

TDL Sexual Health 2017

According to the current working definition, sexual health is:

“...a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled.” (WHO, 2006a)

The quality and scope of sexual and reproductive health testing is significant. But screening needs to be sustained and expanded in order to address HIV and sexual and reproductive health.

2017 Sexual Health in the UK

- the impact of STI's remains **greatest** in heterosexual under 25s, and in men who have sex with men (MSM)
- the **most commonly** diagnosed STI is Chlamydia
- the **largest** proportional increases are Syphilis (+20%)(London +40%) and Gonorrhoea (+ 11%) (London +23%)
- condomless sex accounts for the **largest increases** in MSM

HIV

London has the highest prevalence of sexually transmitted infections (STIs) and HIV in the country and faces significant sexual health challenges.

- nearly half of all people living with HIV in England live in London
- men who have sex with men (MSM) make up 2% of London's adult population yet 24% of newly diagnosed STIs
- 1 in 8 MSM in London have HIV, with 20% undiagnosed
- London has the highest STI rate in England, 65% higher than any other region
- under-25 year olds experience particularly high STI rates – 37% of new infections in Londoners were in those aged between 15 and 24 years
- There are significant increases in syphilis and chlamydia and gonorrhoea



In November 2015 PHE's launched a nationally available service for individuals to order a self-sampling (not self-testing) HIV pack so they could take their own sample at home and post it for laboratory testing and results management. Increasingly patients are accessing online sexual health services and from April 2017, a challenging London project is due to be implemented, giving patients access to services through the internet.* This increased speed of service will bring about significant changes. Patients will have access to information about sexual health, online triage, signposting to the most appropriate service for their needs and the option of ordering self-testing kits. GUM clinics will be open longer hours, and clinics will offer patients the opportunity to triage and self-sample on site and routine STI test results will be available electronically to patients within 72 hours. Patients who are diagnosed with an STI will be offered an appointment within 24 hours or will be fast tracked if they present to a walk in service.

This may also help to address late diagnosis of HIV, as this remains an important public health issue in the UK, with 40% of newly diagnosed individuals classified as late. Certain groups are disproportionately affected by late diagnosis (older adults, heterosexuals and non-national populations, in particular black Africans) and reasons for not testing promptly are, amongst other reasons, mainly linked to individual perceptions of risk, missed opportunities to test by healthcare professionals, fear of disease or disclosure.

Increased HIV and STI testing is key for any prevention/reduction strategy. HIV self-sampling involves the request for a sampling pack online, sampling collection at home (finger prick/blood drops) and posting the sample to a laboratory HIV and other STI testing, with results texted or telephoned within 48 hours.

**Pan London Sexual Health Transformation Programme*

TDL TINIES for self collection blood samples

tinies@tdlpathology.com

The range of tests for Sexual Health Screening includes options for self-collection blood samples (home sample collection not home testing) and postal pathology using TDL TINIES. Orders for TDL TINIES (packs with instructions) can be made up by TDL, by arrangement, or supplied directly to doctors or healthcare companies. This is not point of care testing. All testing is undertaken in the laboratory and results for TINIES and POSTAL PATHOLOGY are always returned directly to the healthcare company or doctor, not to the patient.

Up to 4 tests can be taken from one TDL TINY

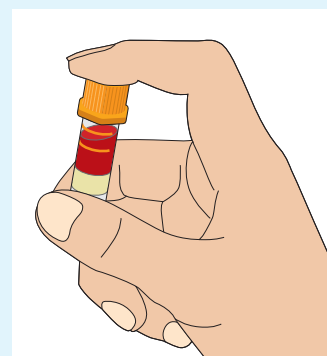
- HIV 1&2/p24 Antigen
- Hep B sAg
- Hep C Abs
- Syphilis IgG/IgM

Packs can also be made up to include urine tube and swabs (e.g. MSM self-collection packs are made up for self-sample collection for:

BLOOD/TINY	URINE	PCR SWABS
HIV 1&2/p24	CT/GC	Rectal
Syphilis		Pharyngeal

Reactive samples must be followed up with a venous sample for confirmatory testing.

For information about self collection packs, please contact Annette Wilkinson on **020 7307 7343** or email tinies@tdlpathology.com. All results will be sent to the healthcare practice/organisation who manage the service.



