

Saving Time. Saving Life.

Rapid molecular
diagnostic tests for
infectious diseases

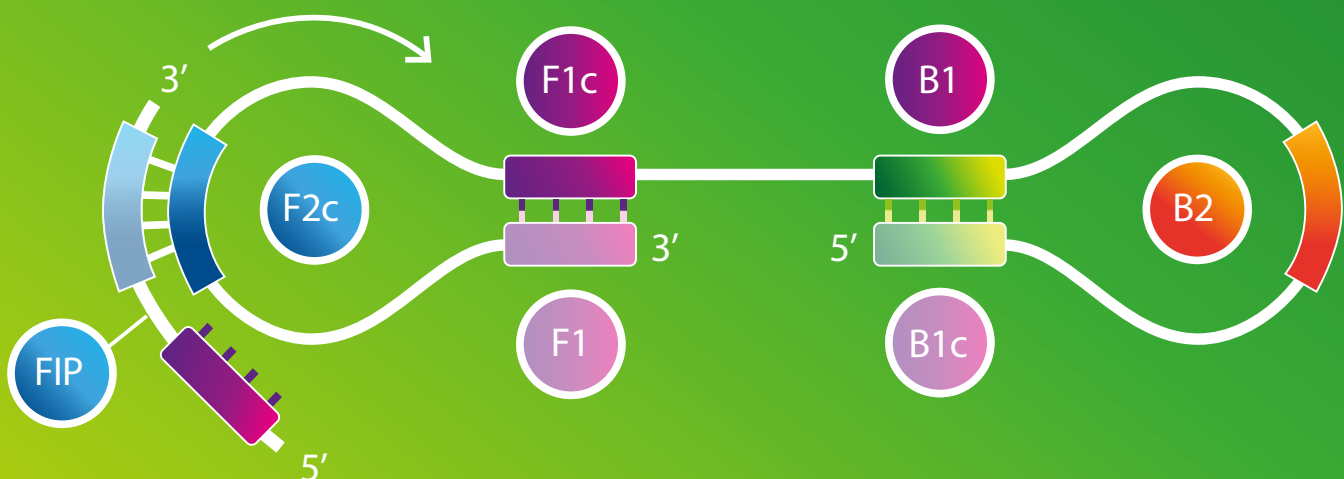


HiberGene Diagnostics Ltd. develops, manufactures and markets molecular diagnostic tests for human infectious diseases.

The HG test menu is diverse and comprises tests for neurological conditions, hospital-acquired infections, women's health and respiratory infections.

HiberGene's enabling technology is loop-mediated isothermal amplification (LAMP). LAMP uses 6 separate primers to form a loop structure with the target DNA sequence. This structure amplifies rapidly to give positive results in well under 40 minutes.

All tests are incubated and read on the *HG Swift*.



DNA Loop Structure

The HG Swift is the instrument of choice for molecular diagnostics of infectious diseases. Its lightweight and compact feel allows for seamless integration into routine daily workflows. Isothermal amplification technology, along with fluorometric detection and unique results-calling software, provides real-time diagnoses in less than 40 minutes.



Detection Method

Detection method	Dual-channel Fluorescence
Temperature control method	Block with 4-zone independent digital PID and heated lid
Temperature control range and accuracy	Ambient - 100°C, $\pm 0.1^\circ\text{C}$
Sample number	Up to 4 samples in two tube format

Physical

Size	250 (L) \times 165 (W) \times 85 (H) mm [10" \times 6.5" \times 3.5"]
Weight	1.75 kg [4 lb]
Operating temperature	0°C – 40°C
Heat output	115 kJ/h (average during operation)
Noise output	< 42 dBA
Environmental protection	IP62

Interfaces

Display/Keyboard	Colour LCD 480 x 272 with resistive touchscreen
Positioning	GPS
Wireless data (1)	Bluetooth 2.0
Wireless data (2)	Wi-Fi
Wired Data	USB 2.0

Electrical

Battery type	Lithium Polymer
Battery capacity	40 Wh
Battery charge time	< 1.5 hrs
External supply	19 VDC

Ordering Information:

Product Name	Catalogue #
HG SWIFT	HGSWIFT
HG Strip Carriers (3x)	HGCAR
HG Set up Block	HGSUB

Giving children a fighting chance.

Rapid molecular test for Meningococcal Disease. Saving Time. Saving Life.

Neisseria meningitidis is the major cause of bacterial meningitis and septicaemia (meningococcal disease), with mortality rates of 15% for meningitis and up to 50% for meningococemia, a life-threatening sepsis.

