SARS-CoV-2
Positive Control Kit

REF P003581

Instructions For Use RUO

PROPRIETARY NAME
ZiP Diagnostics SARS-CoV-2 Positive Control Kit.

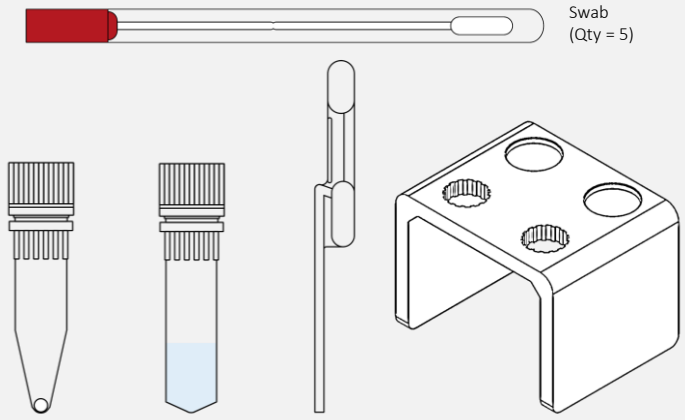
INTENDED USE
The ZiP Diagnostics SARS-CoV-2 Positive Control Kit is a non-infectious, external quality control kit that is non-assay specific. It is intended to be used with nucleic acid amplification tests that detect SARS-CoV-2 virus RNA to assess and monitor their performance through day-to-day, lot-to-lot and operator variation. The ZiP Diagnostics SARS-CoV-2 Positive Control Kit is intended to provide qualitative results only. It does not have a quantitative assigned value and is not intended for use in assay validation or calibration. FOR RESEARCH USE ONLY.

The ZiP Diagnostics SARS-CoV-2 Positive Control material is provided in a lyophilised format. The kit provides the buffer, transfer pipettes and swabs, that allow manual rehydration of the control material and addition of the material to the assay manufacturer's test workflow following the same process as a clinical specimen. The control kit is intended to be used in dedicated point-of-care test spaces by healthcare professionals. The control kit can also be used by laboratory trained professionals in pathology settings. Minimal training is required and comprises of only reading the Instructions for Use (this document). Additional training support is provided by instruction videos available at www.zipdiag.com.

PRINCIPLES OF THE PROCEDURE
External quality controls are used to assess nucleic acid amplification test workflows following the assay manufacturer's recommended procedures. This includes the full process of sample preparation, similar to patient specimen processing. Routine use enables test sites to monitor day-to-day, lot-to-lot, and operator variation, and can assist in identifying increases in random or systemic error. External quality controls can also be used to assess operator proficiency before testing clinical specimens.

The ZiP Diagnostics SARS-CoV-2 Positive Control material contains heat-inactivated whole-genome SARS-CoV-2 virus (isolate AUS/VIC01/2020SARS-CoV-2; Genbank Accession MT007544.1) derived from *in vitro* cell culture supernatant of SARS-CoV-2 infected Vero cells. The control material is formulated in oligosaccharides and polysaccharides for lyophilisation and may contain detergents. The control material does not have assigned values, but examples of possible reactivity (no target values) can be found at www.zipdiag.com. Specific performance will vary among different manufacturer assays, different operators, different lot numbers and different test sites.

KIT CONTENTS
The ZiP Diagnostics SARS-CoV-2 Positive Control Kit contains components suitable for 5 tests. Aside from the Controls Tube Stand, all other components are single-use only. Do not use for multiple tests.



WARNINGS AND PRECAUTIONS
GENERAL USE
- For RESEARCH USE ONLY.
- The control kit is not intended to be used for quantitative purposes or sensitivity determination.
- The control material has been inactivated and confirmed to be non-viable. Still treat as though there is biological risk and use with suitable safety measures, including personal protective equipment.
- Discard used kit components as appropriate for biological waste, following local environmental waste procedures. If country or regional regulations do not provide clear direction on proper disposal, used kit components should be disposed of as per World Health Organisation medical waste handling and disposal guidelines.

REAGENT USE
- Bring control and buffer tubes to room temperature before use.
- If any kit components are cracked, found to be damaged or opened when received, do not use and discard.
- Do not use the SARS-CoV-2 Positive Control Tube if it appears wet.
- Expiration dates are marked on the tubes and outer packaging. Do not use a component if it has passed its expiration date.
- Do not mix kit components from other ZiP control kit types.
- Do not tamper with kit components prior to or after use.
- All kit components are single use items only, aside from the Controls Tube Stand. Do not use with multiple tests.
- The customer is responsible of ensuring compatibility of the control kit with the test assay in use.

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STORAGE INSTRUCTIONS

The ZiP Diagnostics SARS-CoV-2 Positive Control Kit is stable until its expiry date if stored between 2-25°C. Expiration dates are marked on the outer packaging. Do not use a component if it has passed its expiration date. Once the bead is reconstituted, use immediately (as practical).

