SIGNALCHEM
DIAGNOSTICS

User Manual

SignalChem Diagnostics

Clostridium perfringens Enterotoxin One-Pot Detection Kit

To enable rapid testing for the immediate detection of the *C. perfringens* enterotoxin (cpe) gene in canine and feline fecal samples

Format: Single Tube
Specimen: Canine/Feline Feces

Catalog# PE001-K398 (Starter Kit)
Catalog# PE002-K398 (Standard Kit)

Diagnostic Reagents For Accurate And Reproducible Results

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Table of Contents

Introduction 3
Intended Use 3
Disclosure 3
Warnings and Precautions 4
Storage and Stability 5
Kit Components 5
Sample Collection and Preparation 7
Instructions for Diagnostic Test 17
Results Interpretation 19
Limitations 19
References 20
Support 24
Index of Symbols 24
Manual Version History 24

Introduction

SignalChem Diagnostics' *Clostridium perfringens* Enterotoxin One-Pot Detection Kit is an on-site rapid nucleic acid amplification and detection assay for the simultaneous qualitative detection of the enterotoxin (cpe) gene of *C. perfringens* in canine and feline fecal samples.

Clostridium perfringens is a widespread, Gram-positive anaerobic bacterium capable of producing potent enteric toxins. Strains carrying the enterotoxin (cpe) gene are major causative agents of acute diarrhea and gastroenteritis in dogs and cats. Because clinical progression can be exceptionally rapid, timely diagnostic confirmation is critical for effective triage, quarantine, and treatment.

The assay targets a highly conserved region within the enterotoxin (cpe) gene and detects *C. perfringens* strains originating from canine and feline hosts without cross-reacting with host genomic DNA. The assay is calibrated with a clinical cutoff: a positive result indicates a *C. perfringens* target concentration exceeding 300 copies/mg of fecal sample, helping clinicians differentiate clinically significant bacterial overgrowth from low-level background colonization.

Intended Use

The kit is intended for the simultaneous qualitative detection of the enterotoxin (cpe) gene of *C. perfringens* in canine and feline fecal samples, with a clinical cutoff of 300 copies/mg of fecal sample.

The kit is intended for use by animal owners, caretakers, veterinary professionals, and diagnostic personnel in point-of-care settings to support rapid identification of the target and inform triage, quarantine, and treatment decisions. The test result is an aid to assessment and should be interpreted with the animal's clinical presentation and other relevant information.

The kit contains reagents and materials for sample preparation and molecular detection and is designed for use with the CRISPOT® Detection Device (Cat# CSP01-V19A, sold separately). Sample preparation and device setup require approximately 5-10 minutes, followed by a 35-minute amplification and detection run on the device. Upon completion, the CRISPOT® Detection Device will return a positive (red) or a negative (green) result. The device provides rapid preliminary results without requiring samples to be sent to an external laboratory.

This manual applies to both the Starter Kit (Cat# PE001-K398) and the Standard Kit (Cat# PE002-K398).

Disclosure

This product is intended for veterinary diagnostic use with canine and feline specimens only. It is not to be used as a drug, human medical device, food additive, cosmetic, or household chemical. It is not to be used in therapeutic or consumer applications. Not for resale.

Warnings and Precautions

Before Use

- Do not use if the packaging is compromised.
- Do not use after the expiration date shown on the box.
- Do not use if the kit has been stored improperly at any point.
- Components in the standard kit are single use. Do not reuse components.
- Use only the sampling tools and buffers provided in the kit. Do not substitute provided materials with other materials.
- Inspect the condition of all materials and reagents before use. Do not use buffers that have leaked from their containers or appear contaminated (cloudy or dirty). Do not use materials that appear dirty, rusted, or damaged. Do not use master mix tests that appear collapsed or rehydrated.

Safety and First Aid

- Do not eat, drink, or smoke in the area where specimens or kits are being handled.
- Wear disposable gloves when handling specimens and test reagents. Use additional protective equipment as appropriate for the working environment.
- Keep kit and components out of the reach of children.
- If the buffer contacts skin or eyes, flush with copious amounts of water.

Preventing Cross-Contamination

- Ensure the testing area and working surfaces are clean before starting the test.
- Wear disposable gloves when handling specimens and performing the test. Change gloves between samples or whenever contamination is suspected. If disposable gloves are not available, gloves may be cleaned and decontaminated with 10% bleach and reused. Gloves must be cleaned and decontaminated between samples to prevent cross-contamination.
- Always use a new pipette tip for each sample transfer. Do not reuse sampling or testing tools.
- Keep specimens, sample extracts, and test components from different samples separate to prevent cross-contamination.
- If cross-contamination between samples is suspected, do not continue testing the affected samples. Prepare and test new samples.

During testing

- Follow the instructions provided in this manual to ensure reliable test results.
- Begin testing immediately after the master mix is reconstituted and final checks are completed.
- Use the buffers promptly after opening.

After testing

- Do not open used master mix PCR tubes after testing.
- Clean any spills and test area with an appropriate cleaning or disinfecting solution.
- Dispose of used sampling materials, specimens, and test components in sealed waste bags accordance with local regulations for biological or veterinary medical waste.
- Wash hands thoroughly after finishing the tests.

Storage and Stability

- Store the kit at 2-8°C for up to 12 months or at 9-25°C for up to 6 months in their original sealed packaging to protect from moisture or contamination.
- **Protect the master mix tubes from light**. Keep the tube strips in their box until immediately before use. Exposure to light may cause reagent deterioration and lead to inaccurate results.
- Store the detection device according to its instruction manual.

Kit Components

Starter Kit-Only Components

#	Component	Amount
1	Tube Rack	1
2	Adjustable Pipette	1

Standard Kit Components

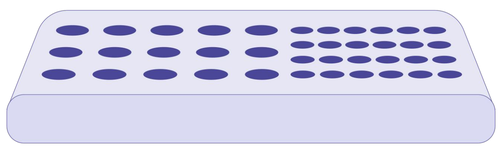
#	Component	16 Reactions	32 Reactions	48 Reactions
3	Pipette Tips	40	80	120
4	Fecal Collection Tubes (incl. 2 mL stabilization buffer/tube)	16	32	48
5	Reaction Buffer ① (blue strip tubes)	16	32	48
6	Reaction Buffer ② (yellow cap tubes)	16	32	48
7	PCR Tube Strips with Lyophilized Master Mix	2 (8-well) strip tubes	4 (8-well) strip tubes	6 (8-well) strip tubes
8	User Manual	1	1	1

Not Provided:

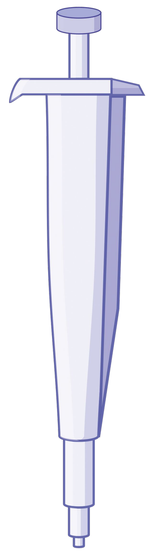
- 10% Bleach
- Paper towels
- Gloves and personal protective equipment
- Permanent marker or labels
- Timer
- Vortex mixer (optional)
- Sealed waste bags for disposal of used consumables

Kit Components

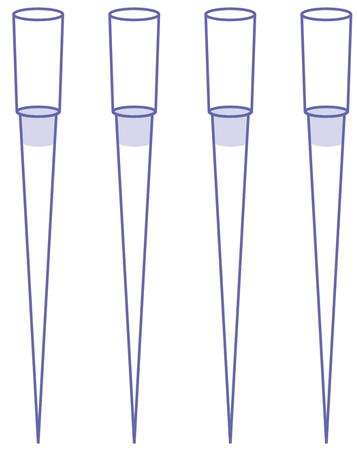
1 Tube Rack
(Starter kit only)



2 Adjustable Pipette
(Starter kit only)



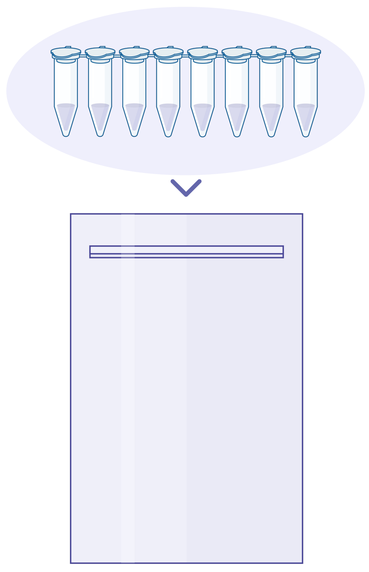
3 Pipette Tips



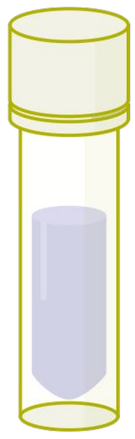
4 Screw-Cap
Collection Tubes



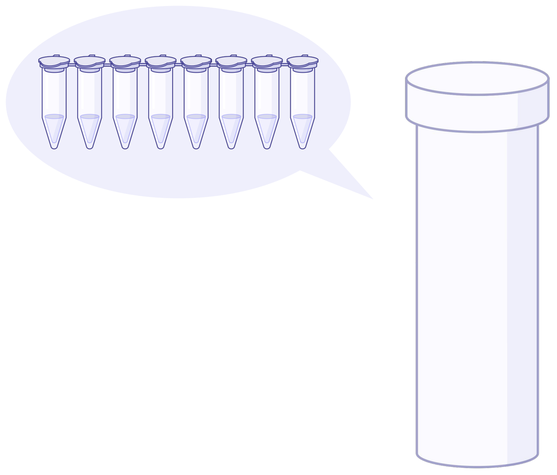
5 Reaction Buffer ①
(Blue-Strip Tubes)



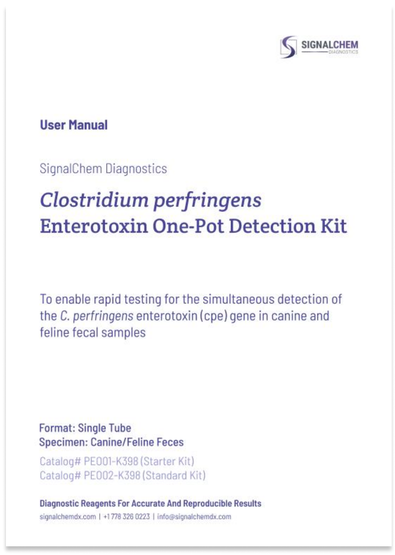
6 Reaction Buffer ②
(Yellow-Cap Tubes)