Early diagnosis of meningococcal disease is vital for prompt and proper treatment. Conventional lab tests, such as culture and PCR, are time-consuming, complex and expensive.

Saving Time. Saving Life.

The HG test offers a new paradigm in meningococcus testing with the ability to test directly from throat swabs in addition to traditional invasive sample types.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

HiberGene Diagnostics is an ISO 13485 certified company.

BSI Certificate Number MD 632990

* FDA submission is planned. Product is not available for sale in the US market.





Speed

- Positive results in 30 mins*
- Negative results in 60 mins



Simplicity

- Supports multiple sample types (whole blood, CSF and Throat Swab)
- Ready to use, freeze-dried reagents



Cost - Effective

Isothermal amplification negates the need for complex, expensive PCR equipment

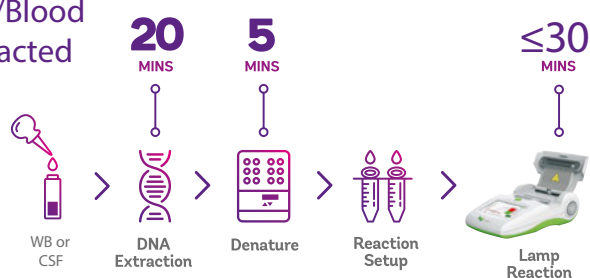


Accurate

- Sensitivity 100%, Specificity 100% for whole blood and CSF using PCR as a reference method
- Detects all NM serogroups including: A, B, C, 29E, W135, X, Y, Z

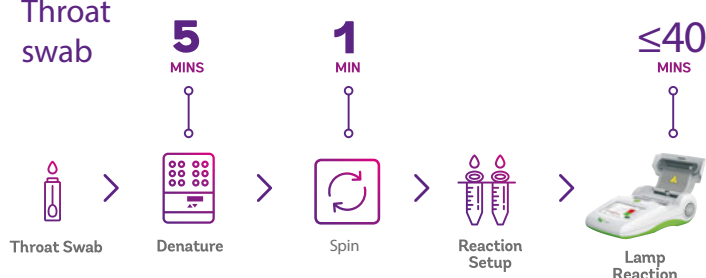
*depending on target load

CSF/Blood Extracted



*CSF Direct protocol also available.
For detailed protocol please see IFU.

Throat swab



Do throat swabs detect carriage?

LAMP showed 100% correlation between 116 positive CSF samples and throat swab samples in young children. Bourke et al., Lancet Infect Dis , 2015

Ordering Information:

Product Name	# of tests	Catalogue #
HG Meningococcus	25	HGMENR
HG Meningococcus Direct CSF	25	HGMENDCSF
HG Meningococcus Direct Swab	25	HGMENDS
HG Meningococcus Control	18	HGMENC
HG SWIFT	—	HGSWIFT
Mini Heating Dry Bath Incubator	—	HGHEATB
Mini Centrifuge	—	HGCFUGE

When knowing matters.

Rapid molecular test
for *Pneumococcus* &
Meningococcus
Saving Time. Saving Life.



Neisseria meningitidis and *Streptococcus pneumoniae* cause up to 87% of bacterial meningitis cases. Bacterial meningitis is an aggressive disease and can be fatal within hours.

Conventional lab tests, such as culture and PCR are time-consuming, complex and expensive. A timely and accurate diagnosis is vital.

Saving Time. Saving Life.

Dual-channel fluorescence detection enables HG Pneumo/Meningo Combo to provide a differential diagnosis between the two leading causes of bacterial meningitis.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

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Speed

- Positive results in 30 mins*
- Negative results in 50 mins



Simplicity

- Minimal training required
- Supports both extracted and non-extracted CSF samples
- Ready to use, freeze-dried reagents



