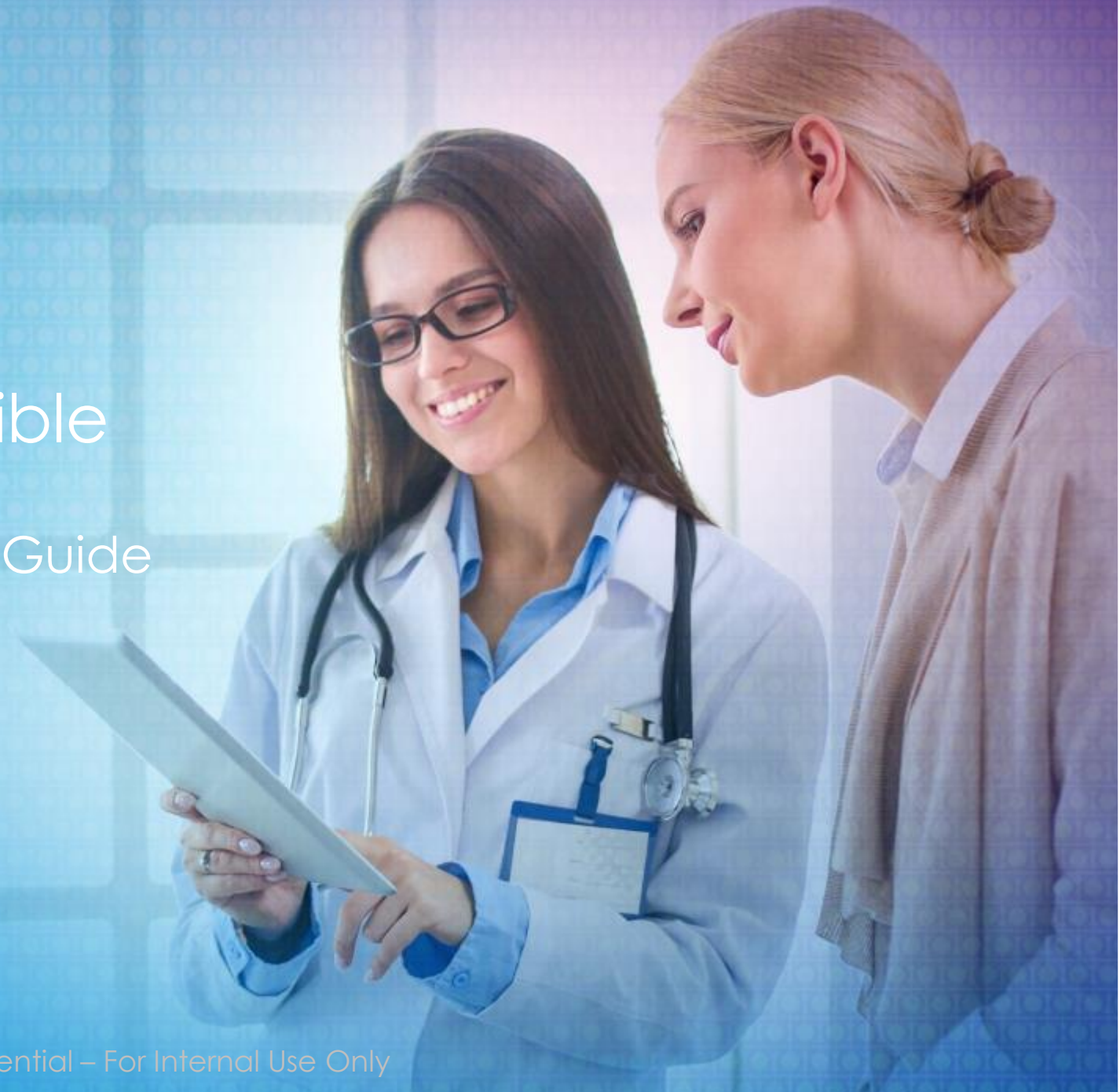




ResistancePlus[®] MG Flexible

Cepheid Internal Demonstration Guide



Confidential – For Internal Use Only

ResistancePlus[®] MG FleXible

1

Cartridge labels

LS-IV0168 v3 yyyy-mm-dd **LOT** nnnnnnn

FleXible for GeneXpert System

Box 1

ResistancePlus[®] MG FleXible

REF S2A-2000410 yyyy-mm-dd

LOT nnnnnnn yyyy-mm-dd

01) 0 83 52224 00038 2

10) nnnnnnn

17) nnnnnnn

CE 0123 IVD UK CA

Plex Mastermix, 2x	1 x 440 µL
MG+235 Mix, 20x	1 x 50 µL
Internal Control Cells	1 x 100 µL
ResistancePlus MG FleXible labels	10 Labels
MG FleXible Mix Label	1 Label

EC REP MedEnvy Pijpstra Magrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands

UK Responsible Person:
SpeedX Ltd
Acra House, 1115 William Road,
London, NW1 3 ER