7 PCR Tube Strips With Master
Mix in White Plastic Tube



8 User Manual


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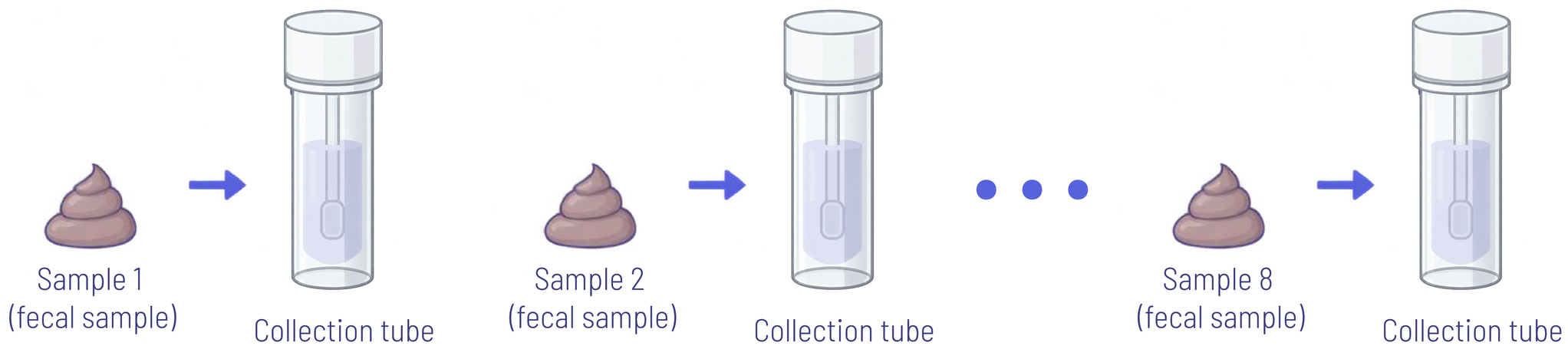
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Sample Collection and Preparation

- Before starting any sample collection or testing, please read the instructions carefully. During sample preparation and testing, adhere strictly to the provided instructions.
- If you are unfamiliar with pipetting, review page 10 and **Steps 5 and 6** prior to starting.

1. Determine the number of tests and label tubes

a. a. Determine the number of specimens to be tested. A maximum of **8 samples** may be processed per run.



b. Label each screw-cap collection tube with a sample ID number before beginning.



c. Record details about samples and sample numbers if needed.

Sample Collection and Preparation

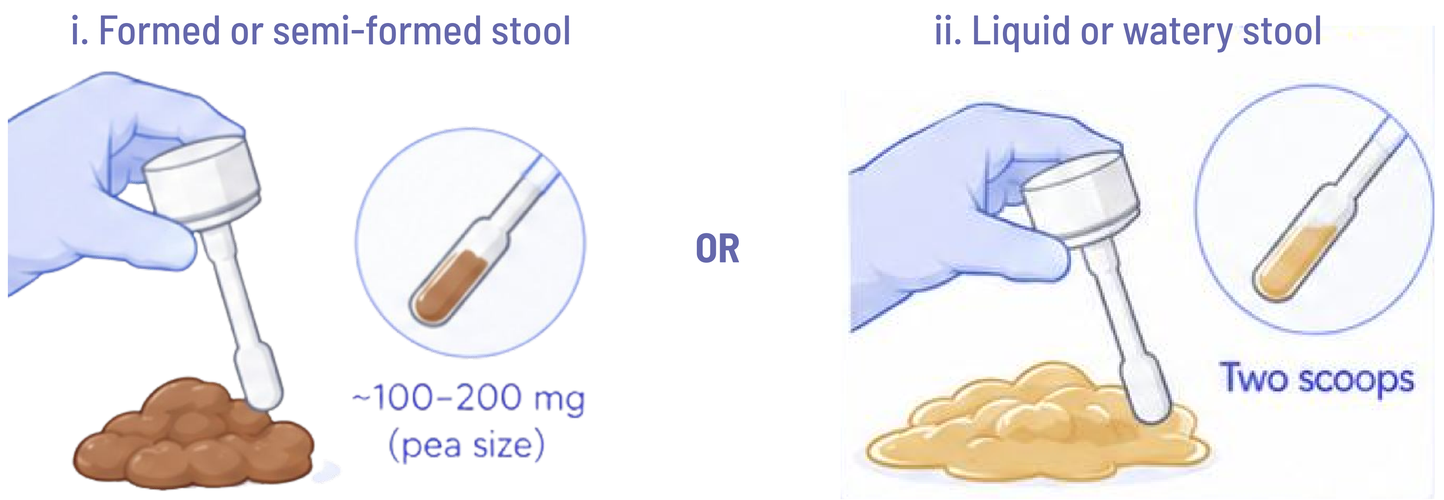
2. Collect Samples

IMPORTANT!

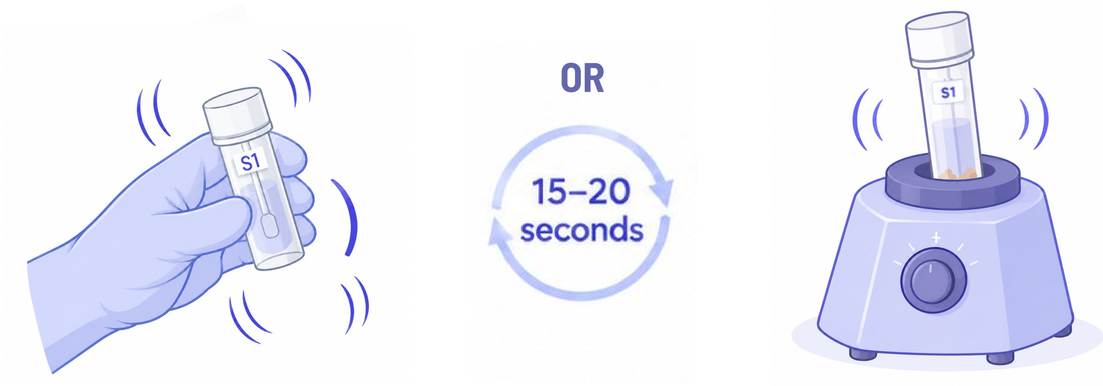
- Specimen Storage: Fresh specimens should be processed within 48 hours of collection. Specimens collected in the DNA/RNA stabilization buffer may be stored at 2–8°C for up to 7 days or at –20°C for up to 30 days.
- Testing promptly after collection is recommended when practical.
- Complete all processing steps (Steps 3-5) for one sample at a time before proceeding with additional samples.
- **Preferred specimen:** freshly collected canine or feline fecal sample gathered during suspected active enteric infection.

a. Unscrew the cap with the integrated scoop from the collection tube.
b. Use the built-in scoop to collect a small portion of fresh feces.
   i. **Formed or semi-formed stool:** collect a portion approximately the size of a pea (~100-200 mg).
   ii. **Liquid or watery stool:** collect two scoops (fill the scoop cavity twice). If the sample contains mucus or solid material, include it in the scoop.

***Note**: Avoid collecting ground litter, soil, or straw.*



c. Insert the scoop back into the collection tube and screw the cap on tightly to fully submerge the sample into the medium.
d. Mix thoroughly by vortexing or vigorous shaking for 15–20 seconds to completely disperse and suspend the sample in medium.

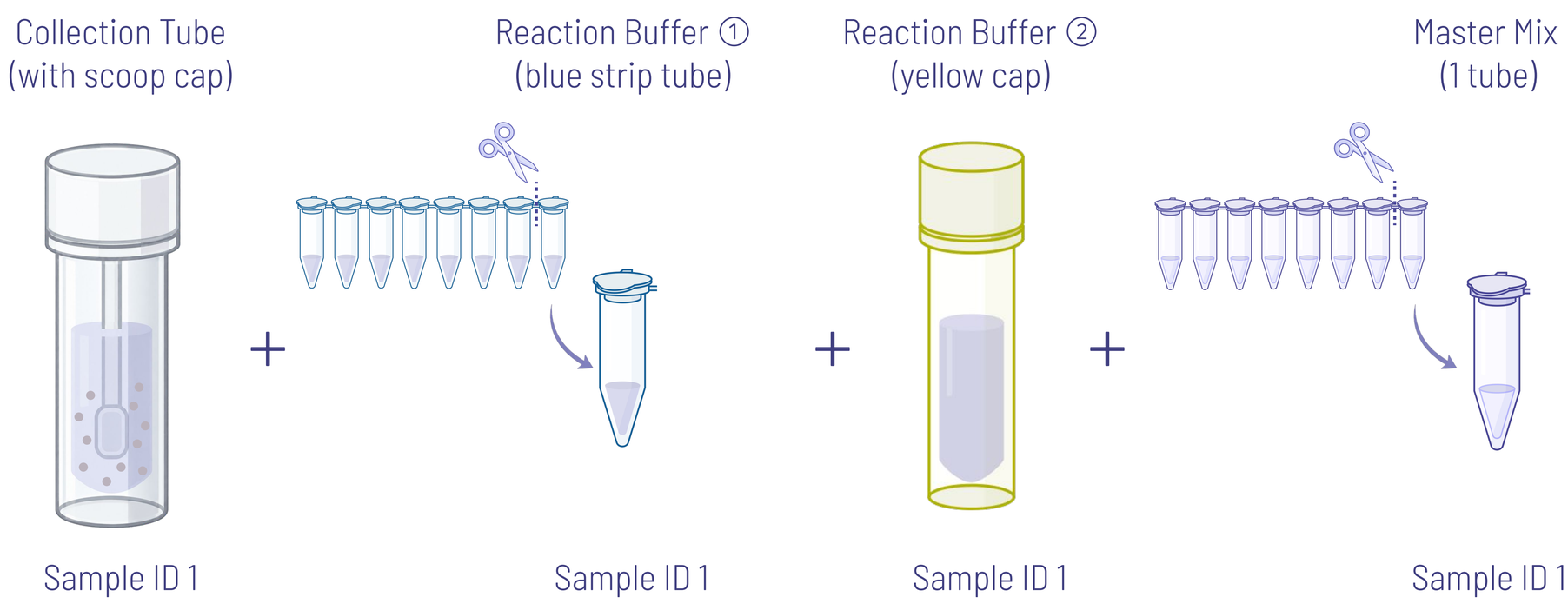


e. Allow the tube to stand upright at room temperature for **5 minutes** to let dense particulate matter settle to the bottom.
f. Repeat **Steps 2–4** for each additional specimen.

