HG CT/NG Positive Control Kit

HGCTNGC

Instructions for Use

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CE 2797

1. Kit Contents

HG CT/NG Combo Control kit contains sufficient material of each control for 18 runs:

	Description
HG CT Positive Control **Part # CT-PC**	1 x 1.1 mL vial Buffered plasmid solution containing preservative Contains: Component 1: Positive Control: Contains: nucleic acid, buffer solution Contains no active ingredients Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This substance is not classified as dangerous according to Directive 67/548/EEC. Ref. SDS HG CTNGR HGCTNGC
HG NG Positive Control **Part # NG-PC**	1 x 1.1 mL vial Buffered plasmid solution containing preservative Contains: Component 1: Positive Control: Contains: nucleic acid, buffer solution Contains no active ingredients Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This substance is not classified as dangerous according to Directive 67/548/EEC. Ref. SDS HG CTNGR HGCTNGC

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/HG Swift Plus Strip Carriers** are supplied with the HG Swift instrument and are used for handling, loading and unloading of HG CT/NG Combo reaction strips. These are also available to order separately (Part # HGCAR).
- **HG Swift/HG Swift Plus Set-up Racks** are supplied with the HG Swift instrument and are used for loading samples into HG CT/NG Combo reaction strips. These are also available to order separately (Part # HGRACK).
- **HG CT/NG Combo assay kit (Part # HGCTNGR)** is a molecular diagnostic assay for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in human clinical samples.

Required but not provided:

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

4. Intended Use

The HG CT/NG Combo control kit contains two vials of positive control material for use with the HG CT/NG Combo assay.

CT positive control (CT-PC) contains a *Chlamydia trachomatis* nucleic acid sequence which is detected by the Target reaction mix, together with the Extraction Control sequence.

NG positive control (NG-PC) contains a *Neisseria gonorrhoeae* nucleic acid sequence which is detected by the Target reaction mix, together with the Extraction Control sequence.

The control kit 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 CT/NG Combo assay kits.

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

5. Precautions

General Precautions

- The HG CT/NG Combo 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.
- Any serious incidents that occur in relation to HGCTNGC must be reported to the manufacturer. This reporting may be completed via the relevant supplier/distributor, or directly to the manufacturer (HiberGene) using the contact details in Section 10 below.