PIN: 2000410-R LS-IV0163 v4

Box 2

ResistancePlus[®] MG Flexible Cartridge

REF S2A-2000410 **MASTER LOT** nnnnnnn

yyyy-mm-dd **CART LOT** nnnnnnn

CE 0123 IVD UK CA

EC REP MedEnvy Pijpstra Magrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands

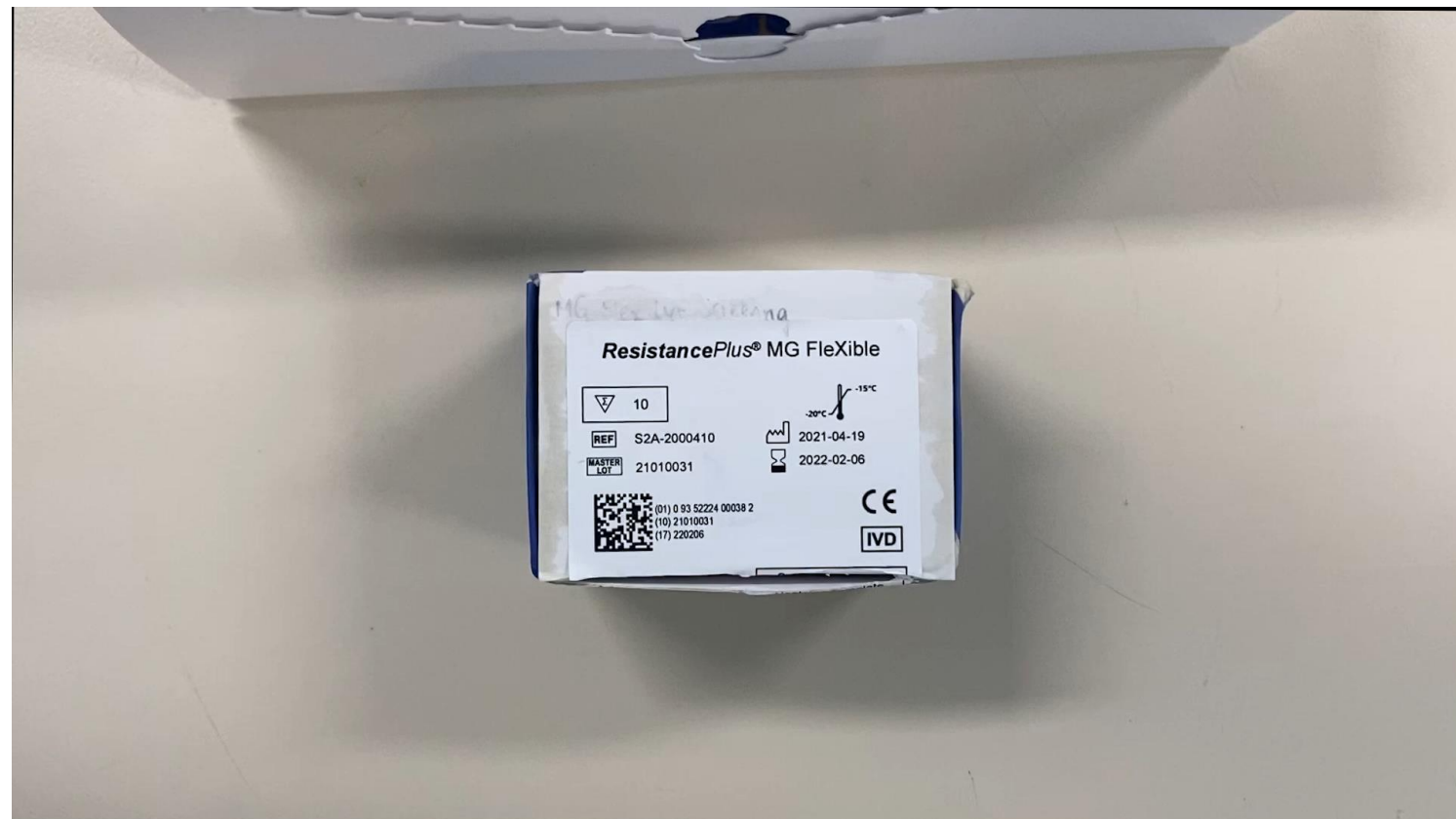
UK Responsible Person:
SpeedX Ltd
Acra House, 1115 William Road,
London, NW1 3 ER

SpeedX Pijpstra
Suite 102, Norder Innovation Center,
Eindhoven, 5505 CD, Netherl.
Tel: +31 2 226 4100

PIN 2000410-CART LS-IV0171 v3

Obtain cartridge labels from Box

Note: Ensure the MASTER LOT number matches between the cartridge labels, Box 1 (reagents) and Box 2 (cartridges)



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Affix cartridge label to the front of the cartridge