Sample Collection and Preparation

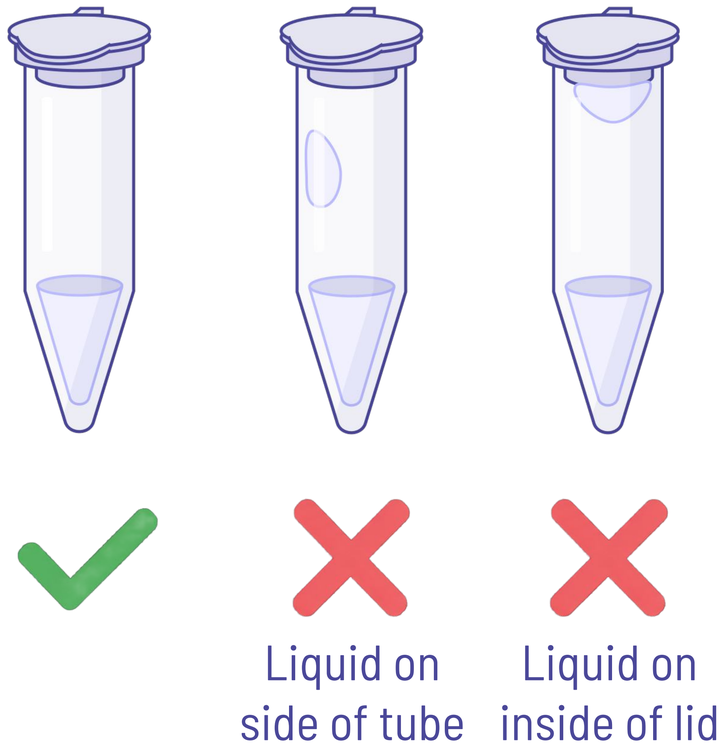
3. Gather and prepare the necessary components

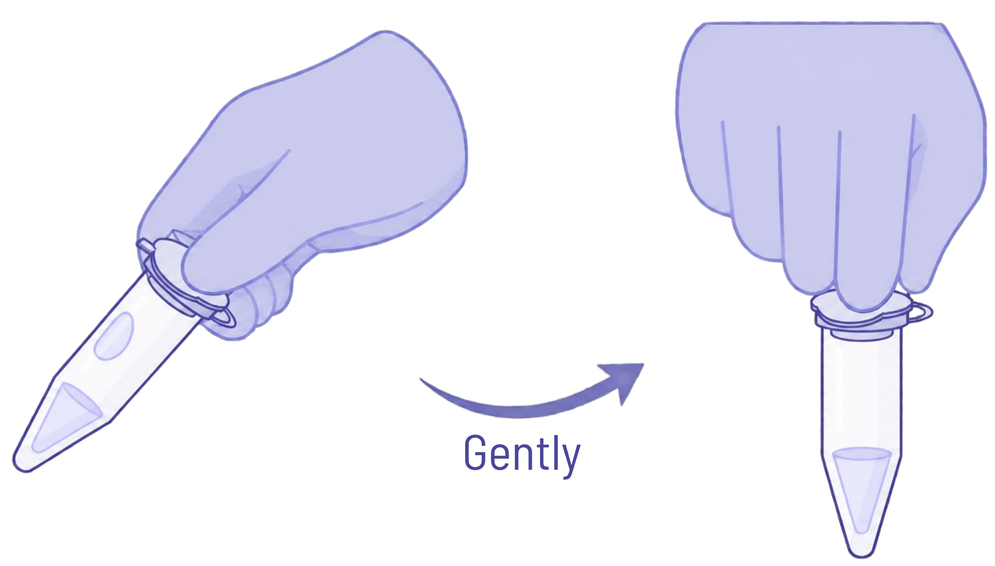
a. For each sample, collect the required components from the kit (1 set for each sample): one screw-cap collection tube, one Reaction Buffer ① tube (blue strip tube), one Reaction Buffer ② tube (yellow cap), and one master mix tube.
b. Allow all components to equilibrate at room temperature for at least 10 minutes before use.
c. Label the lids of all the tubes with sequential sample ID numbers. Immediately return any unused master mix to the box, close the lid tightly, and store as directed.





IMPORTANT!
For all tubes, ensure the contents are at the bottom of the tube. If not, gently tap the tubes on a flat surface or use a wrist flicking technique to get the contents to the bottom.

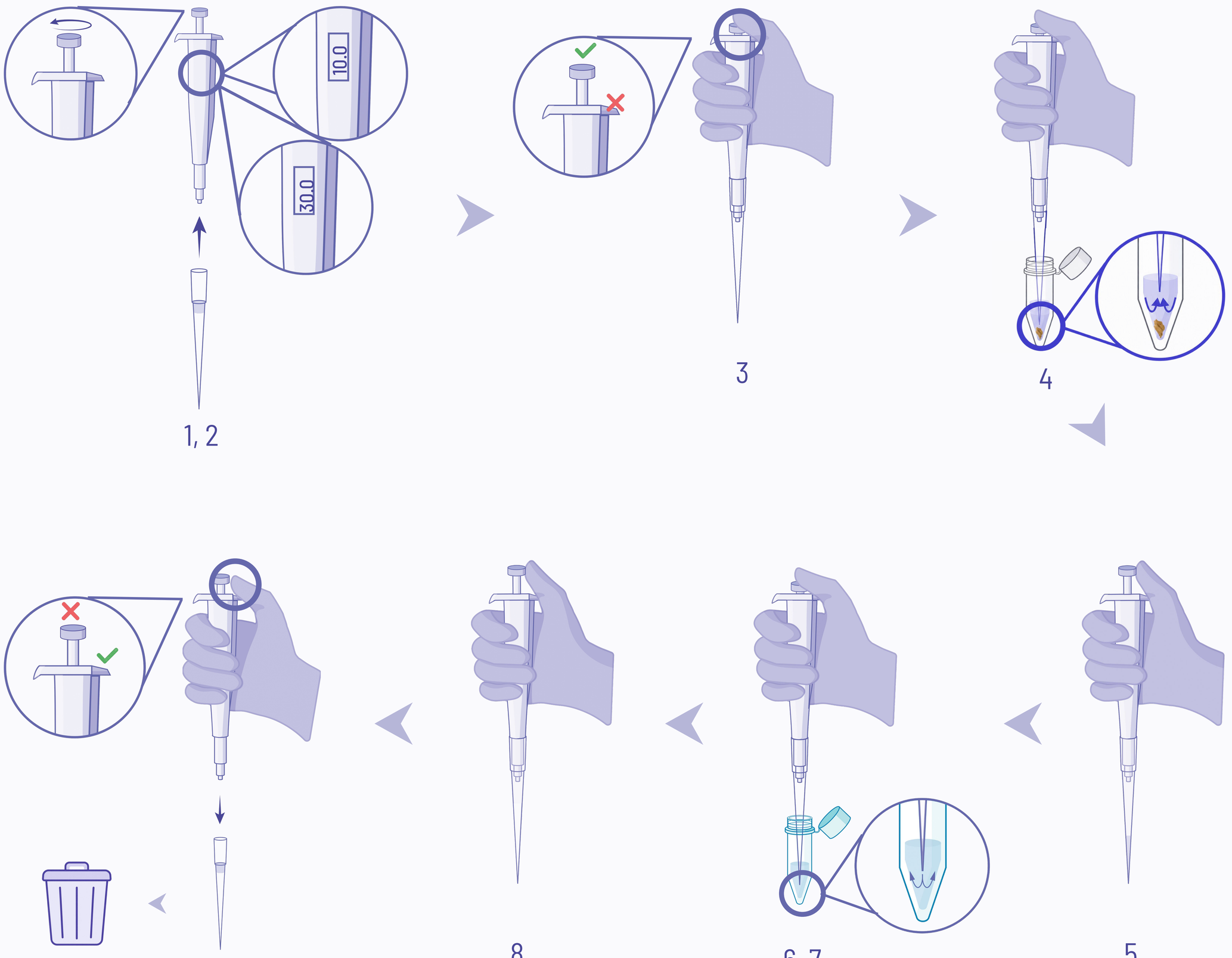




Sample Collection and Preparation

How to use the pipette

1. Turn the dial to adjust the volume. The pipettes are adjustable between a range of 5-50 µL.
2. Using clean or decontaminated gloves, pick up a pipette tip without touching the pointed end, and attach it to your pipette. Ensure the tip is attached securely.
3. Press the plunger down to the first stop (where you first feel resistance)
4. Insert the pipette tip into the liquid.
5. Slowly release the plunger to draw up the desired volume. Observe the liquid enter the pipette tip.
6. Move the tip to the target container.
7. Press the plunger slowly but firmly to the 2nd stop (past the first point of resistance). Observe the liquid exit the pipette tip.
8. While keeping the plunger pressed, withdraw the tip from the liquid to avoid drawing any liquid back in.
9. Dispose of pipette tip.

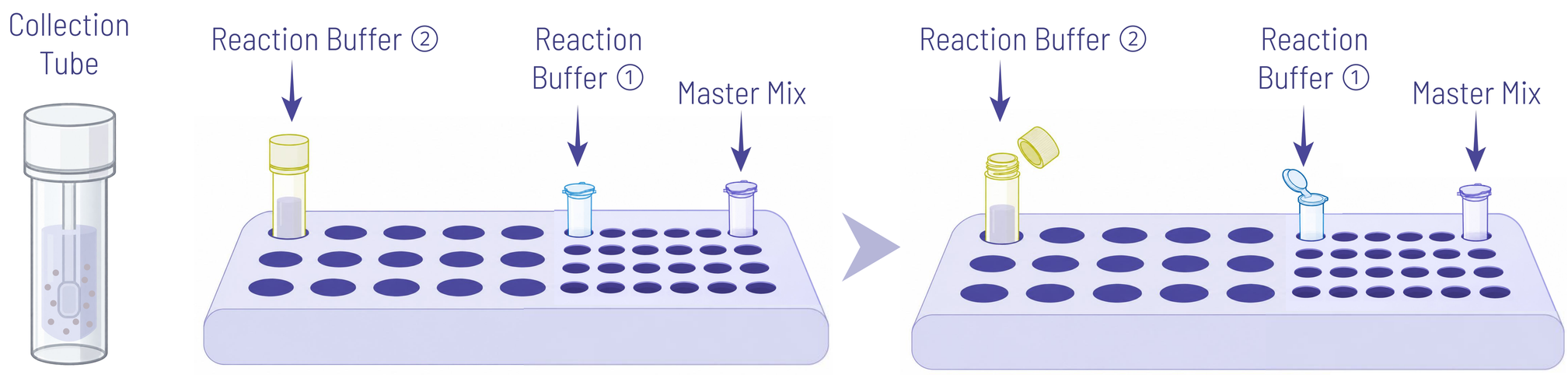


Sample Collection and Preparation

4. Process the specimen

IMPORTANT! Always use **a new pipette tip for each sample** to avoid cross-contamination.

a. Open the Reaction Buffer ① tube (blue strip tube) and the Reaction Buffer ② tube (yellow cap) for the corresponding sample. Make sure the liquid in both tubes is at the bottom (flick downward sharply or tap on the bench.



b. Set the adjustable pipette to **10 µL** and attach a new tip.

c. Aspirate **10 µL** of non-viscous supernatant from **COLLECTION TUBE**.

i. Press down the plunger until the first point of resistance.