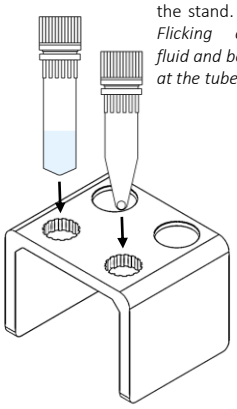
PROCEDURE

Clean work surfaces (See the **CLEANING** section). Prepare the ZiP Diagnostics SARS-CoV-2 Positive Control material using the following steps.

NOTE *Aside from pack opening, all other actions may be completed with one hand. If required, use the other hand to hold onto the side of the Controls Tube Stand for stability.*

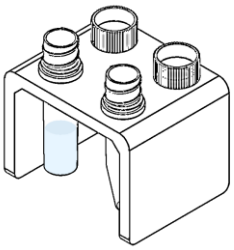
Step 1

Open the Control Reconstitution Buffer A Pack. Remove 1 buffer tube, *flick and insert into the left hole of the Controls Tube Stand. Open 1 SARS-CoV-2 Positive Control Pack. Remove the control tube, *flick and and insert into the right hole of the stand. *NOTE *Flicking ensures fluid and bead are at the tube base.*



Step 2

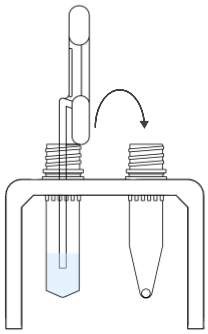
Remove the tube caps (while they are inserted in the Controls Tube Stand), and place the caps behind the tubes, on the circular indentations of the stand.



Step 3

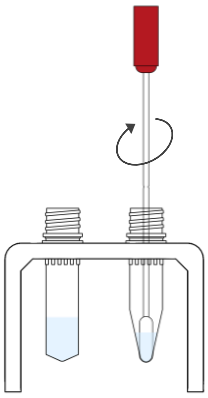
Open the 100 µL Transfer Pipette Pack. Remove 1 transfer pipette. *Aspirate fluid from the buffer tube and dispense into the control tube. The lyophilised bead will dissolve immediately. Some fluid will remain in the buffer tube.

*NOTE *See the **HOW TO USE THE PIPETTE** section on Page 3 for in-depth steps on how to use the pipette.*



Step 4

Open the Swab Pack. Remove 1 swab. Unsheathe the swab and insert the swab head into the bottom of control tube with the dissolved control bead. Rotate the swab head to ensure that most fluid in the tube is absorbed.



The swab can now be used in the test workflow according to procedures provided by the test kit manufacturer. Re-sheathe the swab if transport is required. Dispose used kit components as biological waste. Retain the Controls Tube Stand until the kit is consumed and then dispose.

QUALITY CONTROL

The ZiP Diagnostics SARS-CoV-2 Positive Control Kit does not have a quantitative assigned value. Where required, it is recommended the test site validate each lot of the control kit with the test system prior to use.

INTERPRETATION OF RESULTS

- The ZiP Diagnostics SARS-CoV-2 Positive Control material is formulated to give an expected result of "SARS-CoV-2 Positive". However, each test site must evaluate the product and establish their own acceptance criteria.
- Negative results may be an indication of poor test performance, deterioration or contamination of reagents, instrument failure, human error, or incompatibility of the control with the test system. If a negative result is obtained, ZiP recommends to cease clinical sample testing and review the test system.
- The ZiP Diagnostics SARS-CoV-2 Positive Control is intended to provide a qualitative result only. It is not intended for quantification purposes.
- Ct values (time to amplification) may vary in different test systems and different test kit lots.

LIMITATIONS

- Selection and use of quality control materials should be completed in accordance with local, state, federal, and accreditation requirements.
- The ZiP Diagnostics SARS-CoV-2 Positive Control Kit is not intended to replace the manufacturer's controls provided with the test kit.
- Deviations from procedures and interpretation recommended by test kit manufacturers may produce unreliable results. Improper shipping and/or storage may result in incorrect results.

CLEANING

Clean work surfaces before preparing the control material. Wipe down with disinfectant (e.g., 1% bleach or 5% hydrogen peroxide), leave for 2 minutes, and then wipe down with water. For spillages on work surfaces or the Controls Tube Stand, use absorbent material to mop-up the spillage, and then clean the contaminated area using the procedure above. Discard absorbent material as biological waste.

SUMMARY MATERIAL SAFETY DATA SHEET

Physical and Chemical Properties	
Physical appearance: Control tube: freeze-dried bead Buffer tube: colourless liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See the **WARNINGS AND PRECAUTIONS** section.
Toxicological Properties	
Effects of inhalation:	Not established, use a facemask, and avoid inhalation.
Effects of ingestion:	Not established, avoid ingestion.
Effects of skin adsorption:	Not established, wear gloves and avoid contact with skin.
Suggested First Aid	
Inhalation:	Seek medical advice.
Ingestion:	Seek medical advice.
Contact with eyes:	Rinse eyes with copious amounts of water and seek medical advice.
Contact with skin:	Wash affected area thoroughly with water.