Sexual Health – made easier: Change of content for STD1, STD2, STD3 and STD4

Blood Building Block 1

HIV + Syphilis IgG/IgM

Blood Building Block 2

HIV + Syphilis + Hep B sAg + Hep C Abs

Urine Building Block 3

CT/GC

Urine Building Block 4

DL12 (see lab guide page 17) *CT, GC, Mycoplasma, Ureaplasma, Trichomonas, Gardnerella, Herpes*

PCR Swab Building Block 5

CT/GC

PCR Swab Building Block 6

DL12 (see lab guide page 17) *CT, GC, Mycoplasma, Ureaplasma, Trichomonas, Gardnerella, Herpes*

Reactive results at screening:

- Reactive CT/GC will reflex to repeat confirmatory testing for no additional charge
- Reactive Syphilis IgG/IgM will reflex to RPR/TPPA for no additional charge
- Reactive Hep BsAg will reflex to Hep B Core for no additional charge
- Reactive Hep C Abs will reflex to Hep C Antigen for no additional charge
- Reactive HIV will reflex to confirmatory testing using 3 independent methods for no additional charge

MALE TESTING

STD1 BASIC = **Block 1** + **Block 3**

STD2 MORE = **Block 2** + **Block 4**

FEMALE TESTING

STD3 BASIC = **Block 1** + **Block 5**

STD4 MORE = **Block 2** + **Block 6**

Add additional swabs (culture or NAAT/PCCR) as needed.

STD1 M/F STD QUAD (Urine and Serology)

Serology HIV 1&2/p24 antigen Syphilis IgG/IgM	Urine Chlamydia Gonorrhoea	CHANGE 2017 TAT 2 DAYS
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STD1

B FCRU

STD2 M/F STI PROFILE PLUS (Urine and Serology)

Serology HIV 1&2/p24 antigen Hep B surface Antigen Hep C Abs/Hep C Ag Syphilis IgG/IgM	Urine Chlamydia/Gonorrhoea Mycoplasma genitalium Ureaplasma Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II	CHANGE 2017 TAT 4 DAYS
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STD2

B FCRU If culture swabs are needed please request separately

STD3 FEMALE STD QUAD (PCR swab and Serology)

Serology HIV 1&2/p24 antigen Syphilis IgG/IgM	Vaginal PCR Swab Chlamydia Gonorrhoea	CHANGE 2017 TAT 2 DAYS
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STD3

B PCR

STD4 FEMALE STI PROFILE PLUS (PCR swab and Serology)

Serology HIV 1&2/p24 antigen Hep B surface Antigen Hep C Abs/Hep C Ag Syphilis IgG/IgM	Vaginal PCR Swab Chlamydia/Gonorrhoea Mycoplasma genitalium Ureaplasma Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II	CHANGE 2017 TAT 4 DAYS
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STD4

B PCR If culture swabs are needed please request separately

STD5 SEROLOGY ONLY

HIV 1&2/p24 Antigen Hepatitis B Surface Antigen Hep C Abs Hep C Ag (early detection) Syphilis IgG/IgM	TAT 4 HOURS
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STD5

B

STD6 SEROLOGY ONLY WITHOUT HIV

Hepatitis B Surface Antigen Hep C Abs Hep C Ag (early detection) Syphilis IgG/IgM	TAT 4 HOURS
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STD6

B

STD8 VAGINITIS/BV PROFILE USING CULTURE & PCR SWAB

Candida species Gardnerella vaginalis by PCR Trichomonas vaginalis by PCR	TAT 3 DAYS
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STD8

PCR STM

STD9 SYMPTOMATIC LESION SAMPLE USING PCR SWAB FROM LESION

Syphilis by PCR Herpes Simplex I/II by PCR (from single swab)	TAT 7 DAYS
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STD9

PCR

MYCOPLASMA/UREAPLASMA BY PCR (Urine, Swab or Thin Prep)

Mycoplasma genitalium Ureaplasma urealyticum/parvum	NEW 2017 TAT 2 DAYS
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MUPC

FCRU OR PCR Swab OR TPV

EARLY DETECTION SCREEN (HIV1/HIV2/HBV/HCV by PCR/NAT)

HIV1 and HIV2 (RNA) Hepatitis B Virus (HBV a) Hepatitis C Virus (HCV RNA)	TAT 3 DAYS
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STDX

A 10mls or 2x4mls

EARLY DETECTION SCREEN WITH SYPHILIS (HIV1/HIV2/HBV/HCV by PCR)

