagent. 5µl was added to the RT-PCR reaction (Taqman® Fast Virus 1-Step Master Mix). Up to 50% v/v saliva lysate can be added to RT-qPCR.

Data for non-Arcis methods taken from IFUs, EUAs or other manufacturer produced studies.

Improving sensitivity from 6,000 copies/mL to 4,187 copies/mL reduces false negatives by 33%.

Single reagent reduces saliva prep to single step

- Process samples in 1 minute
- Use liquid handlers to automate pipetting
- Reduce operator error, equipment maintenance and training time through fewer parts and handling steps
- Lower operating costs by avoidance of reagents (ex. alcohols) and consumables (tips, plates, tubes)

| | Bead / Column Extraction | Saliva Direct | One-Step Plus Trans. Media |
|-------------------------|--|--|----------------------------|
| Total time (minutes) | 45 | 24 | 1 |
| Hands on time (minutes) | 26 | 11 | 1 |
| Number of reagents | 9+ | 1 | 1 |
| Equipment | Pipettes, Heater Vortex, Shaker Vacuum, Centrifuge, Magnetic block | Pipettes Heater Vortex Centrifuge | Pipettes |
| Steps to prepare kit | 5 | 1 | 0 |
| Handling steps in lab | 37 | 7 | 1 |
| Tips per plate | 576 | 192 | 96 |

One Step chemistry simplifies PCR testing

| One-Step chemistry eliminates | Lab benefits with |
|---------------------------------|---|
| Infectious viral particles | Inactivated samples on arrival |
| Cold-chain for sample transport | Lower shipping costs and faster setup time |
| Hazardous chemicals | Increased workplace safety and lower disposal costs |
| Heating and centrifugation | Less processing time |
| Saliva viscosity | Automation-friendly sample handling |
| Bead- or column- purification | Increased lab throughput |
| Liquid handling steps | Fewer tips and tubes to purchase |
| RT-PCR inhibitors | 30% greater sensitivity for > 33% fewer false negatives |

Arcis Biotechnology Limited

Founded 2010

Scalable manufacturing facility

Patented chemistry



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