Cost - Effective

Isothermal amplification negates the need for complex, expensive PCR equipment

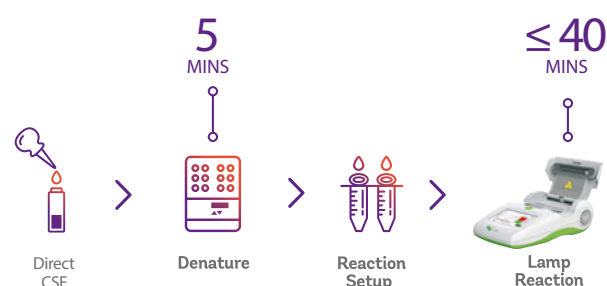


Accurate

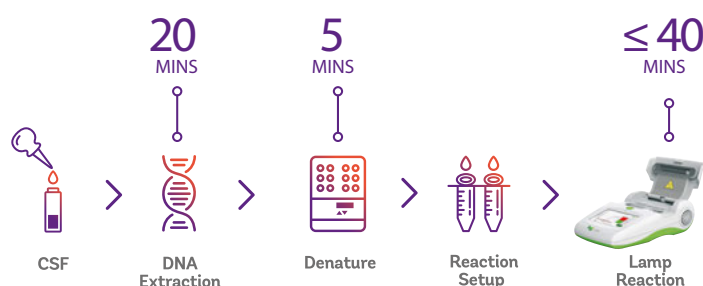
- ≥93% Sensitivity & 100% Specificity for *N. meningitidis* & *S. pneumoniae* for both extracted and non-extracted samples using PCR as reference method.
- Detects all NM serogroups including: A, B, C, 29E, W135, X, Y, Z.
- Detects all SP serogroups including: 19A, 1, 7F, 3.

*depending on target load

CSF direct



CSF extracted



Why test for both?

Neisseria meningitidis and *Streptococcus pneumoniae* are the most common causes of bacterial meningitis in adults and children. ESCMID Guideline, 2016

Ordering Information:

Product Name	# of tests	Catalogue #
HG Pneumo/Meningo Combo	25	HGSPNMR
HG Pneumo/Meningo Combo Control	18	HGSPNMC
HG SWIFT	—	HGSwift
Mini Heating Dry Bath Incubator	—	HGHEATB

Giving expectant mothers peace of mind.

Rapid molecular test for
Group B Streptococcus.
Saving Time. Saving Life.



Group B Streptococcus is the leading cause of severe neonatal infection, affecting 0.5 – 3 in every 1000 live births. It is associated with high mortality (10%) and morbidity (20%) rates.

20 – 30% of pregnant women are colonised with GBS and risk passing the infection to the baby.

Saving Time. Saving Life.

Rapid, simple and accurate, HG Group B Streptococcus is the complete testing solution for antepartum, intrapartum and neonatal testing.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

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BSI Certificate Number MD 632990

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Speed

- Positive results in 50 mins*
- Negative results in 70 mins

*depending on target load



Simplicity

- Minimum training required
- Supports multiple sample types (whole blood, CSF, broth and rectovaginal swabs)
- Ready to use, freeze-dried reagents



Cost - Effective

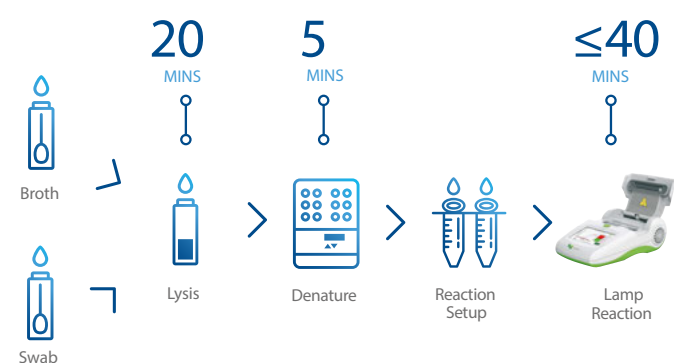
Isothermal amplification negates the need for complex, expensive PCR equipment



Accurate

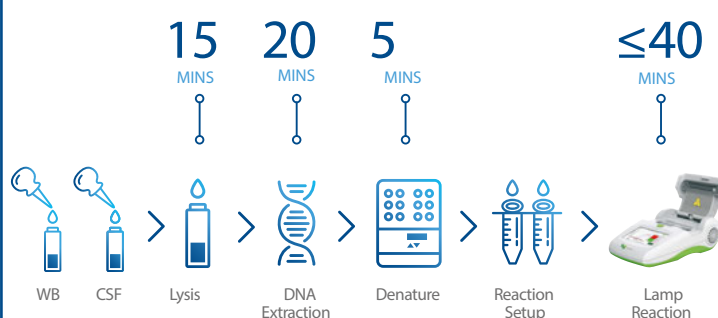
>95% sensitivity & specificity for all sample types.

Maternal testing



For detailed protocol please see IFU

Neonatal testing



Why test during labour?

"The key decision issued after the conference is to recommend intrapartum antimicrobial prophylaxis (IAP) based on a universal intrapartum GBS screening strategy using rapid real time testing."

European Consensus Conference on GBS screening, 2013

"a simple bedside kit that enables labour and delivery staff to perform a test, have a turn-around time of <30 minutes, and have a sensitivity and specificity of ≥ 90%."

US CDC recommendation, 2010

"net benefit of \$6 per birth when using intrapartum molecular screening."