HIV1 and HIV2 (RNA) Hepatitis B Virus (HBV DNA) Hepatitis C Virus (HCV RNA) Syphilis IgG/IgM	TAT 3 DAYS
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STXX

B **A** 10mls or 2x4mls

7 STI PROFILE BY PCR (7 TESTS FROM 1 SAMPLE) (Urine, Swab, Thin Prep or Semen)

Chlamydia trachomatis N. gonorrhoea Mycoplasma genitalium Ureaplasma Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II	All tests can be requested individually. TAT 2 DAYS
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PP12

FCRU OR PCR Swab OR TPV OR Semen

CT/GC/TRICHOMONAS 3 STI'S BY PCR (SWAB) (Urine, Swab or Thin Prep)

Chlamydia Gonorrhoea Trichomonas vaginalis	NEW 2017 TAT 2 DAYS
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CCGT

FCRU OR PCR Swab OR TPV

Mycoplasma/Ureaplasma by PCR

M. genitalium is sexually transmitted, infecting about 1% of people in the UK aged 16–44 (about 250,000) – which means that *M. genitalium* is a more common sexually transmitted infection than gonorrhoea. Most infections are asymptomatic.

When symptomatic:

Men: *M. genitalium* infection is unequivocally associated with non-chlamydial, non-gonococcal urethritis, dysuria, urethral discharge.

Women: cervicitis and pelvic inflammatory disease, increased or altered vaginal discharge, dysuria or urgency, sometimes post coital bleeding.

Testing for *M. genitalium* by PCR/NAAT from first catch void of urine or vaginal swab (PCR) is the only useful method for diagnosis. Anal swab samples are also useful for MSM where as many as 70% of the infections will be missed if this site is not sampled.

Patients with *M. genitalium* infection should be screened for other STIs, including Chlamydia, Gonorrhoea, Syphilis, HIV, and *Trichomonas vaginalis* where appropriate.

A Test of Cure should be routinely performed in all patients due to the high prevalence of macrolide resistance. Test of Cure is recommended and collected no earlier than three weeks after start of treatment.

MYCOPLASMA/UREAPLASMA BY PCR (Urine, Swab or Thin Prep)		
Mycoplasma genitalium Ureaplasma urealyticum/parvum	NEW 2017	TAT 2 DAYS
		MUPC
FCRU OR PCR Swab OR TPV		

Chlamydia/Gonorrhoea/Trichomonas vaginalis

Trichomoniasis vaginalis is a sexually transmitted infection caused by a tiny parasite. Symptoms of trichomoniasis usually develop within a month of infection, although up to half of all infected men and women have no symptoms and therefore sometimes be difficult to diagnose.

When symptomatic

Women

- abnormal vaginal discharge that may be thick, thin or frothy and yellow-green in colour
- unpleasant fishy smell
- soreness, inflammation and itching around the vagina/ inner thighs also become itchy
- dysuria/urinary frequency or pain during intercourse

Men

- pain when voiding or with ejaculation
- urinary frequency
- thin white discharge from the penis
- soreness, swelling and redness around the head of the penis or foreskin

CT/GC/TRICHOMONAS 3 STI'S BY PCR (SWAB) (Urine, Swab or Thin Prep)		
Chlamydia Gonorrhoea Trichomonas vaginalis	NEW 2017	TAT 2 DAYS
		CCGT
FCRU OR PCR Swab OR TPV		

Trichomoniasis is unlikely to go away without treatment, but it can be effectively treated with antibiotics. Most men and women are treated with metronidazole, which is usually taken twice a day for five to seven days.

It's important to complete the whole course of antibiotics and avoid having sex until the infection clears up, to prevent reinfection. Your current sexual partner and any other recent partners should also be treated. There is a high rate of coinfection with other STI's.

7 STIs – Sexual Health Profile by PCR

- Chlamydia
- Gonorrhoea
- Mycoplasma genitalium
- Ureaplasma urealyticum
- Trichomonas vaginalis
- Gardnerella vaginalis
- Herpes Simplex I/II

Choice of Sample types

Urine	✓
PCR Swab	✓
Cytoc Thin Prep Vial	✓
Semen	✓

Tests can be requested individually or as a profile of 7 tests from one sample.