Note: Ensure label on cartridge is straight

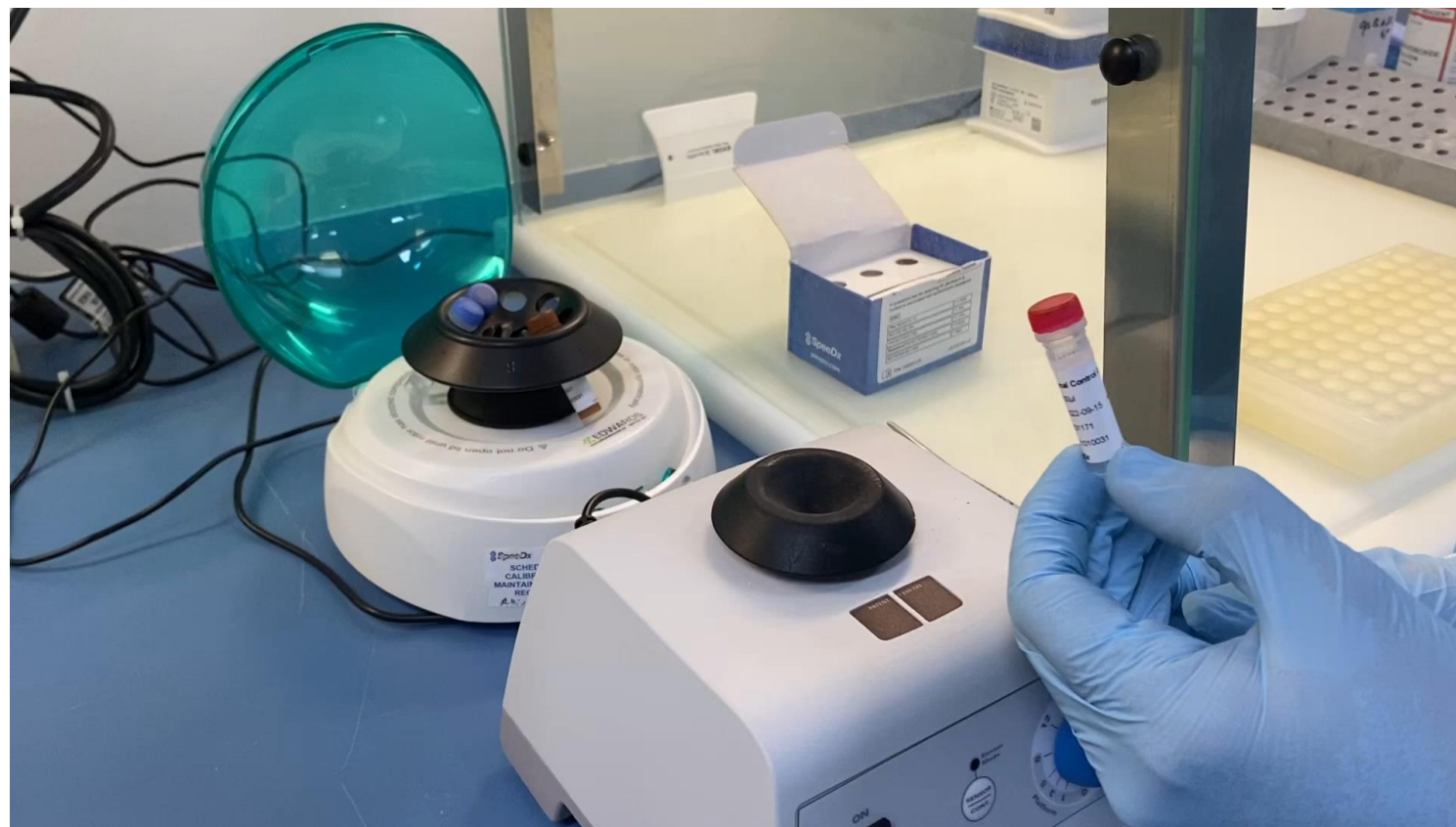


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3

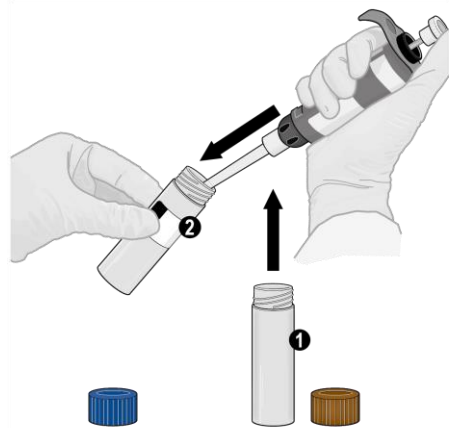


Thaw reagents and internal control. Vortex tubes for 5 - 10 seconds and centrifuge for 5 - 10 seconds at a low speed to collect liquid in the bottom of the tube



