



## HG Mycoplasma genitalium Positive Control Kit

HGMYGC

# Instructions for Use

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## 1. Kit Contents

HG Mycoplasma genitalium Control kit contains sufficient material for 18 control runs:

	Description
<b>HG Mycoplasma genitalium Positive Control</b>	1 x 1.1 mL vial
<b>Part # MYG-PC</b>	Buffered plasmid solution containing preservative

## 2. Shelf life & Storage

- Kits must be stored at 2-8 °C and used before the expiry date on the kit label.
- Opened vials of Positive Control must be sealed tightly before storage at 2-8°C and used before the expiry date on the vial label.

## 3. Accessories

### Supplied by HiberGene:

- **HG Swift Strip Carriers** are supplied with the HG Swift instrument and are used for handling, loading and unloading of HG Mycoplasma genitalium reaction strips. These are also available to order separately (Part # HGCAR)
- **HG Swift Set-up Racks** are supplied with the HG Swift instrument and are used for loading samples into HG Mycoplasma genitalium reaction strips. These are also available to order separately (Part # HGRACK)
- **HG Mycoplasma genitalium assay kit (Part # HGMYGR)** is a molecular diagnostic assay for the detection of *Mycoplasma genitalium* in human clinical samples.

**Required but not provided:**

- Calibrated micropipettes.
- Micropipette tips with filters, certified nuclease-free.
- Centrifuge.
- Vortex mixer.

## 4. Intended Use

The HG Mycoplasma genitalium Control Kit contains positive control material for use with the HG Mycoplasma genitalium assay. The positive control contains a nucleic acid sequence which is detected by both the Target and Extraction Control reaction mixes of the HG Mycoplasma genitalium kit and is intended to be used for Quality Control purposes to detect deterioration in reagent performance, operator-driven variation, and the impact of environmental factors.

Laboratory usage of control material may depend on local regulations and practice, accreditation requirements, and staff proficiency. It is recommended that the control is run, at a minimum, upon receipt of a new lot or new shipment of HG Mycoplasma genitalium assay kits.

The intended end user is a trained laboratory/health professional. Users must have received training from the distributor/Hibergene staff prior to using the device.

## 5. Precautions

### General Precautions

- The HG Mycoplasma genitalium Control kit is for *in vitro* diagnostic use only.
- Training on the test protocol must be carried out before use of the test.
- Surplus kit components should be disposed of in accordance with established safety procedures.
- Never mouth-pipette, eat or drink in the laboratory.
- Pipette tips used should include filters and be certified nuclease-free. Micropipettes used should be calibrated in accordance with applicable guidelines.
- Clean down all work surfaces after assay runs with a disinfectant solution with proven efficacy in DNA removal.
- The instrument should not be used in an area with a high or low magnetic field.
- Kits with damaged packaging or opened pouches should not be used.

