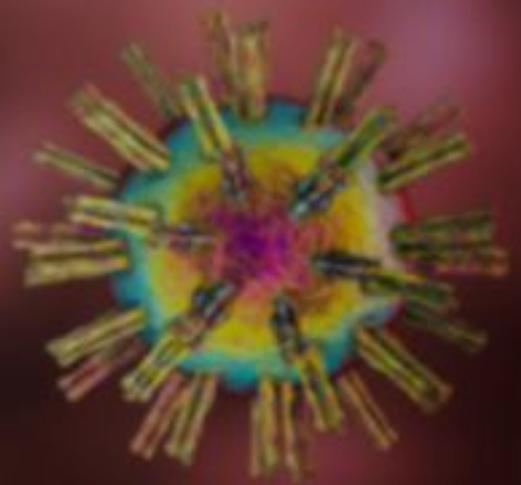
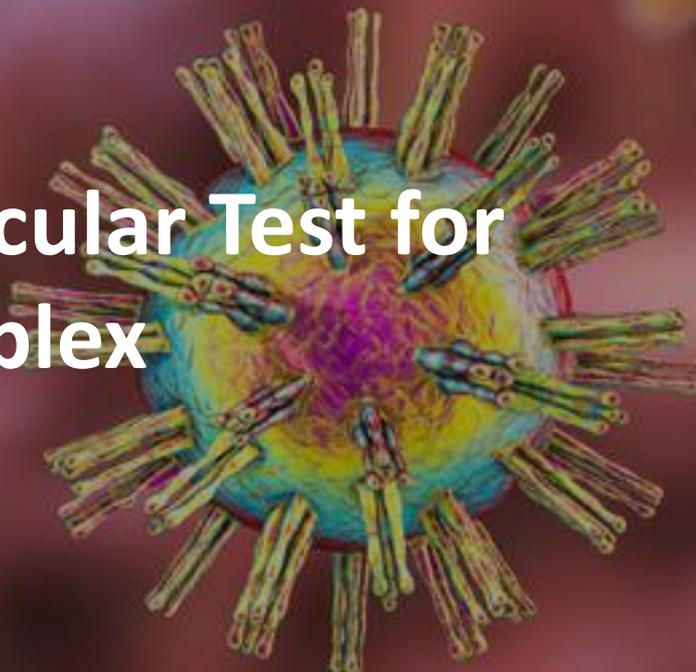


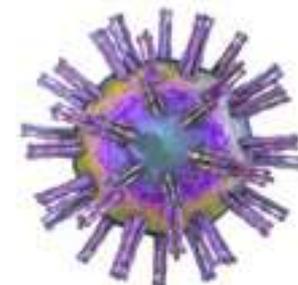
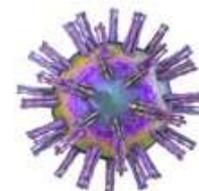
Rapid Molecular Test for Herpes Simplex Virus 1 & 2



Herpes Simplex Virus 1 & 2

- HSV-1 is mainly transmitted by oral contact and can cause both oral herpes (cold sores) and genital herpes [1]
- HSV-2 is a sexually transmitted infection that causes genital herpes. Infections with both HSV1 and HSV2 are lifelong [2].
- An estimated 67% of people under age 50 have HSV-1 infection globally, while 11% of people worldwide aged 15-49 have HSV-2 infection [3], [4].
- Symptoms of herpes include painful blisters or ulcers at the site of infection; infections are most contagious when symptoms are present, but the viruses can also be transmitted when symptoms are absent.

HG HSV 1 & 2 combo assay is a LAMP-based molecular diagnostic test for the direct detection and differentiation of *Herpes Simplex Virus 1 and 2* in genital lesion swab samples.