7 STI PROFILE BY PCR (7 TESTS FROM 1 SAMPLE)	
Chlamydia trachomatis N. gonorrhoea Mycoplasma genitalium Ureaplasma Trichomonas vaginalis	Gardnerella vaginalis Herpes Simplex I/II All tests can be requested individually.
TAT 2 DAYS	
PP12	

FCRU OR PCR Swab OR TPV OR Semen

Sexual Health – Testing for Infection and Infertility by PCR

Being able to test for 7 tests from 1 sample type of choice (First Catch Random Urine sample, PCR swab, Thin Prep Vial or Semen) provides several advantages, and is more cost effective. Tests can also be requested as single assays, or in combination.

Single tests	Code	Urine*	PCR Swab	Cytoc Vial	Semen
Chlamydia trachomatis	CPCR	✓	✓	✓	✓
N. gonorrhoea	CGON	✓	✓	✓	✓
Mycoplasma genitalium	MGEN	✓	✓	✓	✓
Ureaplasma urealyticum	UGEN	✓	✓	✓	✓
Mycoplasma/Ureaplasma	MUPC	✓	✓	✓	✓
Trichomonas vaginalis	TVPC	✓	✓	✓	✓
Gardnerella vaginalis	GVPC	✓	✓	✓	✓
Herpes Simplex I/II	HERD	✓	✓	✓	✓

* first catch random urine

When to test? What to test? How to test?

BLOOD	INCUBATION PERIOD	SAMPLE SITE	TEST	TEST CODE	SAMPLE TYPE	TAT
Syphilis	Bacterial 9–21 days, but up to 90 days	Blood	Syphilis IgG/IgM	SERJ	B	4 hours
Herpes Simplex Virus I/II	Viral IgG 4–6 weeks after exposure IgM 5–35 days after exposure, after which test IgG	Blood Blood	Herpes IgG (past infection) Herpes IgM (current/recent)	HERP HERM	B B	2 days 2 days
HIV	Viral Usually 10–90 days, but up to 180 days	Blood Blood	HIV I&II /p24 antigen	HDUO	B	4 hours
Hep B	Viral Usually 45–180 days, average of 60–90 days	Blood Blood	Hep B surface antigen	AUAG	B	4 hours
Hep C Ab	Viral Usually 9–180 days, average of 45–65 days	Blood Blood	Hep C Antibodies	HEPC	B	4 hours
Hep C Ag	Viral Usually 9–180 days, average of 45–65 days	Blood Blood	Hep C Antigen (See lab guide page 65)	HCAG	B	4 hours

EARLY DETECTION PROFILES BY PCR	INCUBATION PERIOD	SAMPLE SITE	TEST	TEST CODE	SAMPLE TYPE	TAT
7 STIs by PCR	One sample for 7 STI Tests	Urine Cervix Vagina	Chlamydia Gonorrhoea Mycoplasma genitalium Ureaplasma genitalium Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II	PP12 PP12 PP12	Thin Prep Vial or First Catch Urine or PCR Swab	2 days 2 days 2 days
HIV/ HBV/ HCV	Early Detection Screen by PCR Multiplex HIV from 10 days	Blood	HIV 1&2 RNA Hepatitis B (HBV DNA) Hepatitis C (HCV RNA)	STDx	A 10mls or 2x 4mls	3 days

The Self-Collection HPV test provides women with the option to self-collect a vaginal sample, that is then sent to the laboratory for testing. Results will always be sent to the requesting clinician, clinic or healthcare organisation.

HPV	Self-Collected HPV DNA with individual reporting of subtypes 16, and 18 and collective reporting of the other high risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).
HPVZ	Self-Collected HPV DNA with individual reporting of all subtypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

For more information, or to order Self-Collection HPV Test Packs, please contact Annette Wilkinson on 020 7307 7343 or annette.wilkinson@tdlpathology.com

RETESTING/TEST OF CURE

Chlamydia: Allow up to 6 weeks before retesting. NAAT/PCR tests are sensitive and will pick up the DNA from a previous infection if retesting is undertaken too soon after treatment, when a positive result may be a sign of continuing or re-infection from the initial infection.

Gonorrhoea can usually be treated successfully with a single antibiotic injection followed by one antibiotic tablet. **Retesting two weeks after treatment will confirm clearance of gonorrhoea.** Test of cure is recommended following treatment for all gonococcal infections. This is to identify treatment failure and emerging resistance to ceftriaxone and cefixime.

Trichomonas vaginalis: If antibiotics are taken correctly, follow-up tests or examinations for trichomonas shouldn't be needed, but if treatment has not been completed, or there is a chance of becoming re-infected, or symptoms continue, then repeat testing and perhaps different treatment may be indicated.