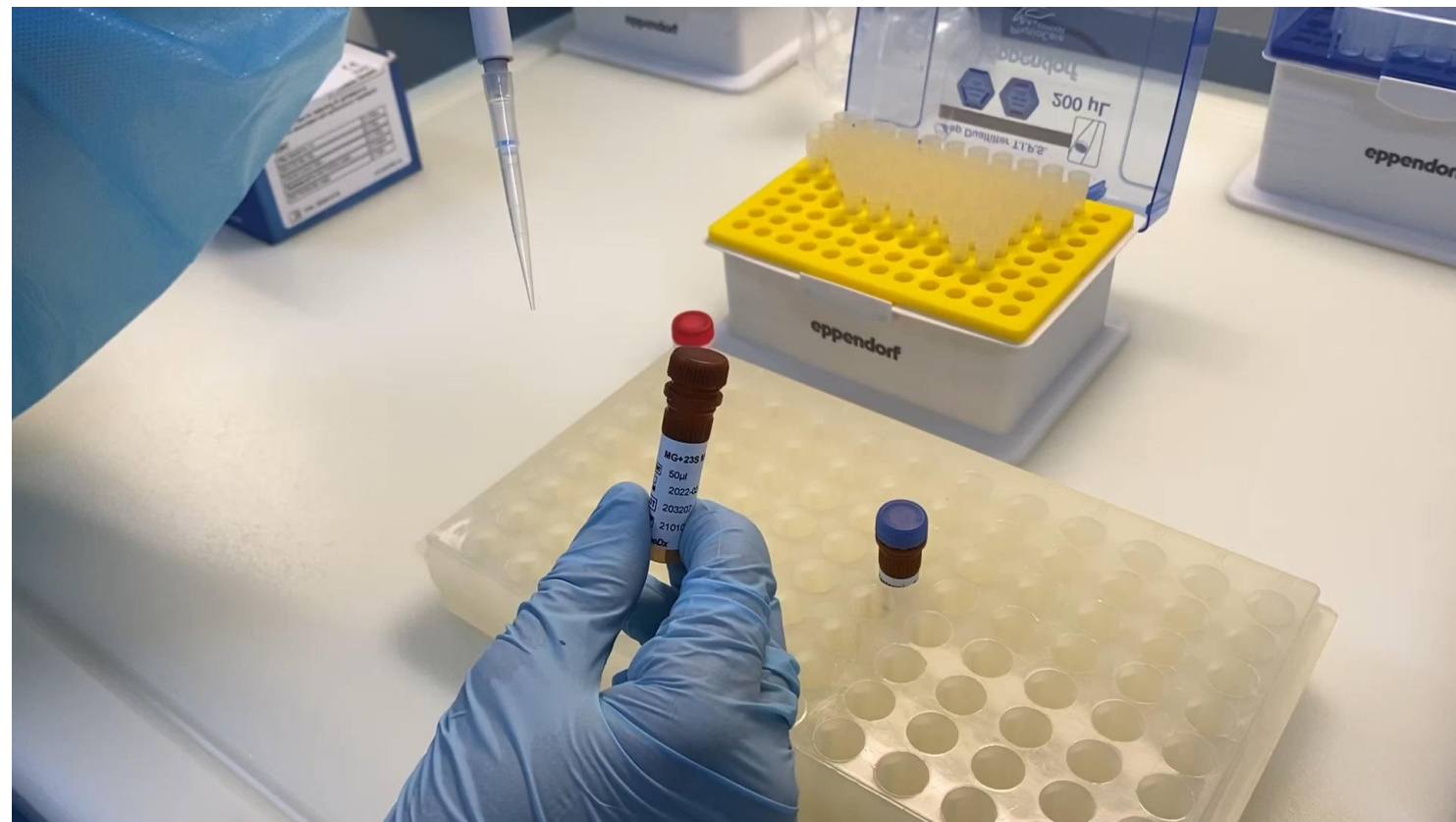
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4



Pipette 44 µL of MG+23S(GX) (**Brown lid**) directly into **Plex** Mastermix tube (**Blue lid**). Recap and tighten lid of the Plex Mastermix tube (**Blue lid**). This is now your combined **Reaction** mix.

*Discard the empty MG+23S (GX) tube (**Brown lid**) after transferring contents*



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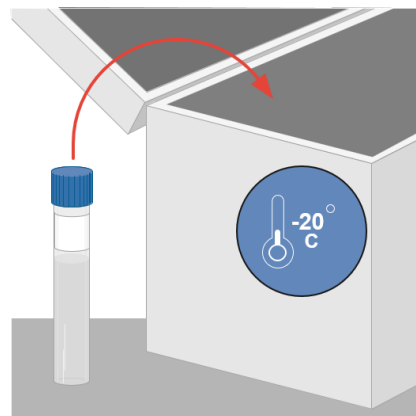


Vortex the combined Reaction Mix tube (**blue lid**) for 5 - 10 seconds and centrifuge for 5 - 10 seconds at low speed