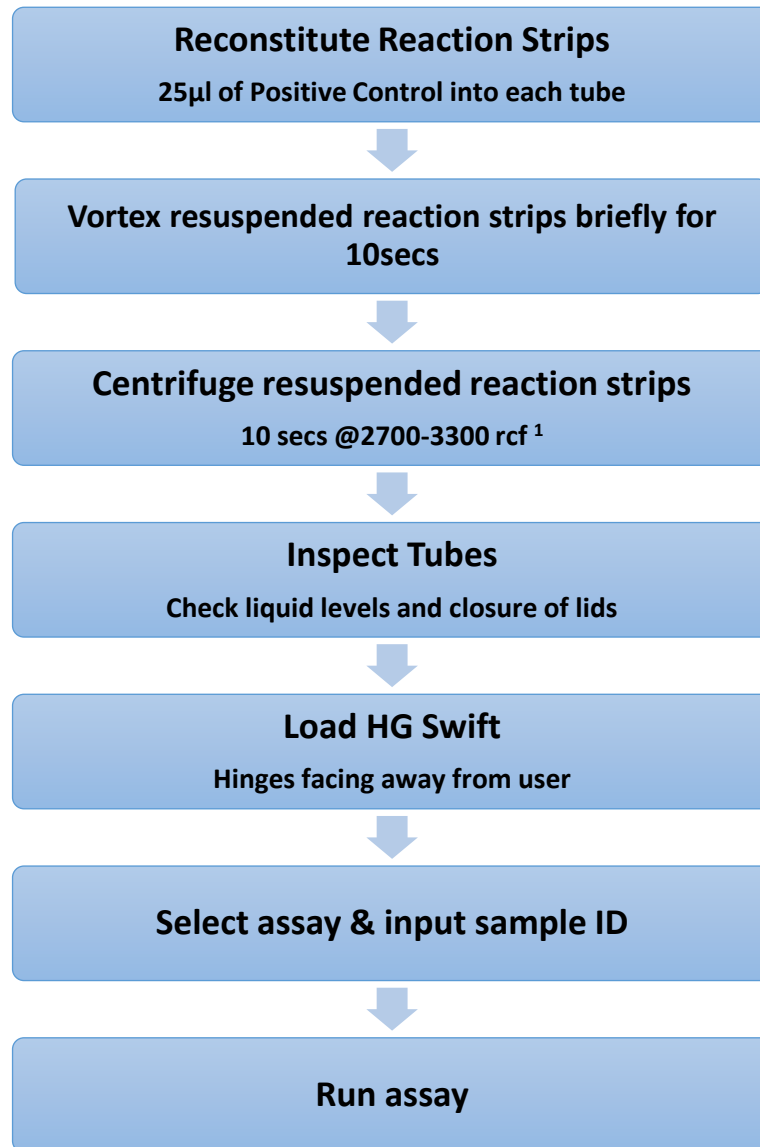
### Preventing amplicon contamination

Escape of amplified material from reaction strips after LAMP amplification can result in laboratory contamination which could impact on subsequent test results. HG Mycoplasma genitalium reaction strips are specifically designed to resist accidental reopening, but the following specific precautions must always be followed:

- After adding sample into tubes, close caps **firmly and completely**.
- **Never** re-open the caps of the reaction strips after closing.
- After the run, remove the reaction tube strip from the HG Swift lifting by the handles of the Strip Carrier.
- Dispose of the used strips firstly into a small sealable plastic bag and then into a bin. Empty the bin regularly and do not allow large amounts of waste to build up on top of bags containing used reaction strips.
- Work areas must be regularly cleaned with appropriate DNA decontamination solutions.
- It is recommended to run NTCs periodically to check for contamination.

## 6. Using the Control

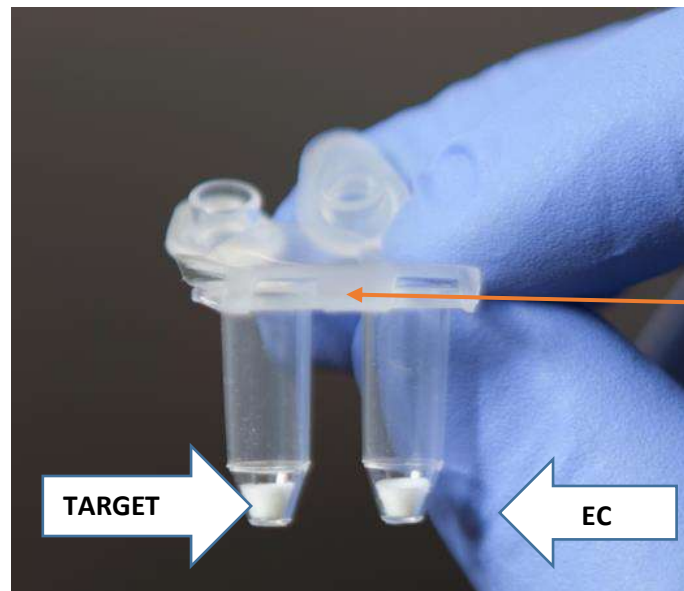
The flowchart below illustrates the workflow to be followed for the positive control:



<sup>1</sup> RCF = Relative Centrifugal Force. This is calculated based on the radius ( $r$ ) of the rotor (in mm) and the centrifuge speed in revolutions per minute (rpm) as follows:  $RCF = 1.12 \times r \times \left(\frac{rpm}{1000}\right)^2$