El Helali et al., 2009

Ordering Information:

Product Name	# of tests	Catalogue #
HG Group B Streptococcus	30	HGGBSR
HG Group B Streptococcus Control	18	HGGBSC
HG Swift	-	HGSWIFT
Mini Heating Dry Bath Incubator	-	HGHEATB



A simple solution for targeted testing

Rapid molecular test for
Chlamydia trachomatis and
Neisseria gonorrhoeae.
Saving Time. Saving Life.

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) are among the most frequently transmitted STIs. It is estimated that 146 million people acquire CT and 51 million people acquire NG annually worldwide.

If left untreated, both infections carry severe health consequences including pelvic inflammatory disease, infertility, complications during pregnancy & infections in new-borns.

Saving Time. Saving Life.

HG CT /NG Combo leverages molecular technology, in accordance with the latest clinical guidelines, to ensure optimal accuracy, direct treatment and limit onward transmission.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU. HiberGene Diagnostics is an ISO 13485 certified company.

BSI Certificate Number MD 632990

* FDA submission is planned. Product is not available for sale in the US market.



Speed

- Positive results in less than 60 minutes*
- Negative results in 70 minutes

*depending on target load



Simplicity

- Follow the same protocol for urine and swab samples
- Ready to use, freeze-dried reagents
- No nucleic acid extraction required



Cost - Effective

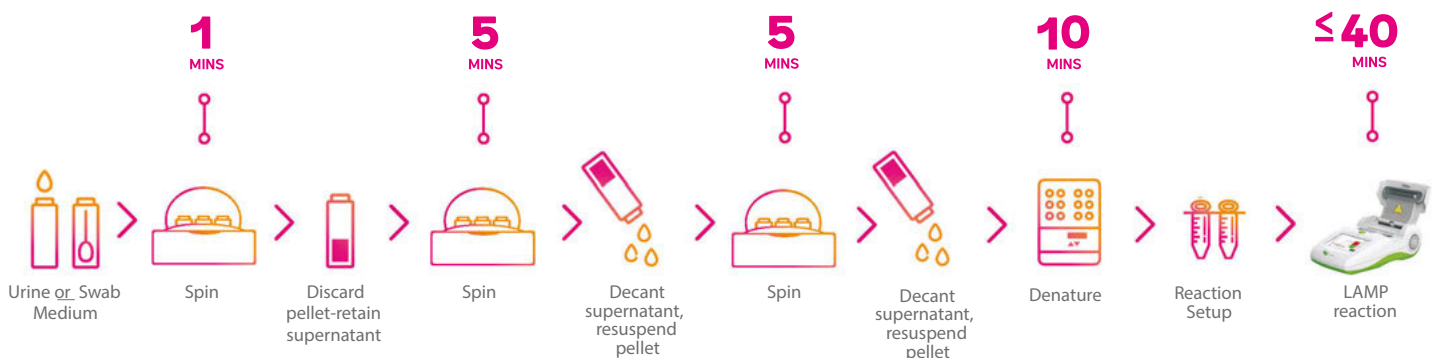
Isothermal amplification negates the need for complex, expensive PCR equipment



Accurate

- Differential diagnosis between CT and NG
- Combined relative sensitivity of >96.8% and specificity of >99.2% for both targets in all sample types using PCR as a reference method.

Urine/Swab protocol



For detailed protocol please see IFU

What is the benefit of an accurate test?

Up to 75% of patients who receive antibiotics for chlamydia and gonorrhoea based on symptoms are subsequently found to be negative for both infections. American Journal of Infection Control, 2016

Ordering Information:

Product Name	# of tests	Catalogue #
HG CT/NG Combo	30	HGCTNGR
HG CT/NG Combo Control	18CT/18NG	HGCTNGC
HG Swift	-	HGSwift
Mini Heating Dry Bath Incubator	-	HGHEATB
Mini Centrifuge	-	HGCFUGE



Improving patient outcomes

Rapid molecular test for *Mycoplasma genitalium*.
Saving Time. Saving Life.

Mycoplasma Genitalium (Mgen) is a recognised sexually transmitted infection (STI) with clinical presentation similar to that of *Chlamydia trachomatis (CT)* .

Prevalence of *Mgen* can range from 1% - 4% in the general population and in higher risk populations can range from 9% - >50%, often exceeding that of *Neisseria gonorrhoeae (NG)* ¹.

Saving Time. Saving Life.

In combination with HG CT/NG Combo, diagnose three of the most common STI's – *C. trachomatis (CT)*, *N. gonorrhoeae (NG)* and *M. genitalium (Mgen)* from a single urine or swab sample.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

HiberGene Diagnostics is an ISO 13485 certified company.