When to test? What to test? How to test?

STI's can be caused by virus, fungus, parasite or bacteria. Anyone who is sexually active may be at risk of acquiring an STI. The risk is higher for those with increased numbers of sexual partners, or who have had sex with someone who has/had many partners, or have had unprotected sex.

STD	INCUBATION PERIOD	SAMPLE SITE	TEST	TEST CODE	SAMPLE TYPE	TAT
Chlamydia CT	Bacterial 1 – 3 weeks, up to 6 weeks	Urine Cervix /Vagina Cervix /Vagina	Chlamydia Chlamydia Chlamydia	CPCR SPCR TPCR	First Catch Urine PCR Swab Thin Prep Vial	2 days 2 days 2 days
Gonorrhoea GC	Bacterial 2 – 7 days, up to 1 month	Urine Cervix /Vagina Cervix /Vagina Cervix /Vagina	Gonorrhoea by PCR Gonorrhoea by PCR Gonorrhoea by PCR Gonorrhoea by CULTURE	CGON SGON TGOON GONON	First Catch Urine PCR Swab Thin Prep Vial Culture swab	2 days 2 days 2 days 2-3 days
CT/GC Combined	Bacterial 1 – 3 weeks, up to 6 weeks	Urine Cervix /Vagina Cervix /Vagina Rectum Throat	CT/GC CT/GC CT/GC CT/GC CT/GC	CCG SCG TCG RSCG TSCG	First Catch Urine PCR Swab Thin Prep Vial PCR Swab PCR Swab	2 days 2 days 5 days 2 days 2 days
Mycoplasma genitalium	Bacterial Symptoms develop at 1 – 3 weeks	Urine GU Site Cervix /Vagina	Mycoplasma genitalium by PCR Mycoplasma genitalium by PCR Mycoplasma genitalium by PCR	MGEN MGEN MGEN	First Catch Urine PCR Swab Thin Prep Vial	2 days 2 days 2 days
Ureaplasma urealyticum	Bacterial Symptoms develop at 1 – 3 weeks	Urine GU Site Cervix /Vagina	Ureaplasma by PCR Ureaplasma by PCR Ureaplasma by PCR	UGEN UGEN UGEN	First Catch Urine PCR Swab Thin Prep Vial	2 days 2 days 2 days
Trichomonas vaginalis	Parasitic 4 – 28 days, many patients are asymptomatic carriers	Urine GU Site Cervix /Vagina	Trichomonas vaginalis by PCR Trichomonas vaginalis by PCR Trichomonas vaginalis by PCR	TVPC TVPC TVPC	First Catch Urine PCR Swab Thin Prep Vial	2 days 2 days 2 days
Gardnerella vaginalis	Bacterial Imbalance of normal flora	Urine GU Site Cervix /Vagina	Gardnerella vaginalis by PCR Gardnerella vaginalis by PCR Gardnerella vaginalis by PCR	GVPC GVPC GVPC	First Catch Urine PCR Swab Thin Prep Vial	2 days 2 days 2 days
Bacterial Vaginosis (BV)	Bacterial Imbalance of normal flora	Cervix /Vagina	Bacterial Vaginosis (BV) Profile by both PCR and CULTURE	STD8	Both Culture & PCR swab	3 days
Herpes Simplex Viral I/II	Viral 2 – 14 days, testing is most appropriate for patients with symptomatic lesion(s)	PCR swab PCR swab	Herpes by PCR Herpes by PCR	HERS HERD	PCR Swab First Catch Urine	4 days 4 days
Human Papillomavirus	Viral HPV is the most common sexually transmitted infection – usually asymptomatic	Cervical cells Cells /papilloma from site (throat /penile/anal)	HPV DNA/mRNA HPV Typed DNA HPV Typed DNA	HPVT HP20 HP20	Thin Prep Vial PCR Swab Cells /Papilloma	5 days 3 days 3 days
Genital warts	Viral Weeks / months after exposure	GU Warts	HPV Typed DNA HPV Typed DNA HPV Typed DNA	HPVT HP20 HP20	Thin Prep Vial PCR Swab Cells /Papilloma	5 days 3 days 3 days
Syphilis/Herpes	Bacterial/ Viral Whenever active lesions are present	Symptomatic Lesion	Syphilis/Herpes Lesion Profile	STD9	PCR Swab	7 days

TEST UPDATE: 5th Generation HIV

TDL has introduced a next generation HIV assay with the Bio-Rad BioPlex 2200 HIV Ag-Ab assay. This is the first commercial screening assay to be able to distinguish between HIV-1 antibodies, HIV-2 antibodies and HIV-1 p24 antigen. In addition to the early detection offered by 4th generation assays, this 5th Generation assay provides more information by specifically identifying HIV-1 or HIV-2 and allows results of antigen and antibody detection to be reported individually. Because antigens and antibodies are detectable at different stages of the infection, reporting of both helps to differentiate between acute and established HIV infection.