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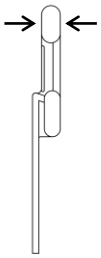
HOW TO USE THE PIPETTE

The ZiP Diagnostics SARS-CoV-2 Positive Control Kit uses single-use 100 µL fixed volume transfer pipettes. Follow the step-by-step instructions below to transfer fluid from the Control Reconstitution Buffer A Tube to the SARS-CoV-2 Positive Control Tube. For an in-depth guide, a *How To Use the Pipette* training video module is available on www.zipdiag.com.

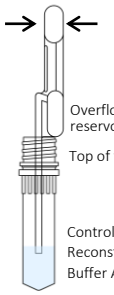
Step 1

With the pipette tip outside fluid, firmly **squeeze** the top bulb.



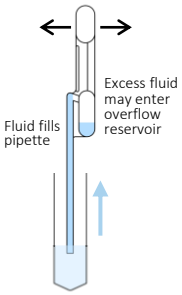
Step 2

Immerse the pipette tip in the Buffer Tube until the base of overflow reservoir contacts the top of tube.



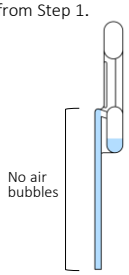
Step 3

Release the top bulb to aspirate fluid.



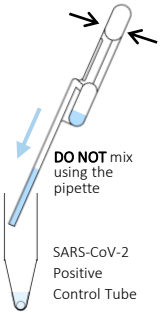
Step 4

Check the pipette for air bubbles. If there are air bubbles, complete Steps 5 and 6 into the Buffer Tube, and start again from Step 1.



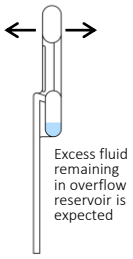
Step 5

Place the pipette tip against the Control Tube wall, firmly **squeeze** the top bulb.



Step 6

With the pipette tip outside fluid, **release** the top bulb.



NOTE ***DO NOT*** *remove tubes from the stand to aspirate and dispense fluid.*
NOTE *In total, 3 pipetting attempts can be completed before the pipette must be discarded, and another one used.*
NOTE ***DO NOT*** *use if liquid enters the upper tubing or the top bulb.*

Occasionally, there are defects in the plastic moulding which may lead to (1) no aspiration, (2) greater dispense volume, and (3) reduced dispense volume. Refer to the figure below for visual depiction. The ZiP Diagnostics SARS-CoV-2 Positive Control material is robust enough to cover some variability in volume input. However, if these issues (or similar) are identified by the user, the defective pipette should be discarded (as biological waste) and replaced with a new one. Each pipette can be used a maximum of 3 times.

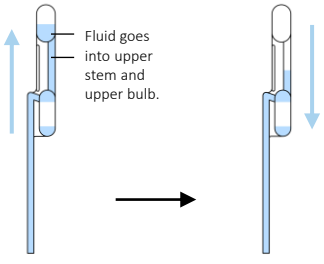
NO ASPIRATION

Aspirate:
No fluid uptake.

GREATER DISPENSE VOLUME

(1) Aspirate:
Fluid goes into the upper stem and upper bulb.

(2) Dispense:
Fluid from upper bulb and upper stem is also dispensed.

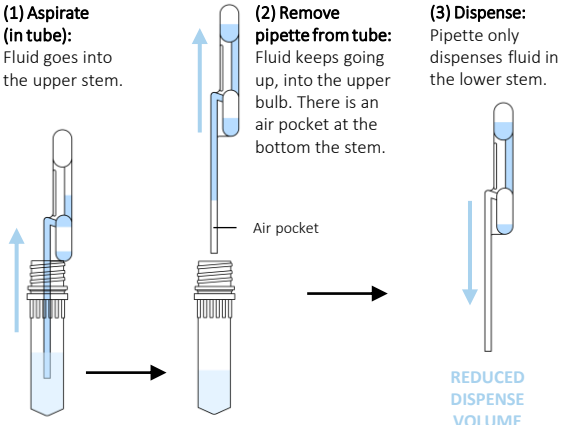


REDUCED DISPENSE VOLUME

(1) Aspirate (in tube):
Fluid goes into the upper stem.

(2) Remove pipette from tube:
Fluid keeps going up, into the upper bulb. There is an air pocket at the bottom the stem.

(3) Dispense:
Pipette only dispenses fluid in the lower stem.



SYMBOL KEYS

REF	Catalogue number	Σ	Contains sufficient for <n> tests
LOT	Lot/Batch number		Date of expiry
IVD	*In vitro* diagnostic medical device		Do not use if package is damaged
CONTROL +	Positive control		For single use only
	Biological risk		Manufacturer
	Consult instructions for use		Temperature limitation

TECHNICAL SUPPORT

If the control kit does not perform as expected, contact ZiP Diagnostics technical support:
Phone +61 (0) 3 8414 5772 | **Email** support@zipdiag.com
www.zipdiag.com/technical-support

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