BSI Certificate Number MD 632990

* FDA submission is planned. Product is not available for sale in the US market.



Speed

- Positive results in less than 60 minutes*
- Negative results in 70 minutes



Simplicity

- Follow same protocol as HG CTNG Combo for urine and swab samples
- Ready to use, freeze-dried reagents
- No nucleic acid extraction required



Cost - Effective

- Isothermal amplification negates the need for complex, expensive PCR equipment



Accurate

- Relative sensitivity of 96.7% and relative specificity of 100% in Urine samples and relative Sensitivity and Specificity of 100% in Swab samples

*depending on target load



For detailed protocol please see IFU

Why use molecular?

Mgen is an extremely fastidious and slow growing organism that is difficult to culture, making nucleic acid amplification testing (NAAT) the only viable diagnostic solution.

1. Baumann L, et al. Sex Transm Infect 2018;94:254–261.

Ordering Information:

Product Name	# of tests	Catalogue #
HG MYG	30	HGMYGR
HG MYG Control	18	HGMYGC
HG Swift	-	HGSWIFT
Mini Heating Dry Bath Incubator	-	HGHEATB
Mini Centrifuge	-	HGCFUGE
Mini Vorex	-	HGVORTEX

A blurred background image showing a medical professional in a white coat holding a clipboard, examining a patient who is lying down with their hands clasped.

Simple, definitive answers

Rapid molecular test for
Herpes Symplex Virus 1 & 2.
Saving Time. Saving Life.

The herpes simplex virus, or herpes, is a highly infectious viral disease that is categorised into two types, herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2).

HSV is a very common condition, with HSV-1 and HSV-2 infection estimated to affect 67% and 11% of the global population, respectively. WHO, 2017

Saving Time. Saving Life.

HG HSV 1&2 leverages molecular technology, in accordance with the latest clinical guidelines, to accurately detect the HSV virus direct from a swab sample in less than 1 hour.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

HiberGene Diagnostics is an ISO 13485 certified company.

BSI Certificate Number MD 632990

* FDA submission is planned. Product is not available for sale in the US market.





Speed

- Positive results in less than 40 minutes*
- Negative results in 50 minutes



Simplicity

- Simple protocol for swab samples
- Ready to use, freeze-dried reagents
- No nucleic acid extraction required



Cost - Effective

- Isothermal amplification negates the need for complex, expensive PCR equipment



Accurate

- Differential diagnosis between HSV 1 and HSV 2
- Swab Sample: Relative Sensitivity and Specificity of 100% for both targets

10
secs



10
secs



10
Mins



10
secs



5
Mins



≤40
MINS



Vortex



Add to
dilution
buffer



Vortex



Denature



Spin



Wait



Reaction
setup



Lamp
Reaction

Why use molecular?

Molecular has been found to be 1.5 to 4 times more sensitive than viral culture and molecular is now the gold standard for genital herpes detection. LeGeoff et al, 2014 .

Ordering Information:

Product Name	# of tests	Catalogue #
HG HSV 1&2	30	HGHSVR
HG HSV 1&2 Control	18 HSV 1/18 HSV 2	HGHSVC
HG Swift	-	HGSwift
Mini Heating Dry Bath Incubator	-	HGHEATB
Mini Centrifuge	-	HGCFUGE
Mini Vorex	-	HGVORTEX



When a rapid result is called for.

Rapid molecular test for
Clostridium difficile .
Saving Time. Saving Life.

Clostridium difficile is the major cause of hospital-acquired diarrhoea. It is highly infectious and can spread rapidly in healthcare facilities if not treated quickly. These outbreaks can be fatal, particularly in elderly patients (up to 20%).

Rapid and accurate detection of the bacterium allows for early treatment and prevents further spreading of the infection.

Saving Time. Saving Life

With rapid and accurate detection across all toxigenic strains of *Clostridium difficile*, direct from stool samples, this test enables timely and effective treatment, preventing harmful outbreaks.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

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BSI Certificate Number MD 632990

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Speed

- Positive results in 30 mins*
- Negative results in 60 mins



Simplicity

- Minimum training required
- Supports unformed stool sample
- Ready to use, freeze-dried reagents