This 5th Generation HIV test is

- One of the best performers for detecting primary HIV infection
- Set at the same price as 4th Gen HDUO
- Useful in a confirmatory algorithm with the advantage of differentiating the individual HIV analytes
- CE marked and evaluated by PHE

TEST	CODE	SAMPLE REQUIREMENTS	TAT
HIV (5th Generation) Ag-Ab Screen (Bio-Rad BioPlex 2200)	HIV5	B SST/Serum or	24 hours
Results report the following: HIV-1 Abs, HIV-2 Abs, HIV-1 p24 Antigen	THV5	B TDL Tiny™	24 hours

UPDATE: Gonorrhoea testing

Like chlamydia, testing for gonorrhoea diagnosis is usually undertaken using highly sensitive and specific NAAT/PCR methodology. The sensitivity of these tests is very high for all specimen types (endocervical swabs, self-taken vaginal swabs, urethral swabs and male urines), except for female urines, where the sensitivity is much lower. Detection of gonococcal infection in rectal and throat samples using NAATs is more sensitive than culture and NAATs are the test of choice at these sites in men who have sex with men (MSM) and other high risk individuals. **Although culture for *N. gonorrhoeae* is less sensitive than NAATs, it is still needed to identify resistance.** Ideally, gonorrhoea treatment should not be commenced until the culture has been confirmed. However, unnecessary delays to treatment should be avoided to prevent onward transmission. Clinicians treating a patient with gonorrhoea should follow the latest evidence-based guidelines developed by the BASHH/Royal College of General Practitioners.

Test of cure

Repeat testing is recommended for all cases of gonorrhoea to monitor treatment failure. Patients with persisting symptoms should be tested with culture at least 72 hours after completion of therapy. Asymptomatic patients should be tested with NAATs, followed by culture if positive, at least two weeks after completion of therapy.

Full STI screen including HIV

Patients diagnosed with gonorrhoea are at high risk of other STIs and should be additionally tested for syphilis and HIV (and chlamydia if not already performed).

HPV as first test for Screening Programmes Progression to Self-Collection HPV Test

Human Papillomavirus (HPV) is the primary cause of nearly all cervical cancer. In most cases, the HPV virus is harmless and causes no symptoms. Most women who acquire HPV are able to clear the infection through their own immune systems. Persistent presence of high-risk types of HPV can cause cervical lesions which over time may develop into cancer if untreated. Testing for HPV determines the presence, or absence, of HPV and will determine whether the HPV type present is high risk for CIN and cervical cancer.

The **Self Collection HPV Test** provides women with the option to self-collect a vaginal specimen that is then sent to the laboratory for testing. There is well documented high level of concordance between the HPV DNA results from self-collected and clinician-collected specimens.

The **Self-Collection HPV Test** is validated, using a CE marked sample collection device for vaginal cell collection. This sample is then sent to the laboratory for processing for 14 high risk HPV DNA subtypes. A negative result means that these high-risk subtypes HPV were not detected and the patient is at extremely low risk of developing high-grade cervical disease/CIN2+ before their next routine visit.

A positive HPV result might indicate an increased risk of developing CIN/cervical cancer, and the report from the laboratory will provide a clear recommendation for follow-up/colposcopy.

The value of HPV DNA testing in cervical cancer screening and disease detection has been proven over and over again. Self-collection of specimens for HPV testing is not intended to replace existing patient management pathways but allows for:

- Those who wish to test following a change of sexual partner
- Option for identifying individual high risk DNA subtypes
- Personal preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears

The Self-Collection HPV test provides women with the option to self-collect a vaginal sample, that is then sent to the laboratory for testing. Results will always be sent to the requesting clinician, clinic or healthcare organisation.

HPVY Self-Collected HPV DNA with individual reporting of **subtypes 16, and 18** and **collective** result for the other high risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).

HPVZ Self-Collected HPV DNA with **individual** reporting of **all subtypes** 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

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