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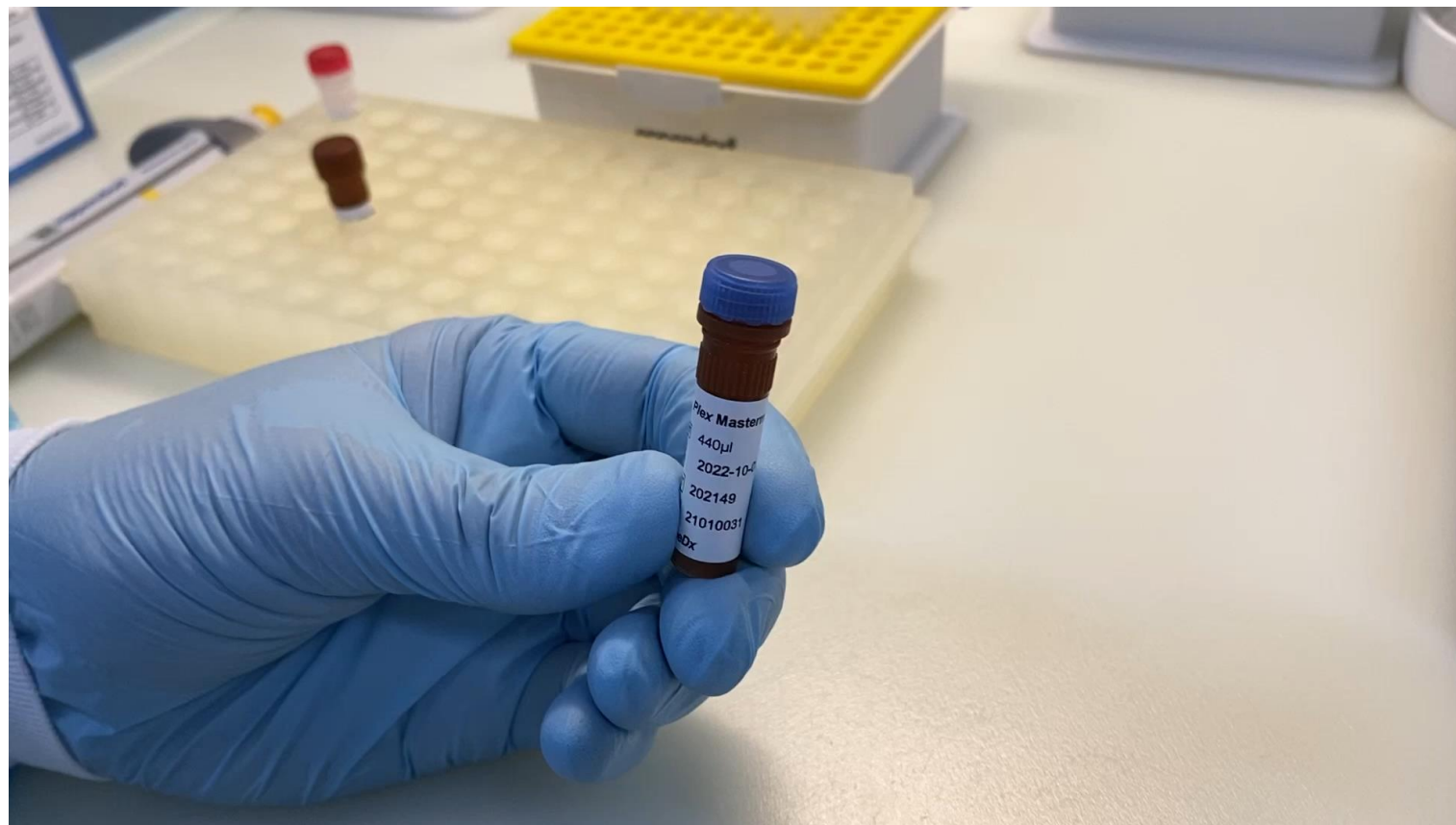
6



The combined Reaction mix is now sufficient for 10 reactions

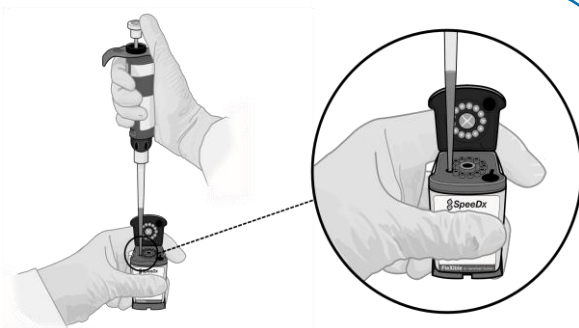
Note: Combined Reaction mix can be stored between -25°C to -15°C for up to 8 weeks or no more than 8 freeze-thaw cycles

Note: Do not prepare aliquots



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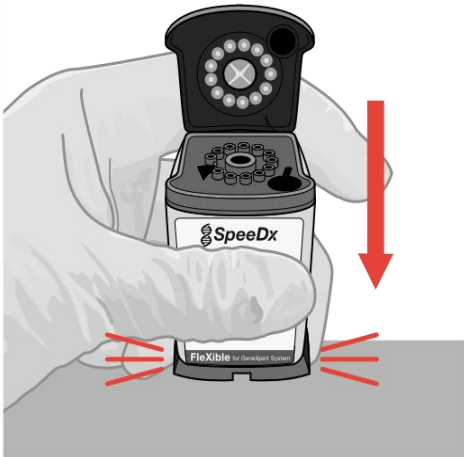
Open lid cartridge and Pipette 44 μ L of combined Reaction Mix (**blue lid**) into Reaction Chamber (left)