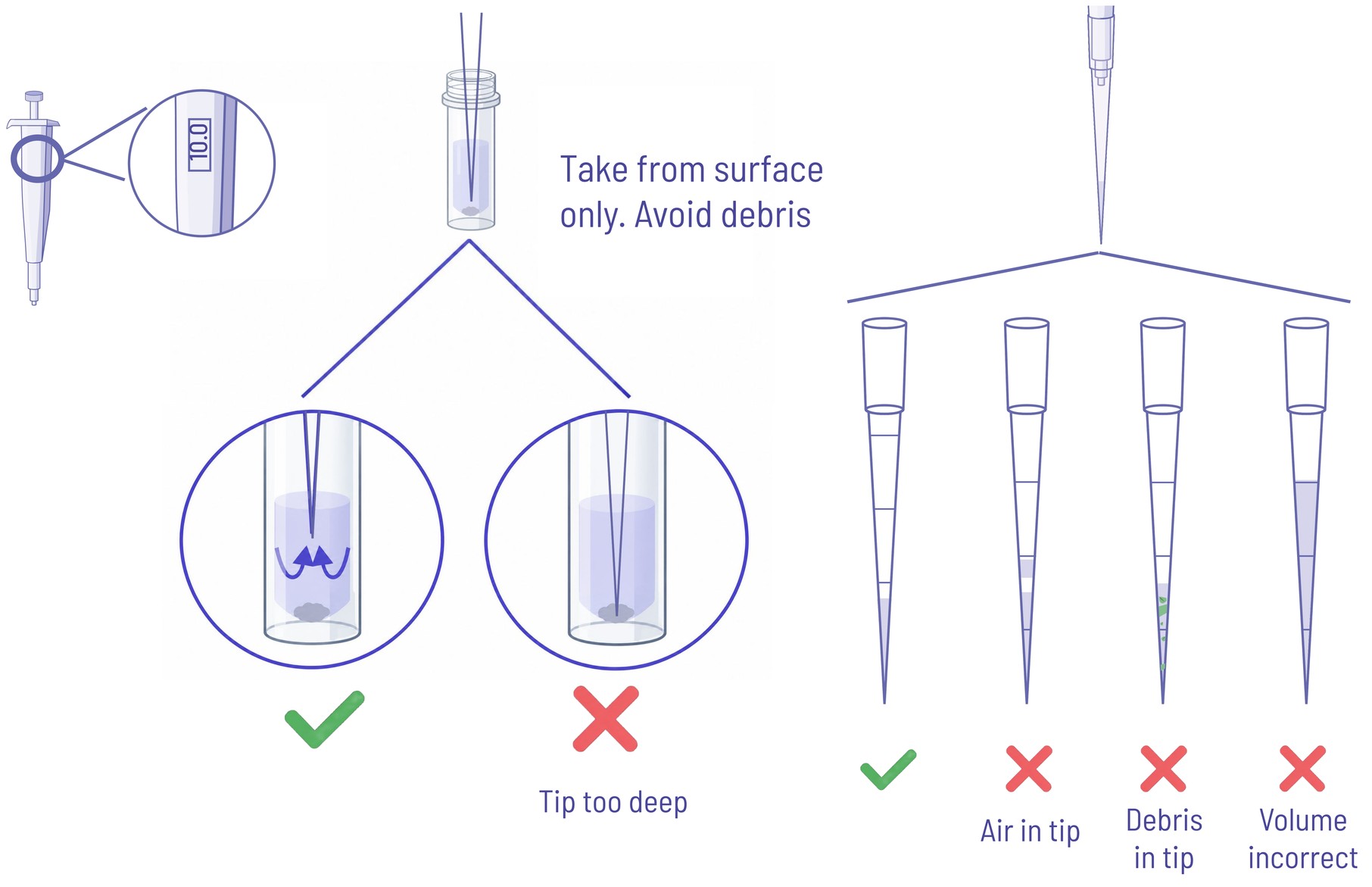
ii. Insert the pipette tip just below the surface of the liquid to avoid debris.

***Note**: Do not insert the pipette tip too deep.*

iii. Slowly release the plunger to aspirate 10 µL, then withdraw the pipette.

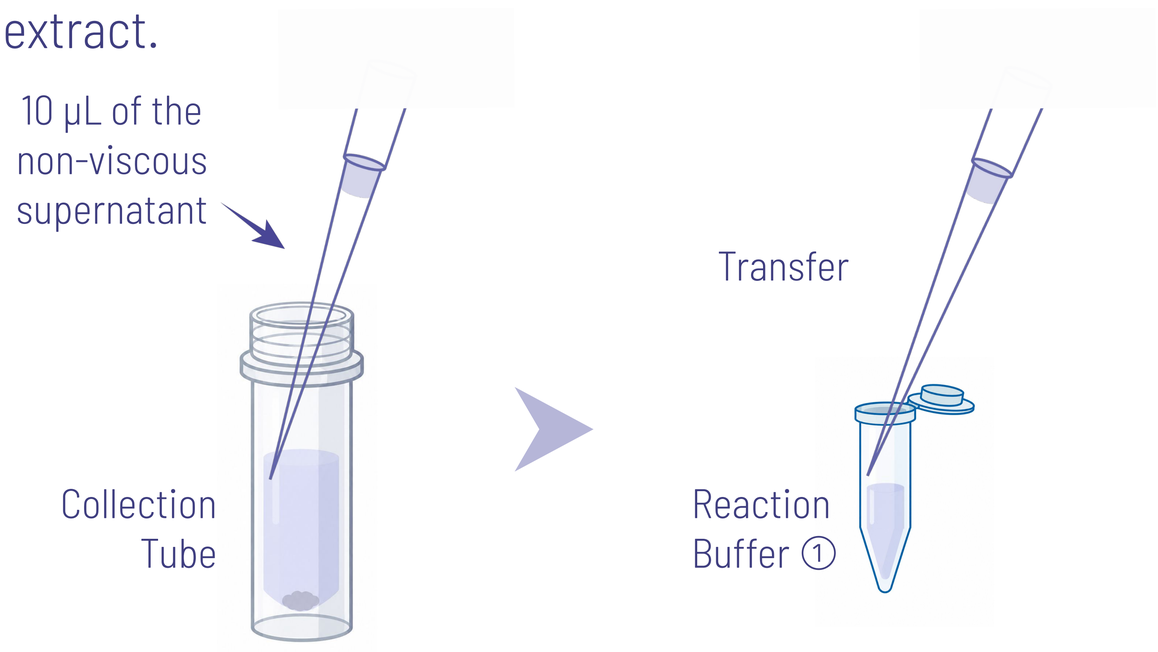
iv. Inspect the pipette tip.

***Note**: Ensure the liquid is below the lowest indicator line and contains no air bubbles or debris. If necessary, discard the tip and repeat with a new pipette tip.*

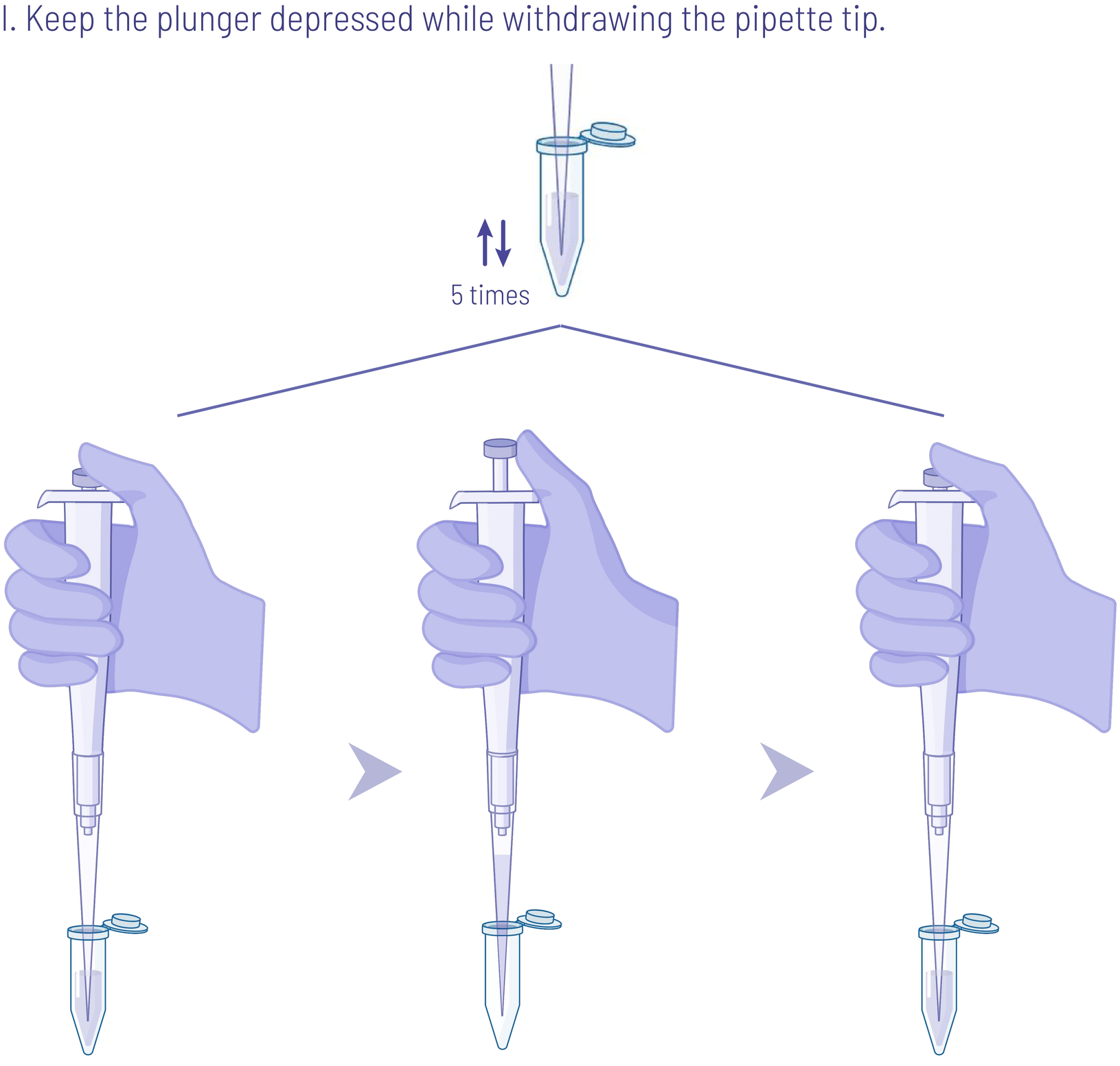


Sample Collection and Preparation

d. Transfer into a labeled **Reaction Buffer** ① tube.
   i. Insert the pipette tip into the reaction buffer ① and press the plunger to the second stop to dispense the extract.