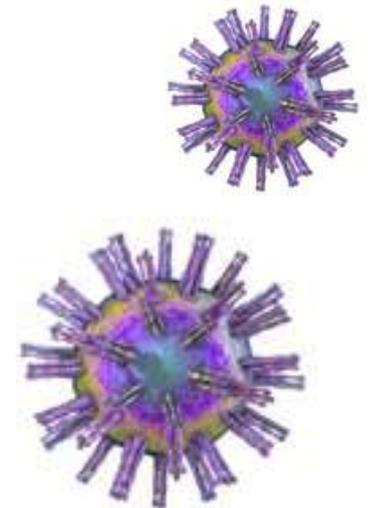


- [1] A. Wald, "Genital HSV-1 infections," *Sexually Transmitted Infections*, pp. 189-90, 2006.
- [2] W. A. Corey L, "Genital Herpes," in *Sexually Transmitted Diseases. 4th ed.*, New York, McGraw-Hill, 2008, p. 399–437.
- [3] Newman L, "Global Estimates of the Prevalence and Incidence of Four Curable Sexually Transmitted Infections in 2012 Based on Systematic Review and Global Reporting," *PLoS One*, p. e0143304, 2015.
- [4] Looker KJ, "Global estimates of prevalent and incident herpes simplex virus type 2 infections in 2012.," *PLoS One*, 2015.

Herpes Simplex Virus 1 & 2

- **HSV can cause severe infections of the nervous system including meningitis and encephalitis.**
- **Neonatal herpes can occur when an infant is exposed to the virus in the genital tract during delivery. Although rare (approximately 0.01% of births globally), this can lead to lasting neurologic disability or death [5].**
- **In addition, HSV-2 infection has been shown to increase the risk of acquiring a new HIV infection by approximately three-fold, while coinfection can increase the risk of HIV transmission to others. Accordingly, HSV-2 is amongst the most common infections in people living with HIV, occurring in up to 90% of cases [6] [7].**

HSV typing into HSV-1 and HSV-2 is recommended in all patients with first-episode genital herpes to guide counselling and management.



[5] Looker KJ, "First estimates of the global and regional incidence of neonatal herpes infection," *Lancet Global Health*, p. 5(3):e300–e309, 2017.

[6] Looker KJ, "Effect of HSV-2 infection on subsequent HIV acquisition: an updated systematic review and meta-analysis," *Lancet Infectious Diseases*, pp. 535-542, 2017.

[7] WHO, "World Health Organization - Herpes Simplex Virus Key Facts," 31 Jan 2017. [Online]. Available: <https://www.who.int/news-room/fact-sheets/detail/herpes-simplex-virus>.

How to sell

Serology has low sensitivity and cannot detect an active infection which may be extremely harmful to immunocompromised patients.

Testing carried out on: symptomatic individuals (immunocompromised patients: HIV patients, patients undergoing chemotherapy. Pregnant women during third trimester of pregnancy. An active infection can be life-threatening to immune compromised patients.

Medication is given when positive result is returned. More testing must be done to confirm an active infection.

The only means of detecting an **active** infection is through viral culture or molecular. Molecular can distinguish between the 2 different infections which is important in guiding antiviral treatment, patient management and counselling.

Molecular is now the gold standard for genital herpes detection [8].

Evaluate clinical and cost benefits of testing using HG HSV instead of less sensitive serology tests



Use HG HSV to detect an active infection and determine appropriate treatment as per global guidelines.

How to sell contd.

Centralised testing is not cheaper and more effective than in-house testing.

Improve testing flexibility and lower costs by choosing **HG HSV 1 & 2** assay.

Follow guidelines and bring MDx inhouse to allow fast diagnosis of at-risk patients giving clinicians more information to make informed treatment plan decisions.

Evaluate clinical and cost benefits of testing in-house instead of sending samples to centralised labs.

Testing is carried out on symptomatic individuals.

Antivirals given when positive result is returned to be taken twice a day for 5 days.