Insert pipette tip vertically as far as it will go inside chamber before expelling liquid



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Gently tap bottom of cartridge on bench to **settle liquid and prevent any air bubbles**



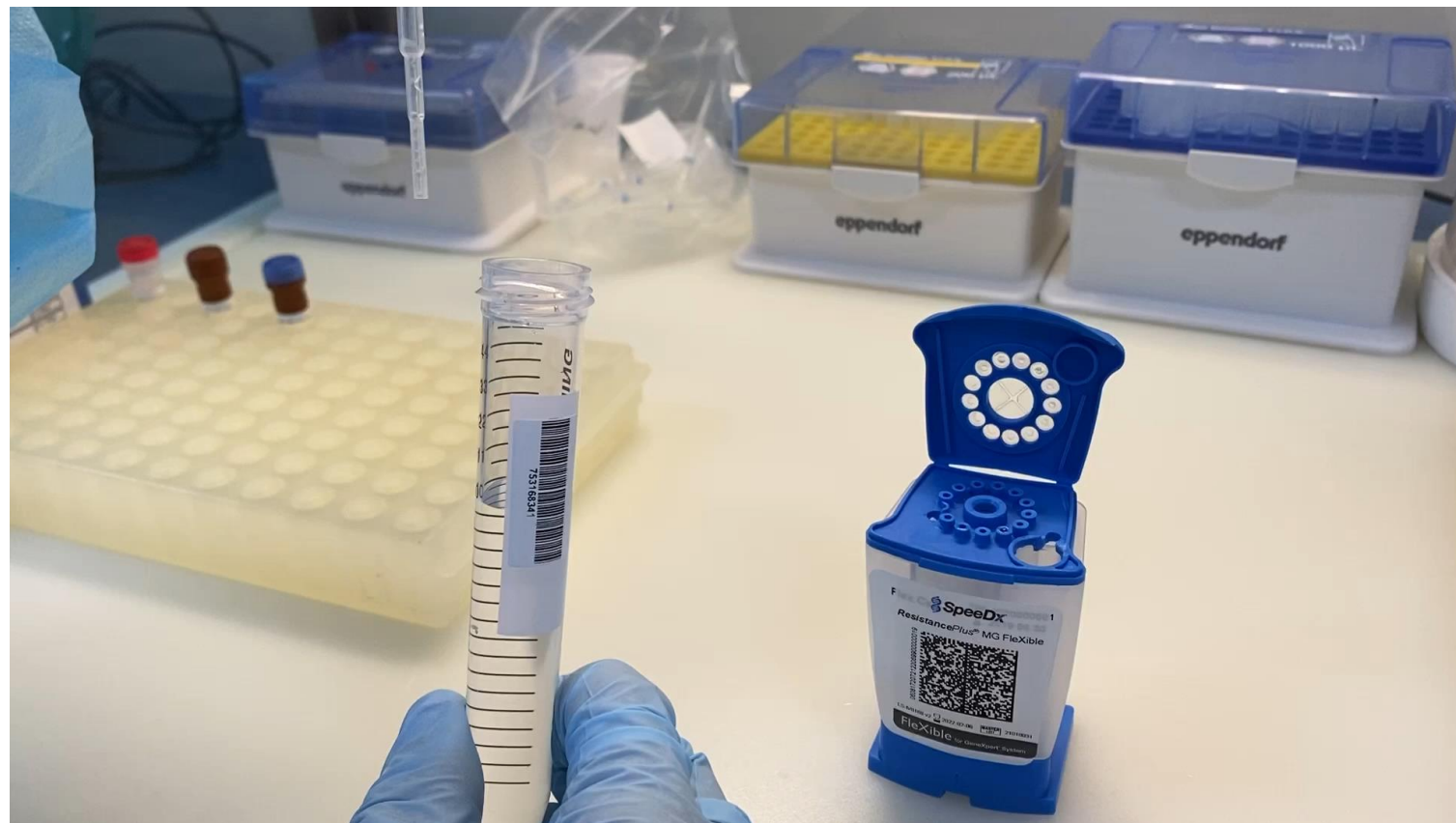
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9



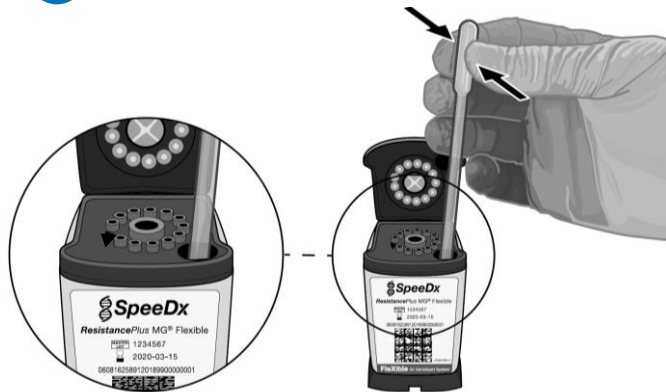
Open sample tube lid. Take provided transfer pipette and **slowly** compress the bulb. Insert pipette into the sample tube and **slowly** release the bulb to fill the transfer pipette above the 1 mL mark on the pipette shaft