### 6.1. Assay set up

1. Open the pouch containing the HG Mycoplasma genitalium reaction strips, tearing across from the notches on the pouch.
2. Remove the reaction strips, one strip per Positive Control to be tested.
3. **It is vital to orient the reaction tubes in the correct direction.** When lids are facing away from the user, the **left-hand tube** in the strip contains the MYG Target reaction mix and the **right-hand tube** contains EC reaction mix, as shown below:



4. Peel off the plastic seal on the tubes carefully, taking care not to disrupt the lyophilized pellet. (If lyophilized pellets are sticking to the sealing film, tap the strip lightly until they fall to the bottom of the tubes.)
5. Place the strip(s) in the HG Swift Set-up Rack in the correct orientation and add 25µl of HG MYG Positive Control to both the target (T) and extraction control (EC) tubes.

6. Close the lid on each tube tightly by pressing firmly on the lids.

***It is critically important to ensure that lids are fully closed before commencing the run.***



7. Reconstitute the reaction mixes by briefly vortexing for 5 seconds. Centrifuge the tubes for 10secs at 2700-3300 rcf to ensure that the reconstituted reaction mix is returned to the bottom of the well, as shown below:

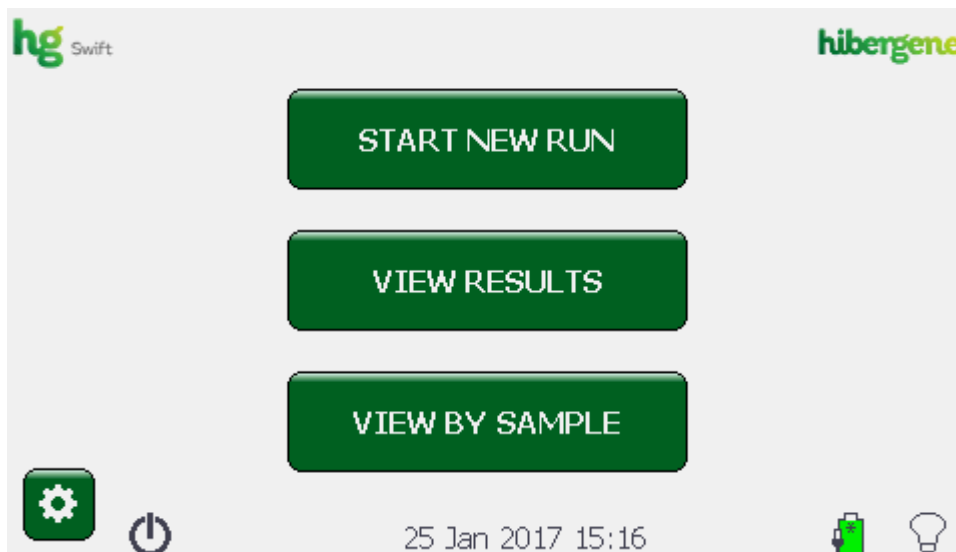


***Visually examine the reaction mix pellet after mixing to ensure lyophilized reaction mixture pellets are fully dissolved.***

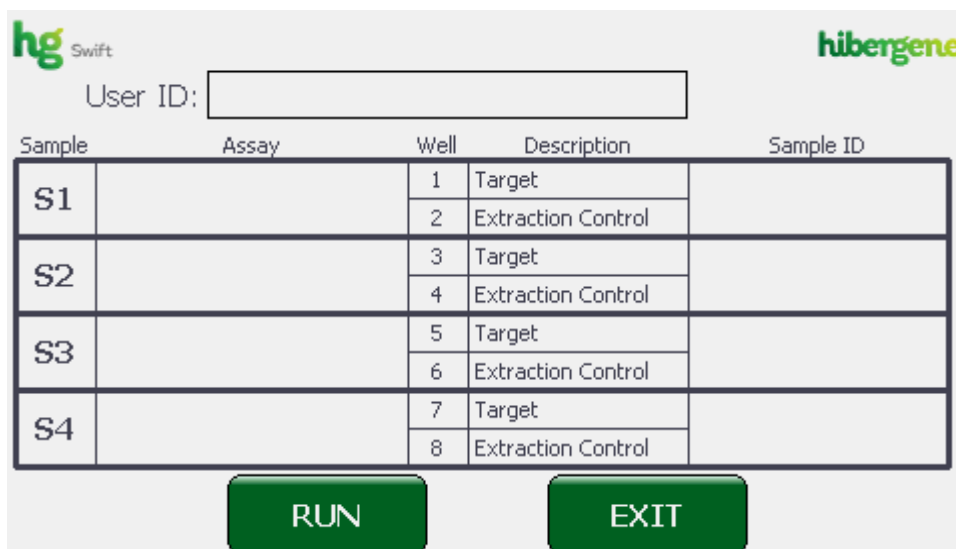
***Final reaction mixtures must be loaded and run on the HG Swift as soon as possible after reconstitution. Do not allow to stand for any longer than 10 minutes before starting the run.***