Cost - Effective

Isothermal amplification negates the need for complex, expensive PCR equipment

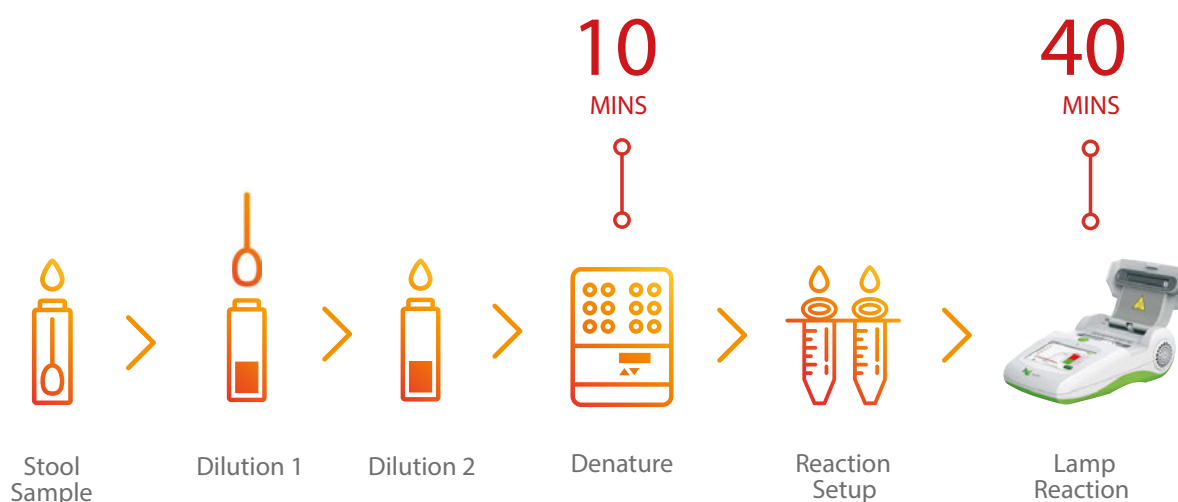


Accurate

- Unformed Stool: Sensitivity 95.5%, Specificity 96.9%, using PCR as a reference method

*depending on target load

Unformed stool



For detailed protocol please see IFU

Ordering Information:

Product Name	# of tests	Catalogue #
HG C. Difficile	30	HGCDIFFR
HG C. Difficile Control	18	HGCDIFFC
HG Swift	-	HGSwift
Mini Heating Dry Bath Incubator	-	HGHEATB

Preventing outbreaks within the community.

Rapid molecular test for
Mycoplasma pneumoniae .
Saving Time. Saving Life.

Mycoplasma pneumoniae is a frequent cause of respiratory tract infections and is a leading cause of community-acquired pneumonia (up to 35%), particularly in children.

The bacterium is easily transmitted through coughing with epidemics reported every 3-5 years. Early detection is essential to minimise the risk of potentially harmful outbreaks

Saving Time. Saving Life.

Using an endogenous control, HG *Mycoplasma pneumoniae* ensures accurate and reliable results every time.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

HiberGene Diagnostics is an ISO 13485 certified company.

BSI Certificate Number MD 632990

* FDA submission is planned. Product is not available for sale in the US market.





Speed

- Positive results in 30 mins*
- Negative results in 50 mins



Simplicity

- Minimum training required
- Supports both throat swab and bronchoalveolar lavage (BAL) samples.
- Ready to use, freeze-dried reagents



Cost - Effective

Isothermal amplification negates the need for complex, expensive PCR equipment

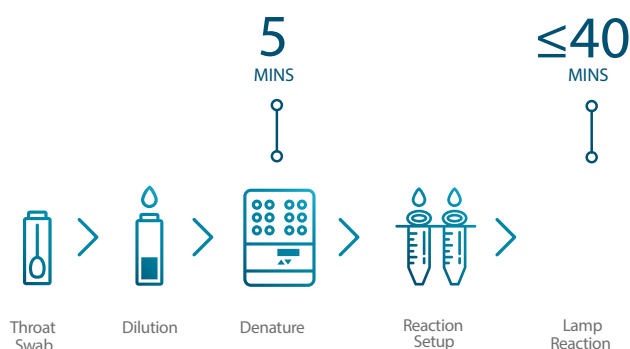


Accurate

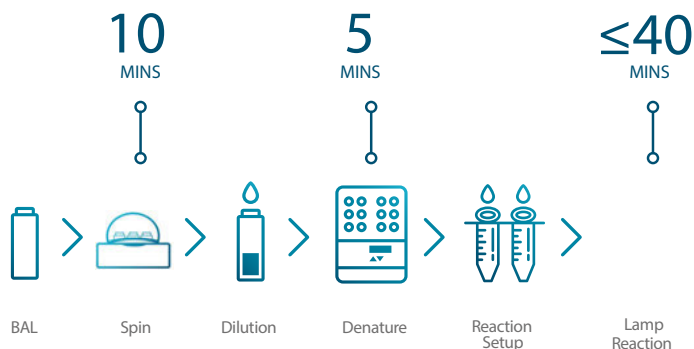
- Sensitivity 95%, Specificity 100% using PCR as a reference method
- Endogenous control ensures accurate and reliable results