Note: The aspirated sample should not contain air bubbles



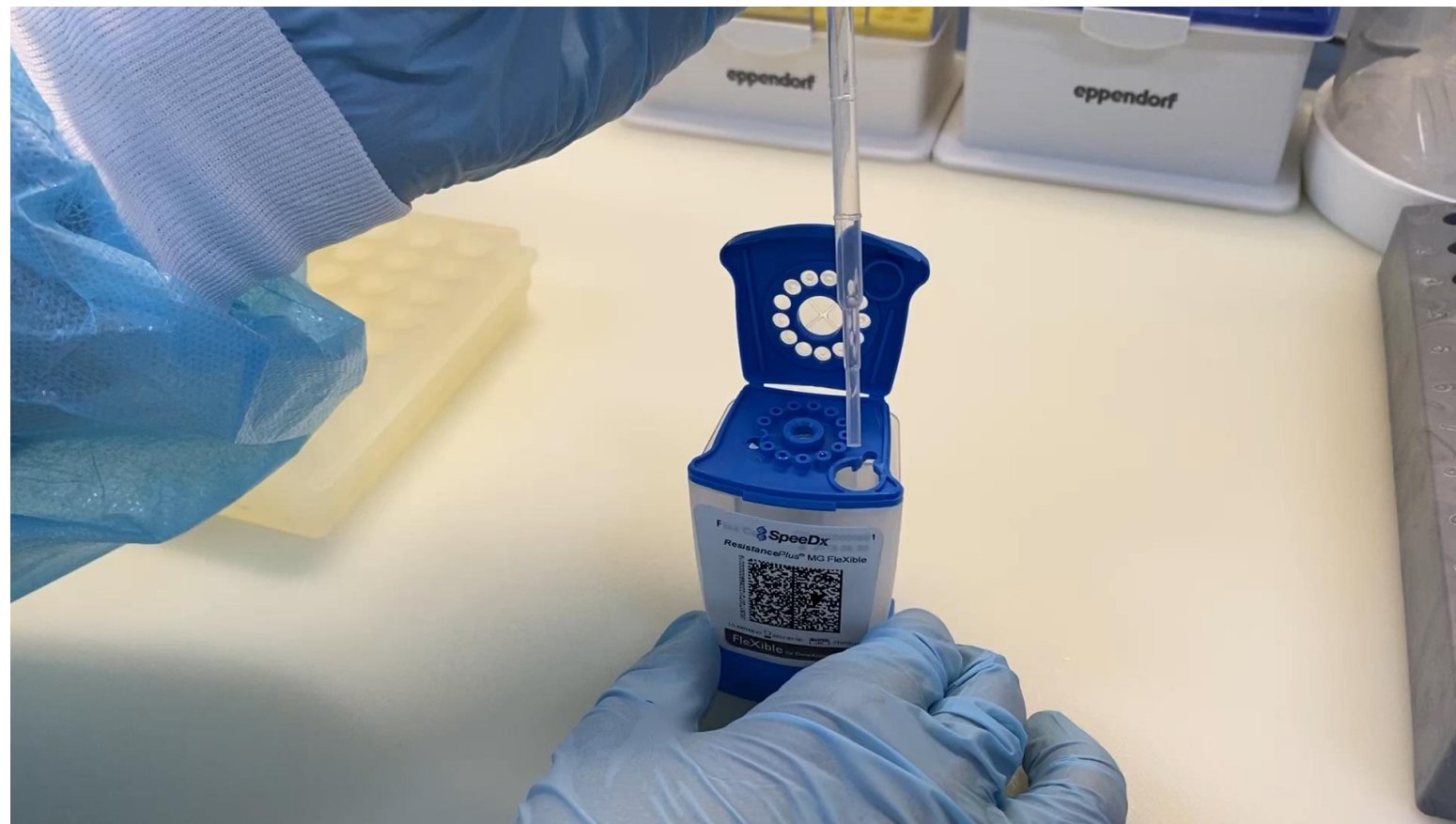
ResistancePlus[®] MG Flexible

10



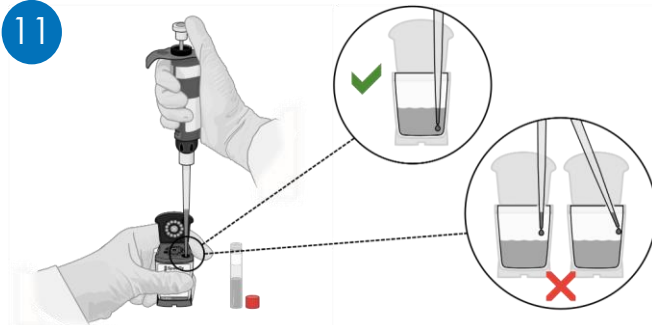
Slowly compress bulb to dispense sample from the transfer pipette into the Sample Chamber of the cartridge (right)