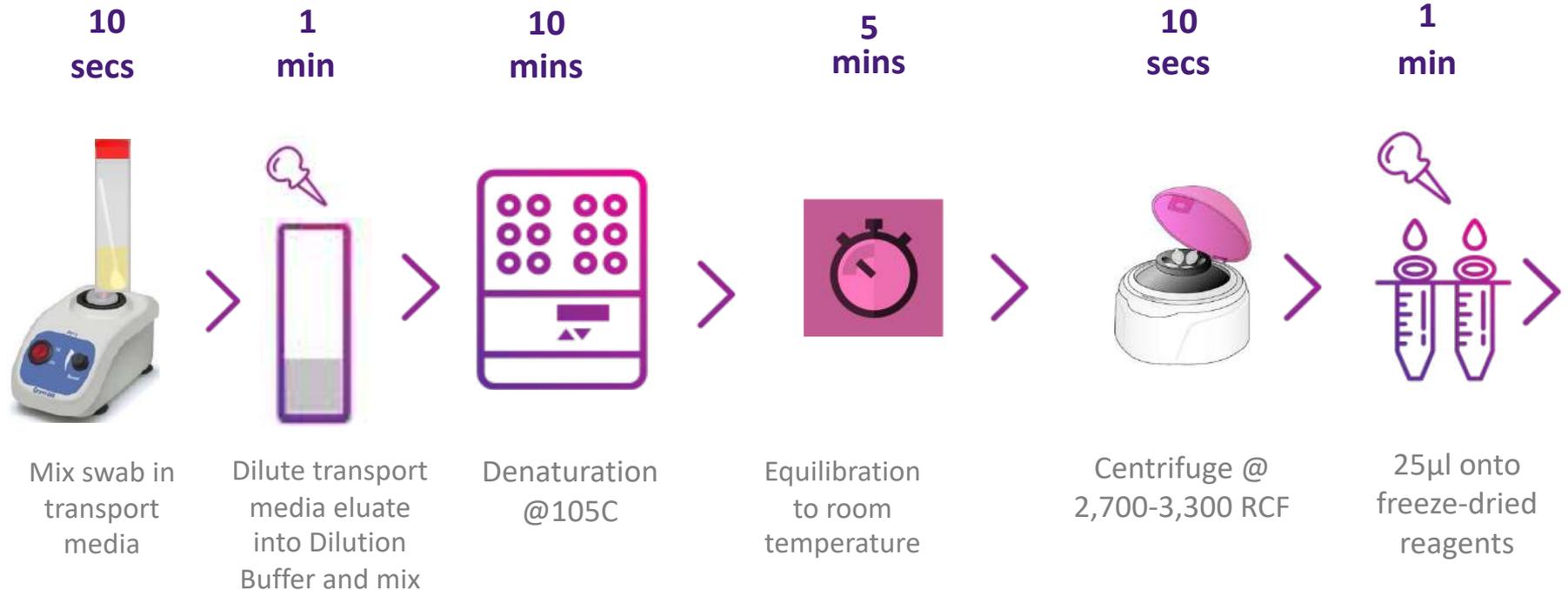
In immunocompromised patients this may be for a longer duration.

Results return from lab and communicated to patient within 1-2 weeks.

Guidelines require immune compromised patients to be treated for a longer period compared to other patient groups [8].

Delivering same-day results to patients allows for earlier treatment and partner notification, minimise risk of onward transmission especially for immune compromised patients and allowing clinicians to make informed decisions regarding birth plans for symptomatic mothers.

Genital Skin Lesions Swab Protocol



40 min
LAMP reaction



58 mins

- Easy protocols
- Affordable testing
- Near patient
- Same day results
- Ready to use freeze-dried reagents

Who to approach?

1. Any customer **currently using conventional testing** methods: mainly serology.
2. Any customer (hospitals, private labs, sexual health clinics, women's health clinics) **that currently outsources** testing to centralised labs.
3. Customers currently **using other MDx** method (requiring confirmatory results).
4. STIs/**Women's health clinics** with laboratory facilities.
5. Larger hospitals that **require overflow** or out-of-hours testing.

HSV 1 & 2 Diagnostics Methods

Method	Sensitivity	Specificity	Time to Result	Difficulty
Culture	Low	Low	> 2 weeks	High
Molecular	High	High	1 hour	Low

Why use molecular?

HSV DNA detection is now considered the gold standard for diagnosis, being more sensitive and specific than cell culture [9].

Nucleic acid amplification tests (NAATs) are now recommended by NICE, European and CDC guidelines due to superior sensitivity and specificity.

Competitors

Company	System	HiberGene Advantages
Cepheid	GeneXpert	Lower Price Faster results Higher specificity No calibration & no maintenance required
Meridian	Alethia	No Mycoplasma genitalium No Chlamydia/Gonorrhoea
Roche	Cobas® 6800/8800 Systems	Lower price Faster results Higher specificity