*depending on target load

Throat swab



Bronchoalveolar lavage



For detailed protocol please see IFU

Ordering Information:

Product Name	# of tests	Catalogue #
HG Mycoplasma pneumoniae	30	HGMYPR
HG Mycoplasma pneumoniae Control	18	HGMYPC
HG Swift	-	HGSwift
Mini Heating Dry Bath Incubator Mini	-	HGHEATB
Mini Centrifuge	-	HGCFUGE

Know your A's from your B's

Rapid molecular
test for Influenza.
Saving Time. Saving Life.



The influenza (flu) virus is a global health concern. It causes up to 500,000 deaths a year during annual epidemics globally and can cost economics over \$85 billion in medical costs and lost earnings.

Conventional flu diagnostic methods either lack sensitivity or take too long leading to the overuse of antibiotics and/or patient isolation while results are confirmed.

Saving Time. Saving Life.

With minimal hands-on time, HG Flu A/B Combo distinguishes between the flu A and B subtypes in as little as 30 minutes, optimising patient management and treatment to reduce healthcare costs and improve outcomes.



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

HiberGene Diagnostics is an ISO 13485 certified company.

BSI Certificate Number MD 632990

* FDA submission is planned. Product is not available for sale in the US market.



Speed

- Positive results in 30 mins*
- Negative results in 60 mins



Simplicity

- Minimal hands-on time
- No nucleic acid extraction required
- Ready to use, freeze-dried reagents



Cost - Effective

- Isothermal amplification negates the need for complex, expensive PCR equipment
- Quicker results reduce isolation costs and enable earlier discharge of patients

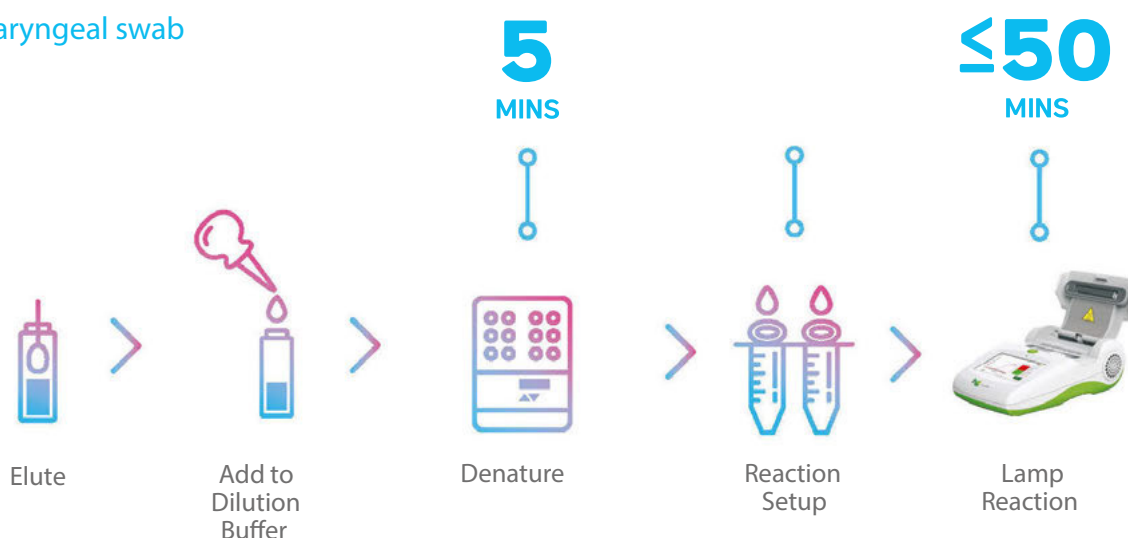


Accurate

- Differential diagnosis between influenza A and B subtypes
- Sensitivity limit of 400 TCID₅₀/ml (fluA) and 6 TCID₅₀/ml (fluB)

*depending on target load

Dry nasopharyngeal swab



For detailed protocol please see IFU

Why use molecular?