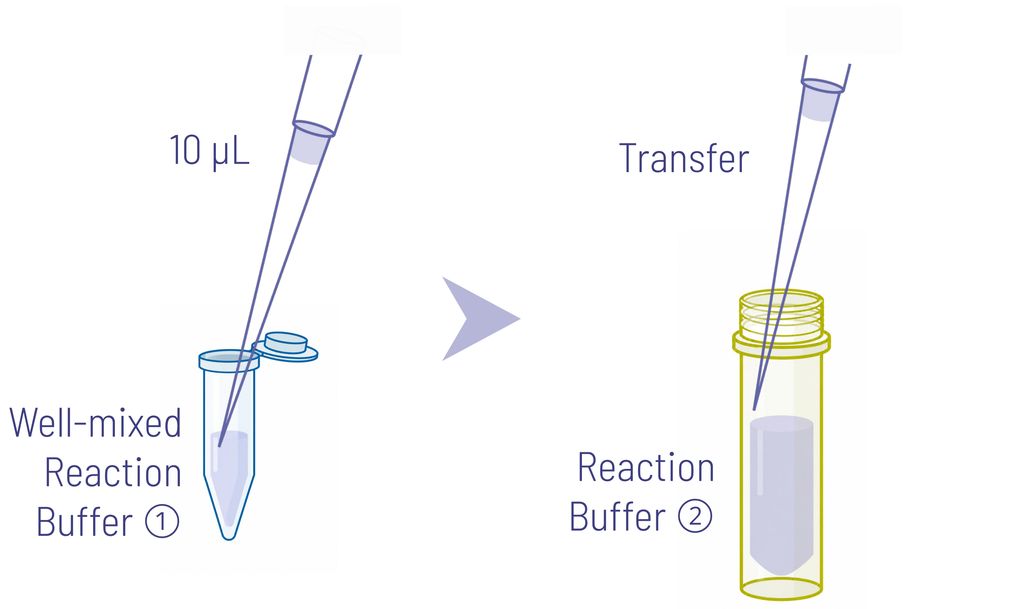


e. Mix by pipetting up and down 5 times.
   I. Keeping the pipette tip below the liquid surface, slowly aspirate some of the mixture into the tip and dispense it back into the tube.
   II. Repeat for five complete cycles, avoiding bubbles.
   III. Keep the plunger depressed while withdrawing the pipette tip.

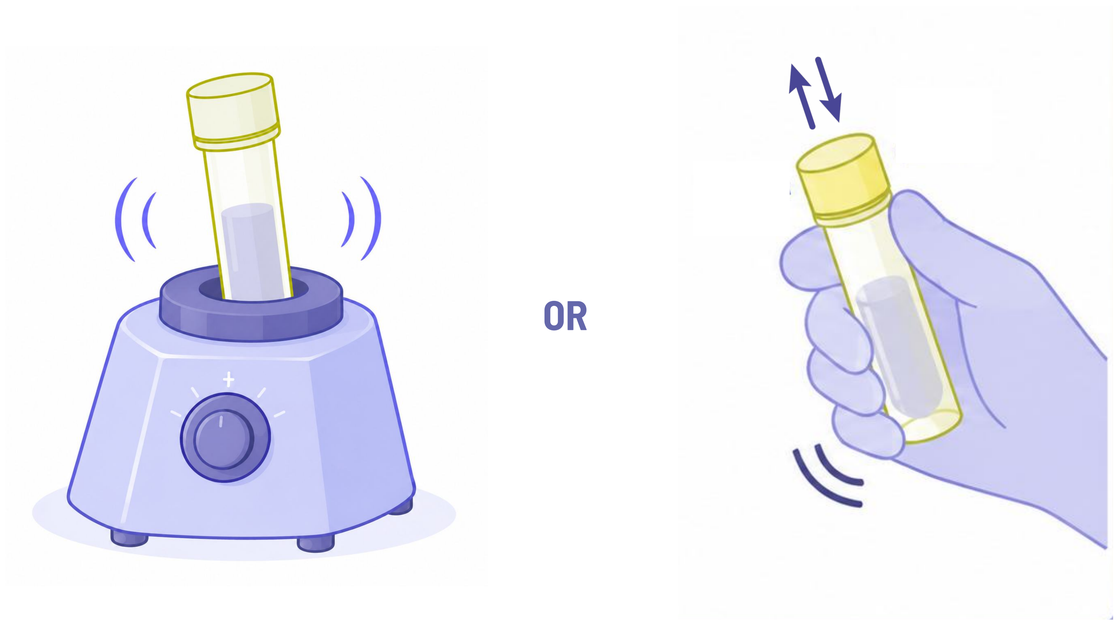


Sample Collection and Preparation

f. Aspirate **10µL** of well mixed Reaction Buffer ① into a labeled **Reaction Buffer** ② tube (yellow cap).



g. Cap Reaction Buffer ② immediately and vortex or agitate vigorously for 10–15 seconds.



h. Use the resulting processed sample for testing.

****IMPORTANT!**** Tap the tube on a surface to ensure all of liquid is at the bottom. Place the tube back into the tube rack.

***Note**: After this step, diluted extracts can be left (for 30 minutes maximum) while additional samples are processed.*

i. If processing more than 1 sample, repeat Steps 3-4 one sample at a time with the remaining samples using new buffers and materials.

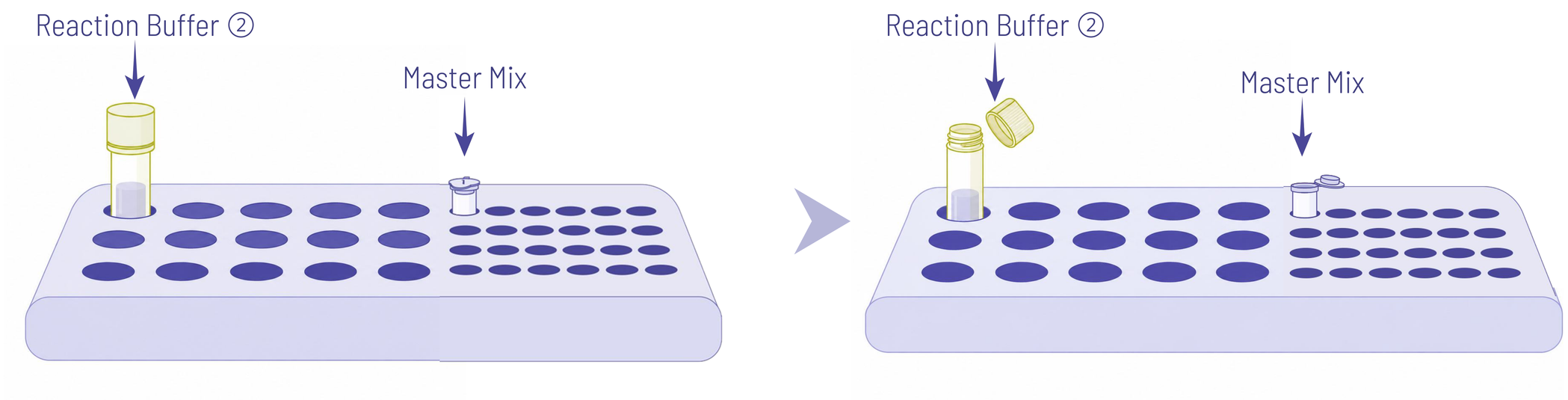
****IMPORTANT!**** Before proceeding to Step 5, ensure Steps 2-4 have been completed for all samples.

Sample Collection and Preparation

5. Add sample to master mix tube

** Carry out Step 5 for one sample at a time as promptly as possible. Instructions are provided for processing one sample, as an example.

a. Carefully open the lids of the reaction buffer ② tube (yellow cap) and the labeled master-mix tube with the corresponding sample ID.



b. Set the adjustable pipette to **30 µL** and attach a new tip.