Note: Excessive force can create bubbles. Gently pipette to avoid unnecessary bubbles



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Pipette 10 μ L of Internal Control Cells (**Red lid**) into Sample Chamber (Right)

Note: Ensure pipette tip is **correctly immersed in the sample** before expelling the liquid

Note: The Internal Control Cells can be stored between -25°C to -15°C and undergo no more than 8 freeze-thaw cycles



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Close the cartridge lid.
Do not mix or shake cartridge

Note: The cartridge should be loaded
within 30 minutes of preparation



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13



Place in the GeneXpert[®] instrument.
Start test

Note: The cartridge should be loaded
within 30 minutes of preparation



ResistancePlus[®] MG FleXible box 2 storage

Tip:

Usual GeneXpert[®] cartridges boxes are larger than GeneXpert cartridge boxes.



As for any GeneXpert[®] cartridges, ensure FleXible boxes are stored with label on top to avoid buffer leaks.

Lab settings recommendations

The **ResistancePlus**[®] MG Flexible Instructions For Use Section 6 state:

6 Associated products and consumables

General lab consumables

- Gloves and clean lab coats
- Vortex mixer
- Benchtop centrifuge for 1.5 mL tubes
- **Micropipettors covering the range 10 - 100 μ L**
- **Sterile aerosol-resistant, DNase/RNase free, pipette tips**
- Sterile transfer pipettes capable of transferring at least 1 mL volume

The **vortex mixer** is important to ensure proper homogenization of the reagents (which can be slightly viscous) after thawing or mixing. Poor homogenization may cause errors and inconsistent results

Centrifuging after vortexing is crucial to collect all liquid at the bottom and avoid volume loss.

It is recommended for the user to pipette microvolumes whilst sitting down in a stable position

Lab settings recommendations

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- **Micropipettors covering the range 10 - 100 μ L**
- **Sterile aerosol-resistant, DNase/RNase free, pipette tips**
- Sterile transfer pipettes capable of transferring at least 1 mL volume

Micropipettors must be calibrated to guarantee precise microvolume dispensing.

They should be paired with the manufacturer-recommended **tips**. Many generic tips exist on the market but are not all equivalent and well adapted to any pipet, even though they seem to fit.

At the μ L level, imprecision can impact performance. From what we have observed with users:

- When adding MG+23S(GX) mix (**Brown** lid) into Plex Mastermix tube (**Blue** lid), more than 44 μ L may lead to probe check failure error 5006. Less may lead to probe check failure error 5007/5017.
- Adding too much combined reaction mix may lead to error 5006, as well as a cumulated volume loss that would in the end prevent using the kit for the expected 10 reactions. This is despite the extra volume (44 μ L) that is provided in the combined reaction mix.

Processing recommendations

The **Quick Reference Guide** is very helpful to guide users step by step, it is designed to be placed at the bench.

Details are significant, **do not skip or modify the order***.

ResistancePlus® MG FlexiBle Cartridge Preparation Card

Refer to the Instructions for Use for detailed instructions, precautions, and warnings.

- 1 Obtain cartridge label and ensure the MASTERLOT number is identical to the reagent and cartridge boxes.
- 2 Affix cartridge label to the front of the cartridge. Ensure label on cartridge is straight.
- 3 Thaw reagents and internal control. Vortex, then centrifuge tubes at low speed.
- 4 Pipette 44 μ l of MG+23S (GX) (brown lid) directly into Plex Mastermix tube (blue lid). Recap & tighten. This is now your combined Reaction mix.
- 5 Vortex, then centrifuge, combined Reaction mix tube (blue lid), at low speed.
- 6 The combined Reaction mix is sufficient for 10 reactions and can be stored between -25 to -15°C for up to 8 weeks / no more than 8 freeze-thaw cycles. Do not prepare aliquots.
- 7 Pipette 44 μ l of combined Reaction Mix (blue lid) into Reaction Chamber (left). Insert tip vertically as far as it will go before expelling liquid.
- 8 Gently tap bottom of cartridge on bench to settle liquid and prevent any air bubbles.
- 9 Aspirate 1 ml of sample from sample vial with disposable transfer pipette. Ensure no bubbles.
- 10 Transfer pipette into the Sample Chamber (right), and slowly compress bulb to release sample.
- 11 Pipette 10 μ l of Internal Control Cells (red lid) into Sample Chamber. Ensure pipette tip is correctly immersed in the sample before expelling the liquid. The Internal Control Cells can be stored between -25 to -15°C and undergo no more than 8 freeze-thaw cycles.
- 12 Close the cartridge lid. Do not mix or shake cartridge.
- 13 Place in the GeneXpert. Start test within the timeframe specified in package insert.

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* Dispensing the internal control cells before the sample or not immersing the tip in the sample may cause IC failure. 10 μ L is a small volume that may remain attached to the tip and be discarded with it, or it could remain on the inside of the cartridge wall instead of falling into the sample at the bottom.