## 6.2. Run set up

1. Turn on the HG Swift using the power switch located at the back of the instrument.
2. Select START NEW RUN:



The Run Table will then be displayed:





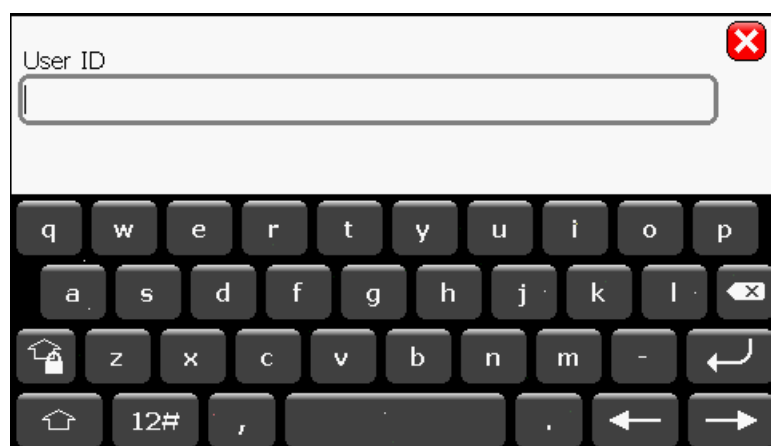
3. Load the reaction strip(s) onto the block of the HG Swift using a Strip Carrier, as shown below:



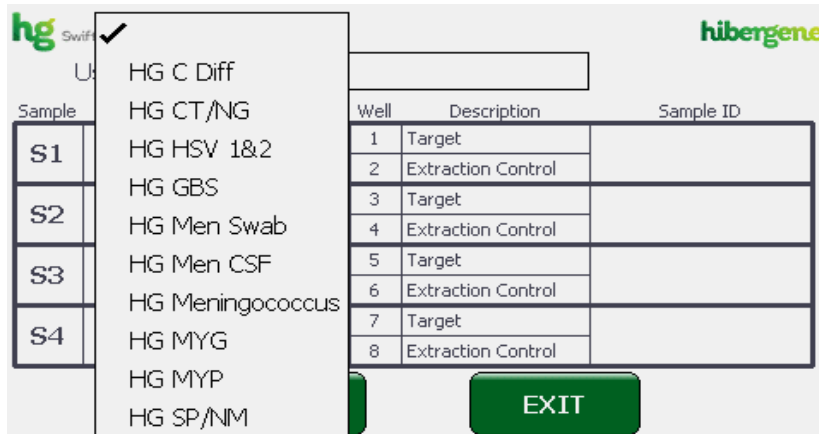
***The reaction strips must be loaded IN THE CORRECT ORIENTATION as shown above, with hinges towards the rear of the instrument.***

***Once reaction strips are loaded into the instrument, press down firmly on the lids a final time to ensure they are closed***

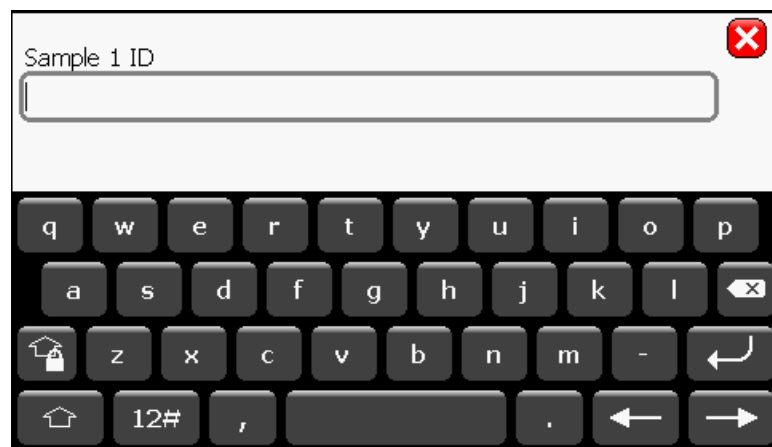
4. Enter the User ID using either the on-screen keyboard or a barcode reader attached to the HG Swift USB port:



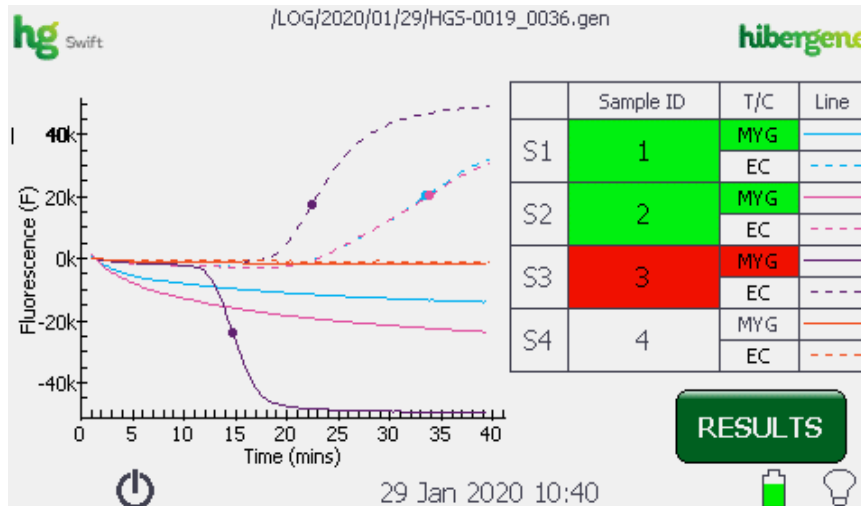
- For each sample to be tested, select HG MYG from the dropdown assay menu:



- Enter an identifiable sample ID (e.g. “HG MYG Control”) for the positive control using the on-screen keyboard:



7. Press RUN. The HG MYG run will take 40 mins to complete. During the run the fluorescence of all samples will be displayed (see example below). The run may be aborted by pressing the STOP button:



The sample status which is displayed can be interpreted as follows :

Displayed	Description
<i>M. genitalium</i> Pos	<i>Mycoplasma genitalium</i> detected in the sample
<i>M. genitalium</i> Neg	<i>Mycoplasma genitalium</i> not detected in the sample
Invalid	Extraction Control did not amplify. This indicates issues with sample treatment or the presence of inhibitors. No sample result will be returned, and the sample should be re-tested.

## 7. Validity Criteria

In order for the run to be considered valid, the following criteria must be met:

- **HG Mycoplasma genitalium Control is identified as a valid Positive sample**
- **The amplification time for HG Mycoplasma genitalium Control is  $\leq 30.41$  minutes.**

If the Positive Control does not meet these criteria, check the Troubleshooting guide below and repeat the testing. If invalid results continue to be generated, contact your local distributor.











## 8. Limitations of Use

- The control may not perform correctly if these instructions are deviated from.

## 9. Troubleshooting

Observation	Potential Causes	Actions
Positive Controls do not amplify correctly	Incorrect volume of control added	Check calibration of pipettes
		Repeat assay ensuring the correct volume of sample extract is added
	Reaction mixture not present at bottom of tube after reconstitution	Repeat assay ensuring that sample is at correct level by vortexing and centrifugation after resuspension of pellet
	Use of expired materials	Check expiry date and repeat testing with new kit if necessary

## 10. Interpretation of Symbols

	In Vitro Diagnostic Medical Device
	Catalogue number
	Batch number
	Use-by date
	Temperature limitation
	Do not reuse
	Manufacturer
	Contains sufficient for <n> tests
	Consult instructions for use (at <a href="http://www.hibergene.com">www.hibergene.com</a> )
	IFU can be requested by phone if not accessible online



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