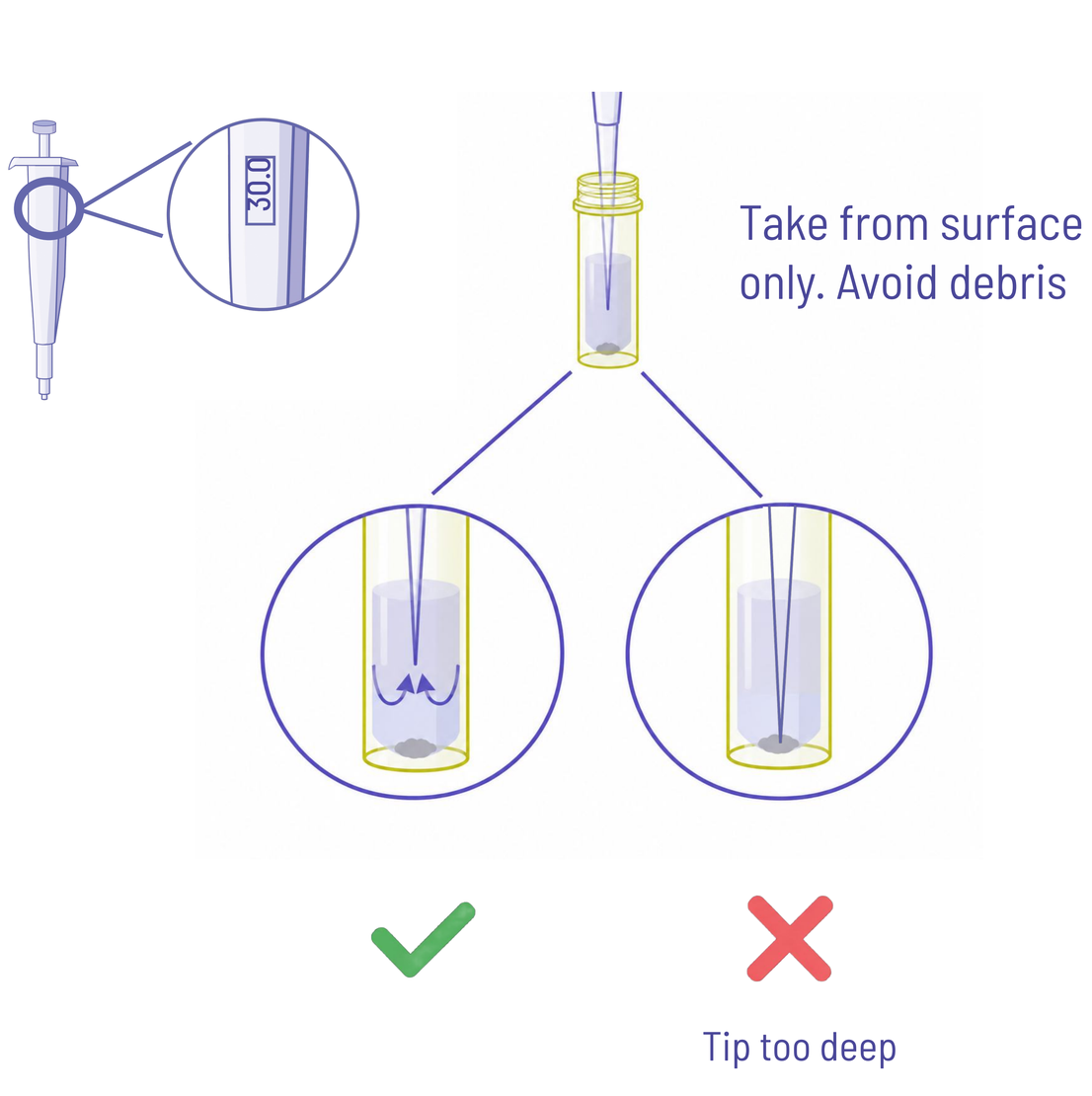
c. Using a fresh pipette tip for each tube, aspirate **30 µL** of the processed sample from the **Reaction Buffer ②** tube (yellow cap).

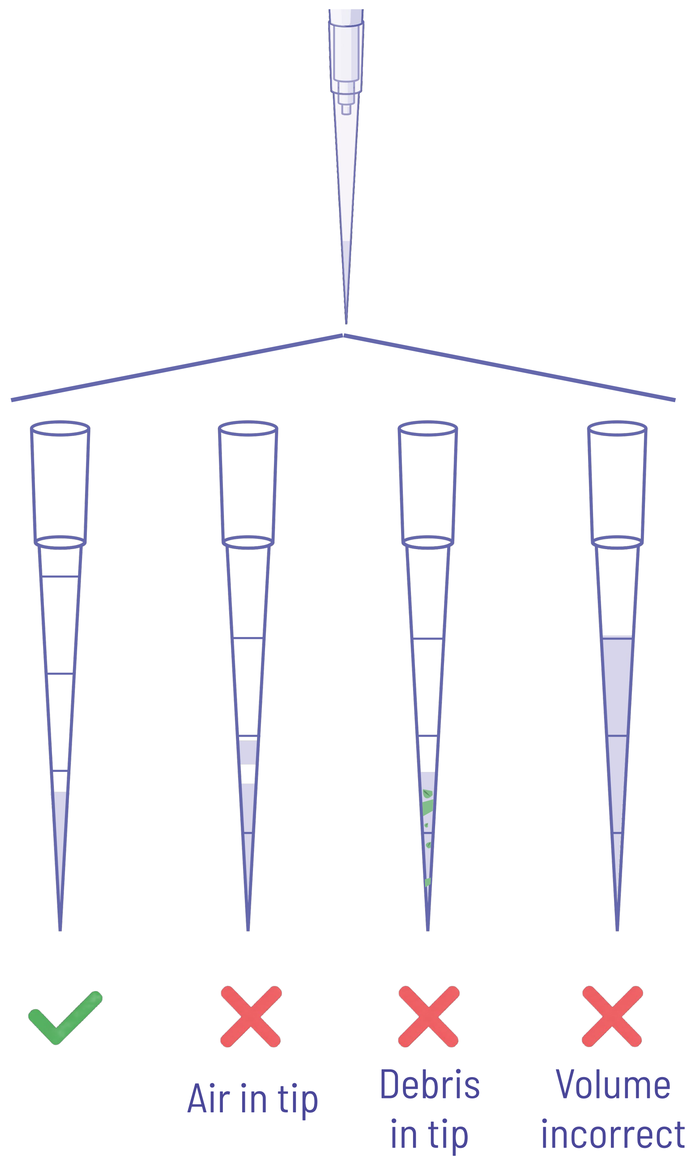
i. Press down the plunger until the first point of resistance.

ii. Insert the pipette tip just below the surface of the liquid to avoid debris.
Note: Do not insert the pipette tip too deep.

iii. Slowly release the plunger to aspirate 30 µL, then withdraw the pipette.

iv. Inspect the pipette tip.
Note: Ensure the liquid is between the lowest and middle indicator line and contains no air bubbles or debris. If necessary, discard the tip and repeat with a new pipette tip.



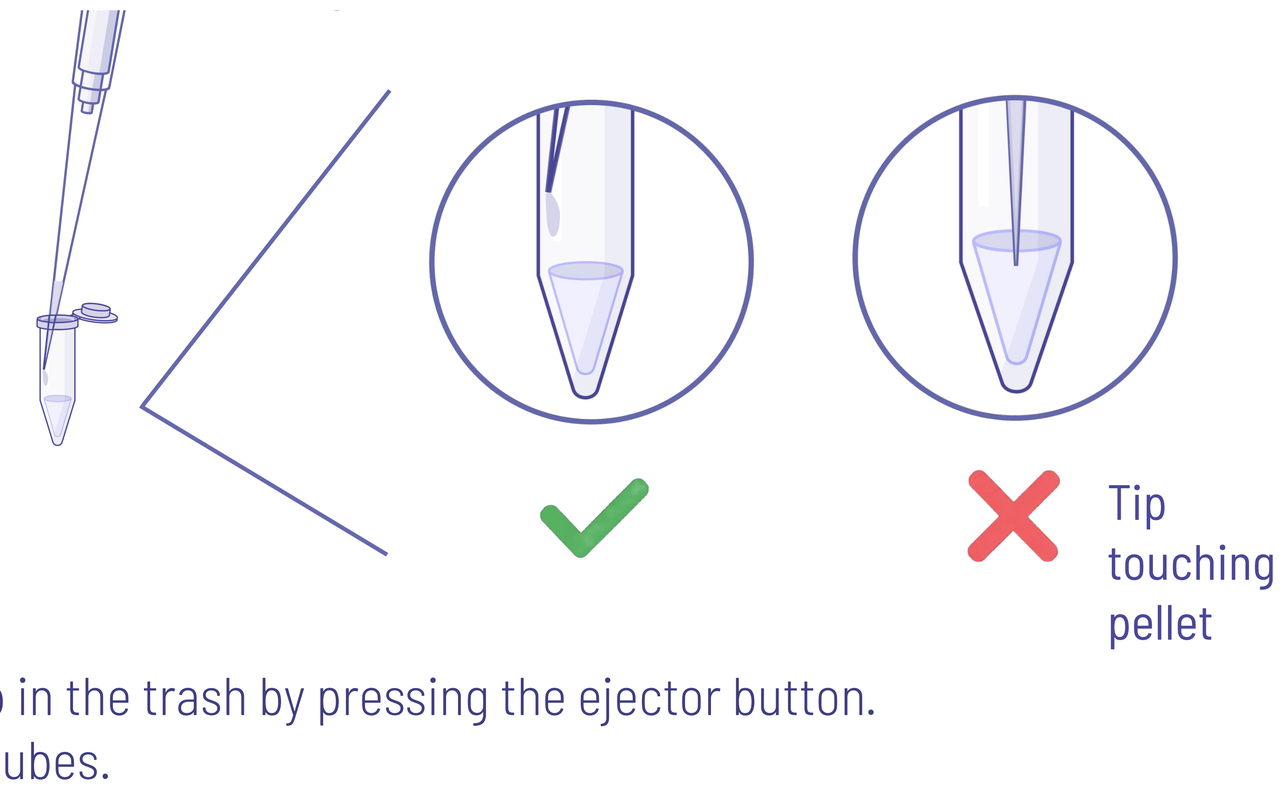


Sample Collection and Preparation

d. Transfer **30 µL** of the processed sample (from the Reaction Buffer ② tube, yellow cap) to the master mix tube.
   i. Insert the pipette tip into top half of the tube and press the plunger to the second stop to dispense the extract.
   ii. Keep the plunger depressed while withdrawing the pipette tip.

Note:

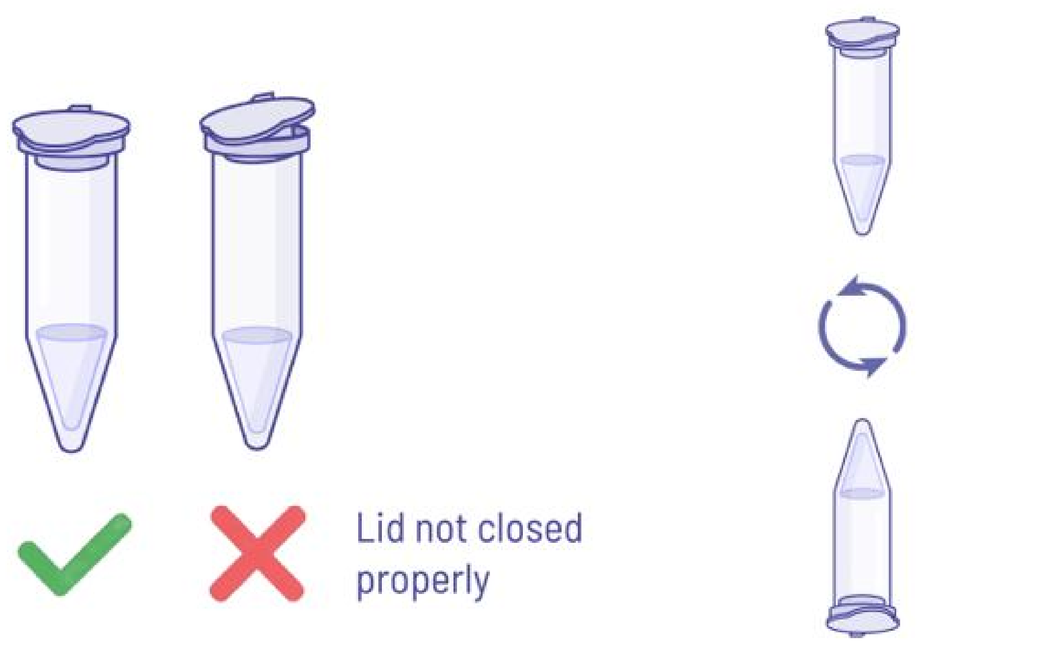
- *Avoid direct contact between the pipette tip and the lyophilized pellet.*
- *When dispensing, gently touch the tip to the inner wall of the tube slightly above the reagent pellet.*



e. Eject the tip in the trash by pressing the ejector button.
f. Close both tubes.