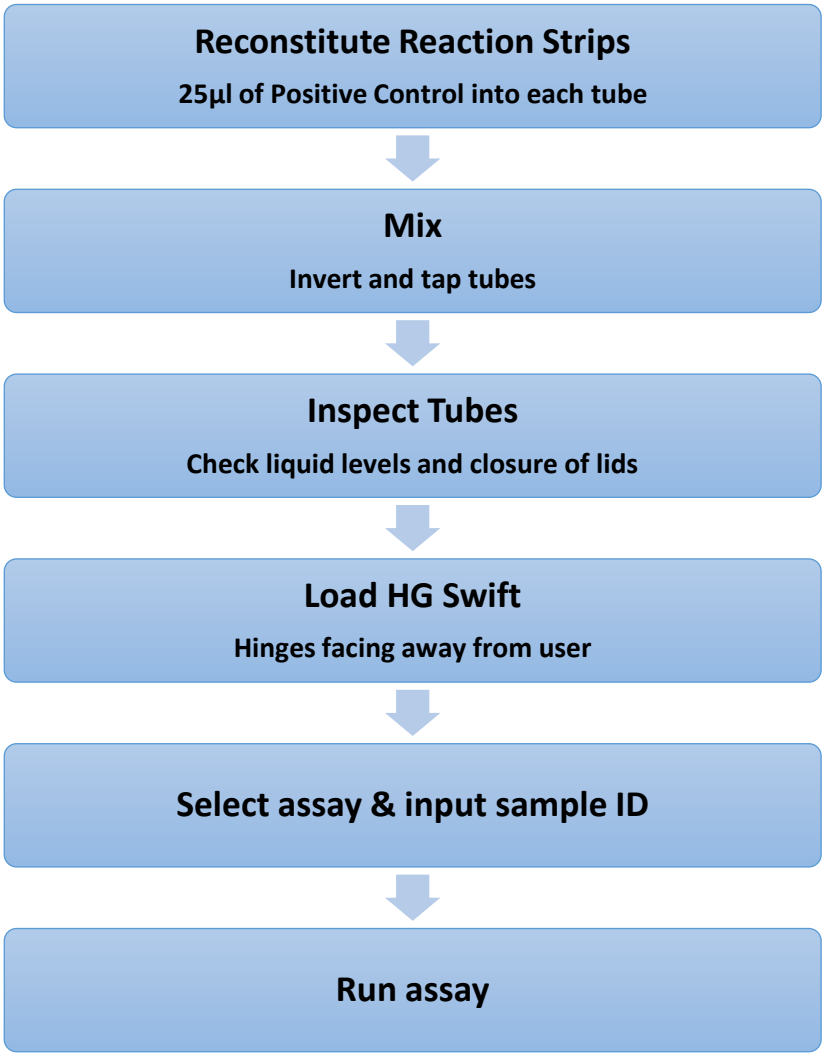
Preventing amplicon contamination

- Escape of amplified material from reaction strips after LAMP amplification can result in laboratory contamination which could impact on subsequent test results. HG CT/NG Combo 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/HG Swift Plus 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.

6. Using the Control

The flowchart below illustrates the workflow to be followed for each of the positive controls (CT & NG):



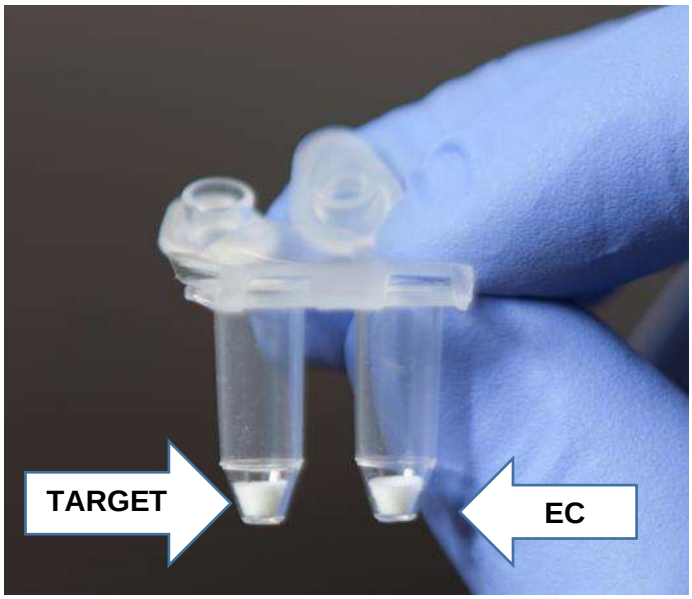
6.1 Assay set up

1. Open the pouch containing the HG CT/NG Combo reaction strips, tearing across from the notches on the pouch.

2. Remove the reaction strips, one strip per test to be conducted.

Note: *It is recommended to test CT and NG Positive Controls together in a single instrument run.*

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 **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 lyophilised 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/HG Swift Plus Set-up Rack in the correct orientation and add 25µL of sample 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 vortexing briefly – minimise foaming of the solution. The vortexed reaction strips should then be briefly centrifuged (e.g. 10 sec at 3300 rcf) to ensure that all liquid is returned to the bottom of the tubes, as shown below:

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

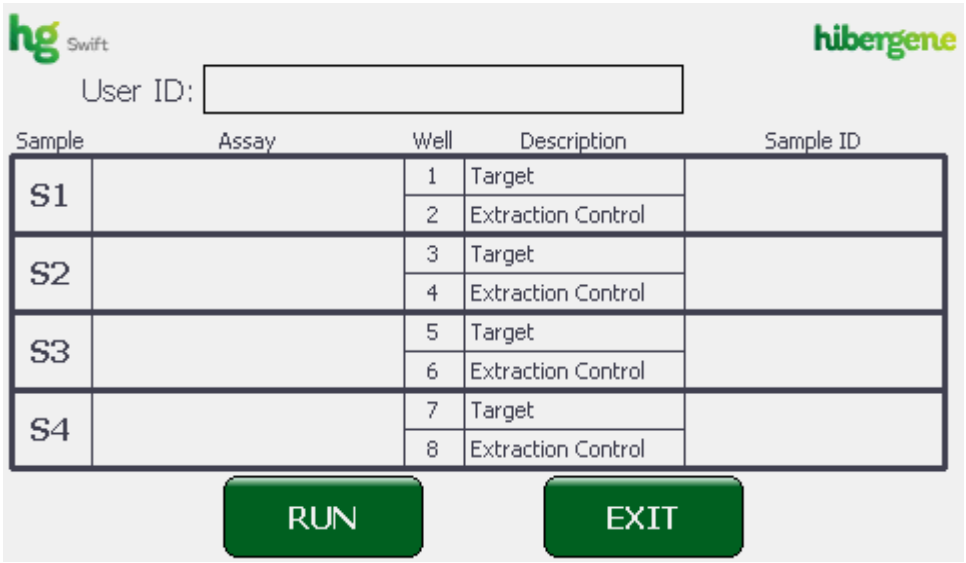
Final reaction mixtures must be loaded and run on the HG Swift/HG Swift Plus as soon as possible after reconstitution. Do not allow to stand for any longer than 10 minutes before starting the run.

6.2 Run set up

1. Turn on the HG Swift/HG Swift Plus using the power switch located at the back of the instrument.

2. Select START NEW RUN:

The Run Table will then be displayed:

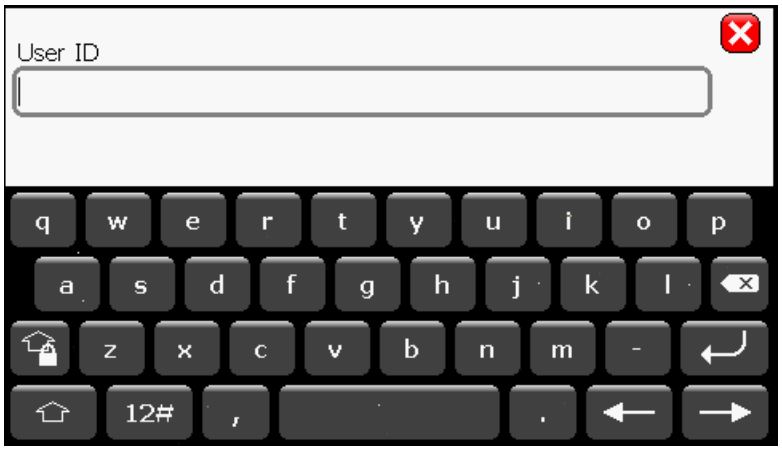


3. Load the reaction strip(s) onto the block of the HG Swift/HG Swift Plus using a Strip Carrier, as shown below:

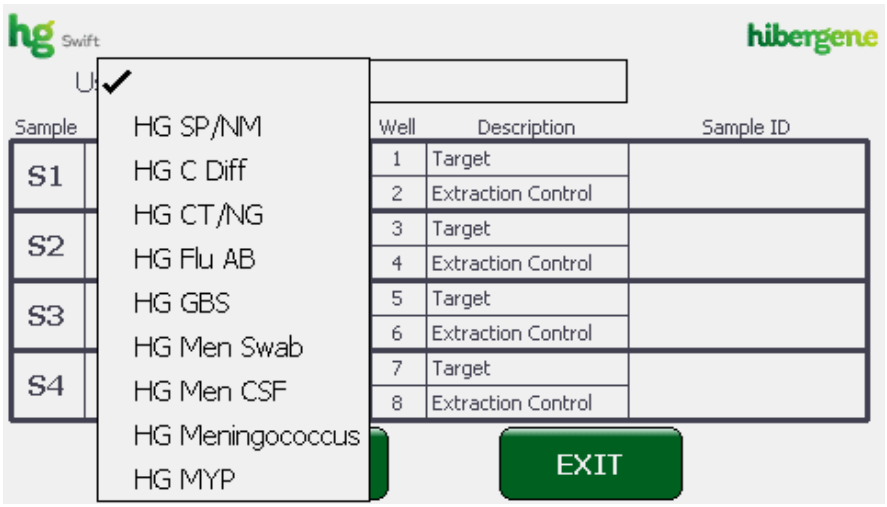
The reaction strips must be loaded IN THE CORRECT ORIENTATION as shown above, with hinges towards the rear of the instrument.