By using a rapid molecular test for influenza up to 65% of patients can be discharged early or admitted without requiring isolation. NHS Ambulatory Care Guide, 2018

Ordering Information:

Product Name	# of tests	Catalogue #
HG FluA/B Combo	30	HGFLUR
HG Flu A/B Combo Control	18 Flu A/18 Flu B	HGFLUC
HG Swift	-	HGSWIFT
Mini Heating Dry Bath Incubator	-	HGHEATB



Protecting those most at risk

Rapid molecular
test for Respiratory
Syncytial Virus.
Saving Time. Saving Life

Respiratory syncytial virus (RSV) is a leading cause of mortality and morbidity globally. Intensive care patients and infants are most at risk with over 33 million cases and almost 200,000 deaths in children under five annually worldwide.

Although there is no treatment available, a specific diagnosis is essential for effective infection control and improved patient outcomes.

Saving Time. Saving Life.

**HG RSV A/B Combo quickly and easily identifies those infected,
streamlining patient management and preventing onward transmission.**



For complete instructions, please refer to the Instructions for Use at bit.ly/HG_IFU.

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BSI Certificate Number MD 632990

* FDA submission is planned. Product is not available for sale in the US market.



Speed

- Positive results in 30 mins*
- Negative results in less than 60 mins



Simplicity

- Minimal hands-on time
- No nucleic acid extraction required
- Ready to use, freeze-dried reagents



Cost - Effective

- Isothermal amplification negates the need for complex, expensive PCR equipment
- Quicker results reduce isolation costs and enable earlier discharge of patients

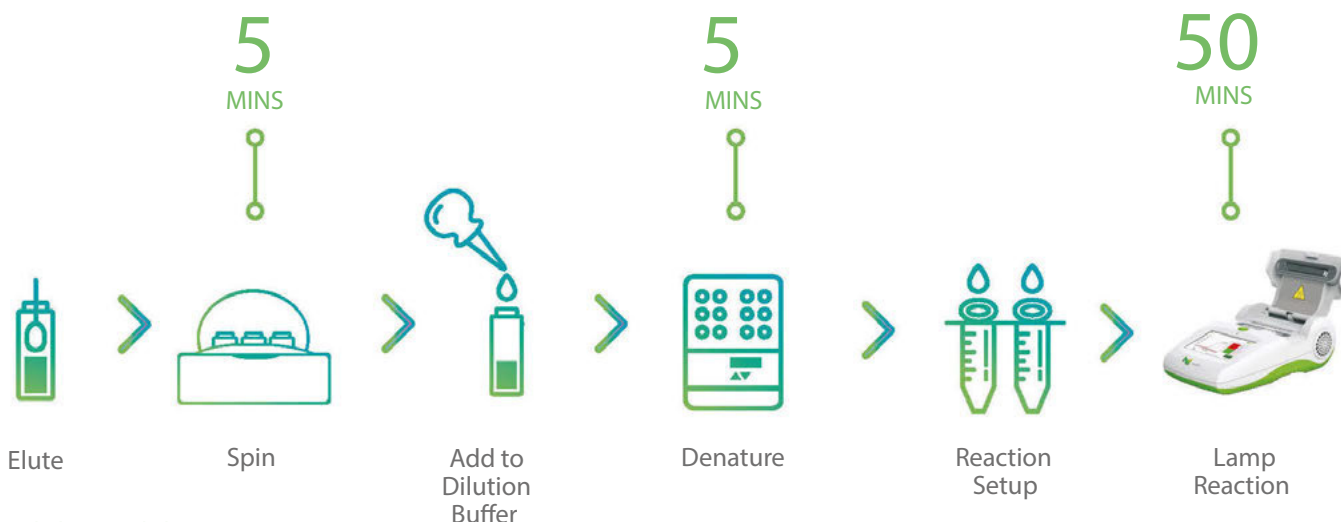


Accurate

- Differentiation between A and B strains
- Sensitivity limit of 183.2 TCID₅₀/ml for RSV A and 7.7 TCID₅₀/ml for RSV B in nasopharyngeal swabs

*depending on target load

Dry nasopharyngeal swab



For detailed protocol please see IFU

Why use molecular?

Timely detection has been shown to help reduce hospital transmission by up to 67% while effective patient isolation can reduce associated hospitalisation costs by up to 30%. *Drysdale et al., 2016*

Ordering Information:

Product Name	# of tests	Catalogue #
HG RSV A/B Combo	30	HGRSVR
HG RSV A/B Combo Control	18 RSV A / 18 RSV B	HGRSVC
HG Swift	-	HGSWIFT
Mini Heating Dry Bath Incubator	-	HGHEATB
Mini Centrifuge	-	HGCFUGE



Minimal Training Required



Rapid



Touch Screen



Molecular Testing



Dual-channel
Fluorescence



Battery & Mains
powered



Stable, Freeze-Dried Reagents



Low Capital Cost

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Health Technologies



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