****IMPORTANT!**** Ensure the master mix tube is properly closed and the lid sits flush.

g. Gently invert or flick the master mix tube (PCR tube) until the pellet is fully resuspended and rehydrated.

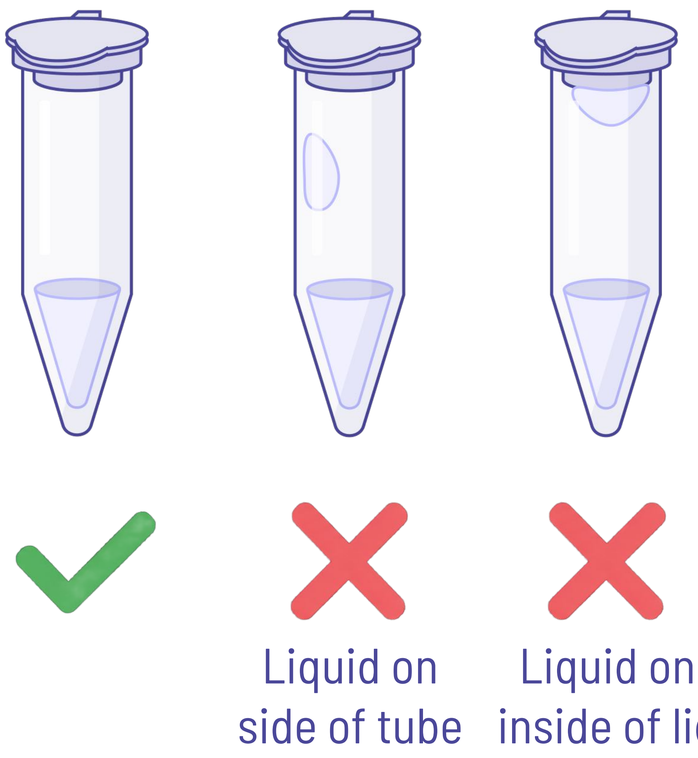


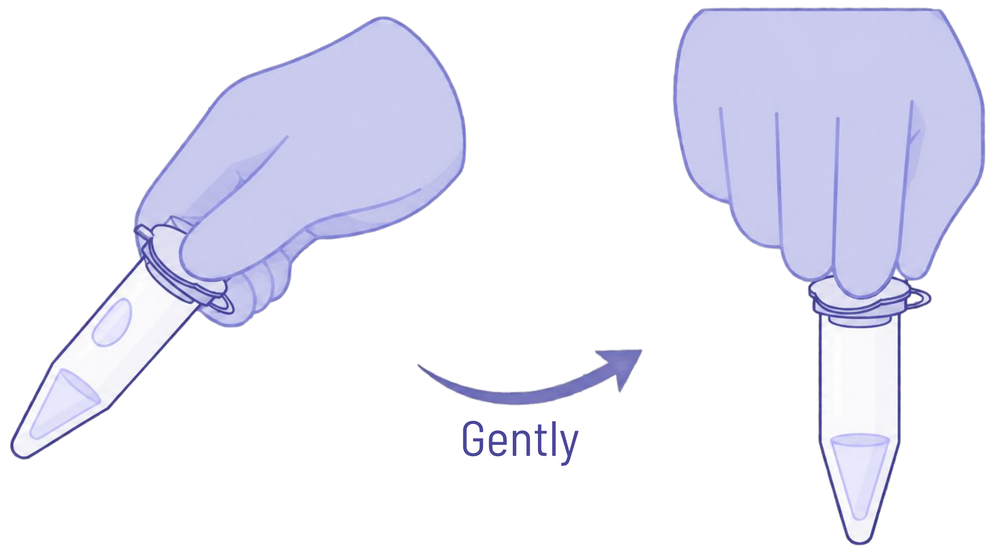
h. If running a second sample in the same batch, repeat **Step 5** with a new master mix tube, continuing to use a fresh pipette tip for every tube.

****IMPORTANT!**** Complete **Step 6** immediately after **Step 5**. Initiate testing in the device within 15 minutes of rehydrating the pellets.

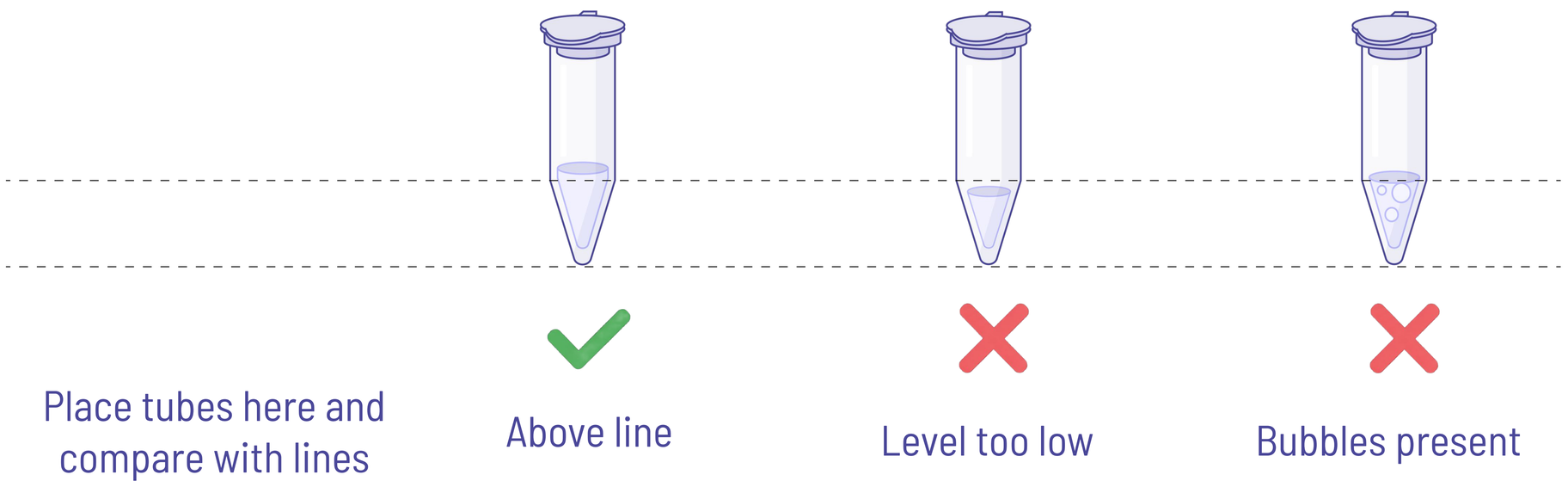
Sample Collection and Preparation

6. **Complete pre-test checks**
   a. Check the liquid position.
   CRITICAL! Ensure all liquid is at the bottom of the master mix tubes and no large bubbles are present. Gently flick or tap the tube to bring any liquid droplets to the bottom.
      i. If a microcentrifuge is available, briefly centrifuge the tube to bring the entire volume to the bottom and eliminate any air bubbles.





   b. Check the liquid volume.
   CRITICAL! Hold the tube upright and compare the liquid level with the reference line shown below. The liquid level should be at or above the line.
   IMPORTANT! Do not proceed if the liquid level is too low or large bubbles are present



Instructions for Diagnostic Test

1. Set up and run the diagnostic test in the CRISPOT® Device

a. Set up and turn on the CRISPOT® Device (refer to the "CRISPOT Detection Device IFU").

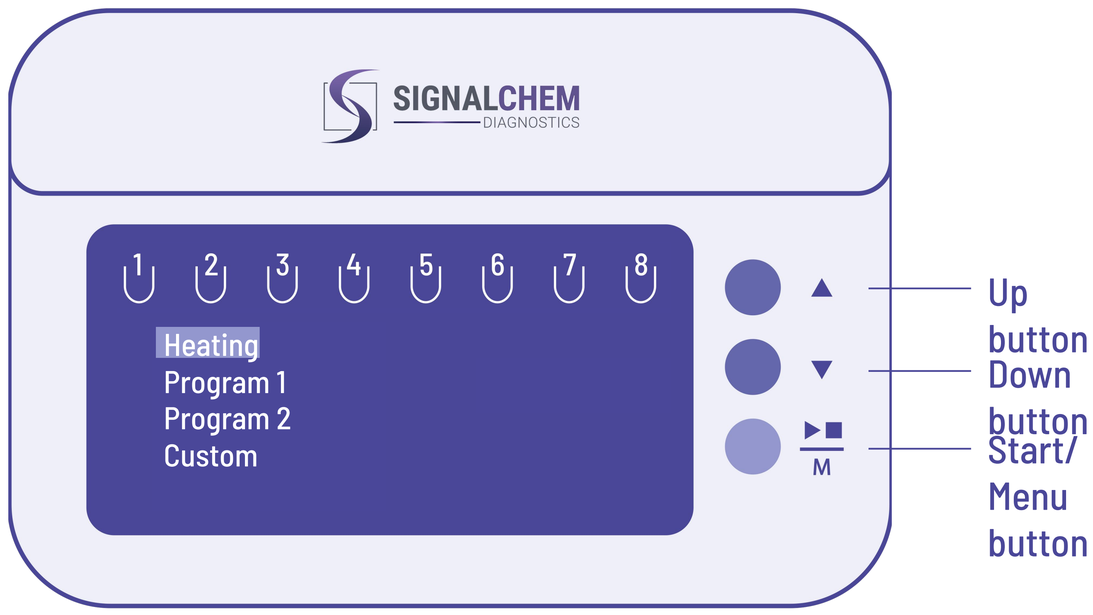
b. Preheat the device.

i. Using the "▲" and "▼" arrow buttons of the portable device, select "Heating".

ii. Run the heating program by pressing the "▶■" button.

iii. Wait until the temperature shows "60°C".

iv. Stop the heating program by pressing the "▶■" button **twice**.



c. Open the device lid and place the loaded master mix tube(s) into the CRISPOT® device reaction chamber in any well. Remember to record the corresponding well numbers and sample information for each sample.