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

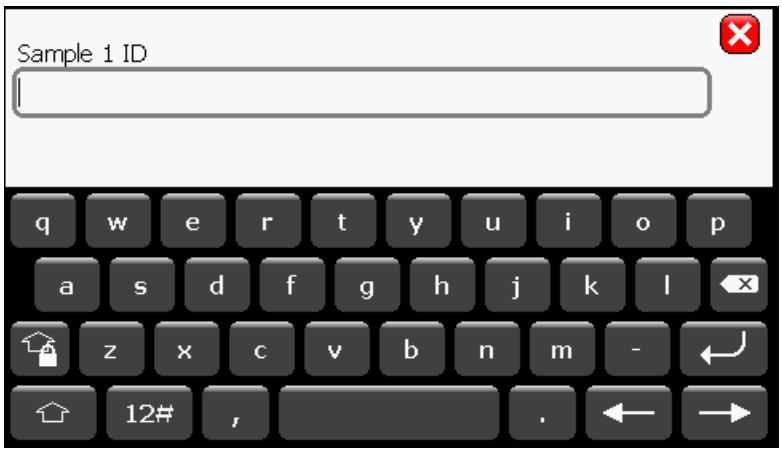
4. Enter the User ID using either the on-screen keyboard or a barcode reader attached to the HG Swift/HG Swift Plus USB port:



5. For each control to be tested, select HG CT/NG from the dropdown assay menu:

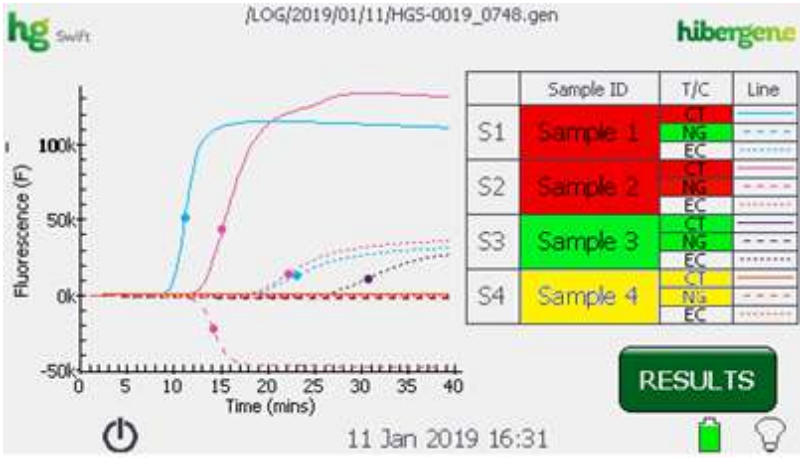


6. Enter an identifiable sample ID (e.g. “HG CT Control”) for the positive control using the on-screen keyboard :



7. Press RUN.

8. The HG CT/NG Combo 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.



7. Validity Criteria

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

- **Both CT and NG Positive Controls are identified as valid Positive samples**
- **The amplification time for CT is ≤ 13.02 minutes.**
- **The amplification time for NG is ≤ 19.20 minutes.**

If the Positive Controls do 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 controls 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 tapping after mixing
	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
	Positive Control
	Use-by date
	Temperature limitation
	Do not reuse
	Manufacturer
	Contains sufficient for <n> tests
	Consult instructions for use (at www.hibergene.com)
	IFU can be requested by phone if not accessible online

	Hibergene Diagnostics Ltd. Block 2, Bracken Business Park, Sandyford, Dublin 18, Ireland. Tel: +353 1 905 3160 Email: mdx@hibergene.com www.hibergene.com

11. Changes from the Previous Revision

IFU Section	Change(s)
3. Accessories	References to the HG Swift Plus have been added
5. Precautions	General Precautions have been added to align with other HiberGene product IFUs. Precaution also added in relation to the reporting of serious incidents to the manufacturer. Reference to the HG Swift Plus added to 'Preventing amplicon contamination'.
6. Using the Control	References to the HG Swift Plus have been added throughout this section
Footer	The IFU revision effective date has been added to the footer