***Note**: Press down gently to ensure the strips are fully and correctly seated in the wells of the device.*

d. Close the lid and initiate the test.

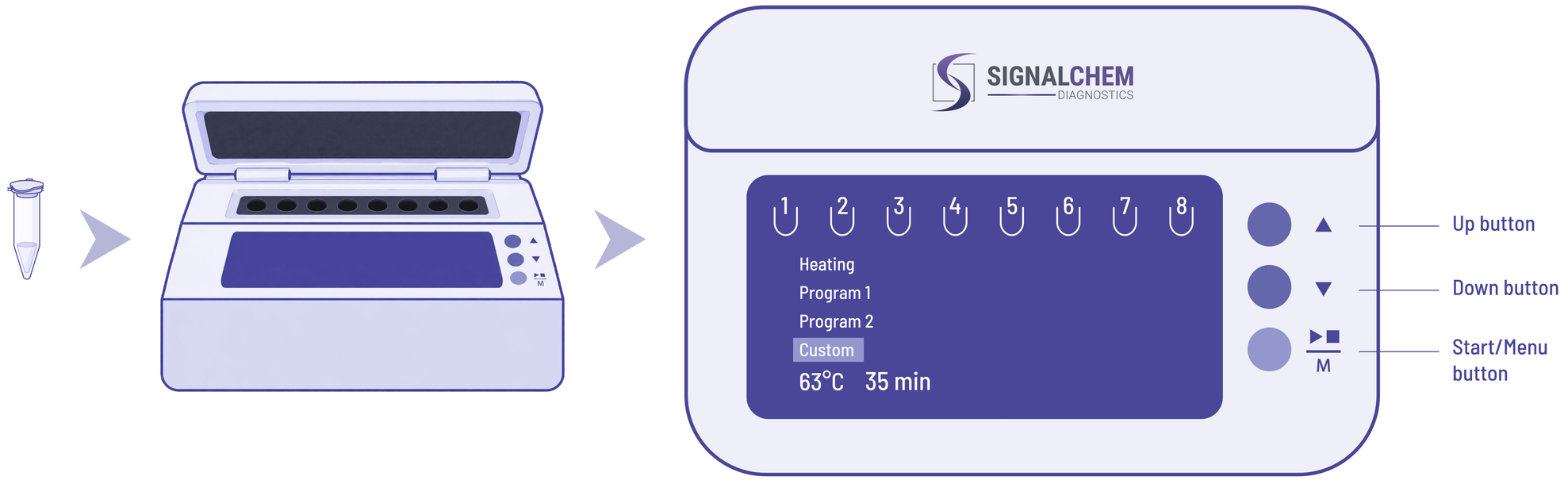
i. Using the "▲" and "▼" arrow buttons of the portable device, select "**Custom**".

ii. Verify that the display shows the correct run settings: **63°C** and **35 minutes**.

iii. III. Close the lid and start the run by pressing the "▶■" (Start) button. The display will show "Testing..."

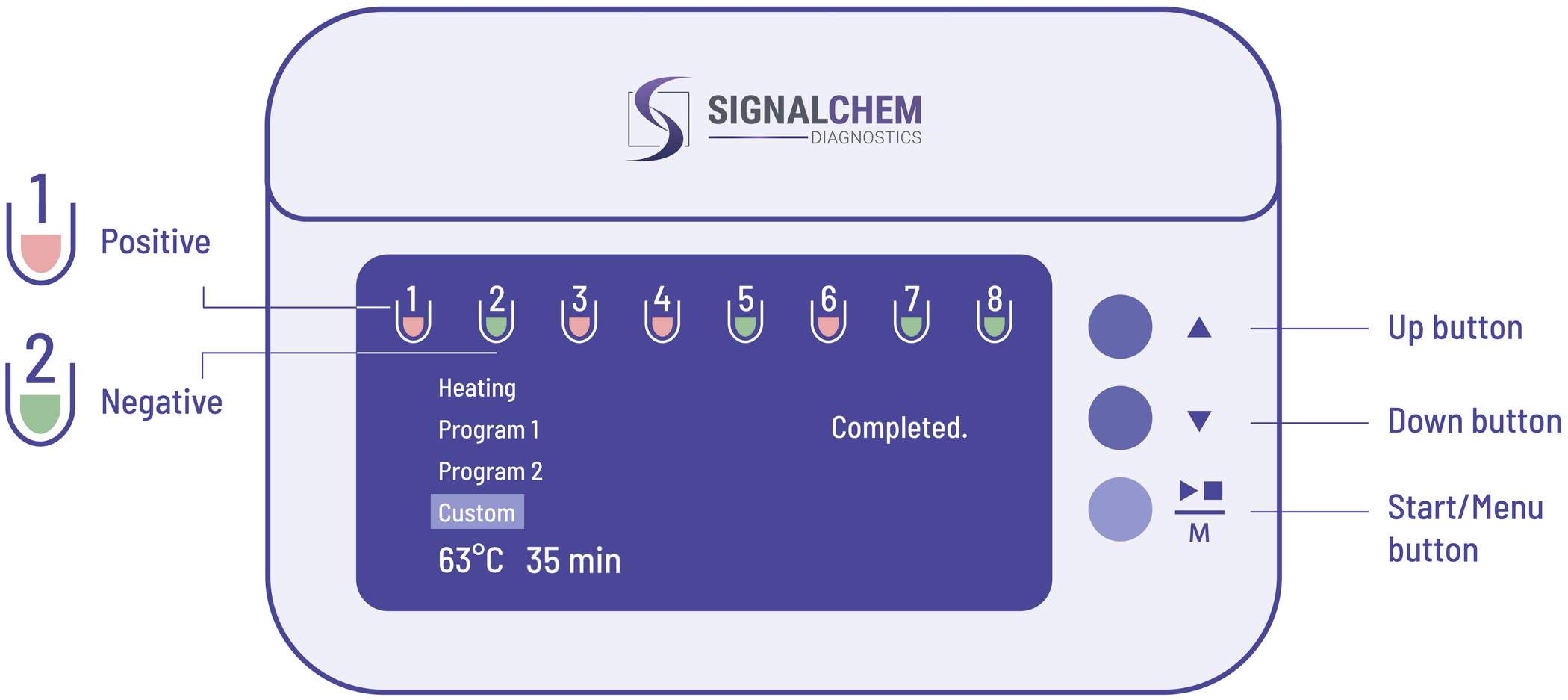
***Note:** The device should default to CUSTOM. Do not select any other program, as incorrect heating parameters will invalidate test results. The test will run for approximately 35 minutes. Do not open the lid or move the device during operation.*

e. When the run finishes, the screen will display "**Completed**."



Instructions for Diagnostic Test

2. **Determine results**
   a. When the test has completed, "Completed." will appear on the right half of the screen.
   b. The infection status of each sample will be displayed.
      i. **Red** indicates positive.
      ii. **Green** indicates negative.
   c. Record results immediately (write down or photograph).
      Note: *Don't press any buttons or turn off the machine before recording the results.*



3. **Disposal of samples and tests**
   a. All kit materials can be disposed of in regular garbage. Dispose of razors into sharps containers.
      ****IMPORTANT!**** To prevent contamination, DO NOT open master mix tubes once they have been tested in the CRISPOT® device.

Results Interpretation

A **positive (red) result** indicates that enterotoxin (cpe) gene nucleic acid of C. perfringens was detected at a concentration exceeding 300 copies/mg of fecal sample.

A **negative (green) result** indicates that target-specific nucleic acid was not detected above the 300 copies/mg clinical cutoff, or that the well is unused. A negative result does not completely exclude the presence of *C. perfringens*, particularly when levels are low or sample quality is inadequate.

Results for each well correspond directly to the sample layout configured for the run.

Test results should be interpreted together with clinical signs, patient history, and other diagnostic findings. If test results are inconsistent with the clinical presentation, additional testing using an appropriate laboratory method may be considered.

Limitations

Specimen requirements

- This assay is intended for testing fresh canine and feline fecal specimens as specified in this manual.
- Proper sample collection, handling, and preparation are important for reliable test results. Avoid collecting ground litter, soil, or straw with the specimen.
- Test specimens as soon as possible after collection.

Analytical limitations

- The assay detects target-specific nucleic acid sequences of the enterotoxin (cpe) gene of *C. perfringens*.
- Genetic variation within the target regions may affect assay performance and detection sensitivity.
- Positive and negative results are reported relative to the 300 copies/mg clinical cutoff.
- Samples with a target concentration at or below the cutoff will read as negative.

Procedural limitations

- Failure to follow the specified sample preparation and testing procedures may result in invalid or inaccurate results.
- Cross-contamination during sample collection, preparation, or testing may result in false-positive results.
- Improper or inadequate sample preparation, insufficient target material, or the presence of assay inhibitors may result in false-negative results.

Limitations on interpretation of results

- This assay provides qualitative results relative to a fixed clinical cutoff and does not report the actual target concentration.
- *C. perfringens* can be present in the feces of healthy animals. Results should not be used alone to diagnose *C. perfringens*-associated disease.
- A positive result indicates detection of target-specific nucleic acid but does not indicate bacterial viability or excludes the presence of other enteric pathogens.
- A negative test result does not completely exclude the presence of the target, particularly when the target level is below the assay's clinical cutoff or detection limit.
- Test results should be interpreted together with clinical signs, patient history, and other diagnostic findings. Additional testing may be considered when test results are inconsistent with the clinical presentation.

References

- Weese JS, Staempfli HR, Prescott JF, Kruth SA, Greenwood SJ, and Weese HE. The roles of Clostridium difficile and enterotoxigenic Clostridium perfringens in diarrhea in dogs. Journal of Veterinary Internal Medicine. 15(4):374–378, 2001.
- Freedman JC, Shrestha A, and McClane BA. Clostridium perfringens enterotoxin: action, genetics, and translational applications. Toxins. 8(3):73, 2016. doi:10.3390/toxins8030073.
- Uzal FA, Freedman JC, Shrestha A, Theoret JR, Garcia J, Awad MM, Adams V, Moore RJ, Rood JI, and McClane BA. Towards an understanding of the role of Clostridium perfringens toxins in human and animal disease. Future Microbiology. 9(3):361–377, 2014.

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Index of Symbols

Do not reuse	Manufacturer	Catalog number
Temperature limit	Batch code	Consult instructions for use
Caution	Use by	

Manual Version History

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