

TDL Sexual Health 2019



Sexual Health Screening services continue to become easier to access for everyone, with testing and results becoming available more quickly through both private, NHS clinics, and increasingly available **online sexual health services**.

Online services allow patients to opt for self-sampling at home. Routine STI screening test results are often sent electronically to patients within a few hours or days of samples being received in the laboratory, depending on the nature of the test and the arrangements of the organisation providing the service. This allows patients who are diagnosed with an STI to be fast tracked for treatment.

Sexually transmitted infections (STIs) have been highlighted frequently in media stories in the past year, many of which have been negative in content, with headlines such as 'Highest syphilis rates since 1949!' and 'Untreatable gonorrhoea superbug!'. Of course it is not as simple as this and to understand the context of where we are with sexual health, we need to go beyond the headlines to look at figures for syphilis, chlamydia, gonorrhoea and genital warts, and acknowledge the increasing focus on antibiotic-resistant infections and the current state of sexual healthcare in England.

HIV Rapid RNA HIV-1 QUALITATIVE – Results in 4 Hours

HIV Rapid RNA HIV-1 QUANTITATIVE – Results in 4 Hours

For some patients **earlier diagnosis of HIV infection** is important. **Xpert HIV-1 Qual** is a qualitative test that provides molecular testing for earlier diagnosis (from 10 days). (Cepheid)

FOR PATIENTS ON TREATMENT FOR HIV

Xpert HIV-1 Viral Load accommodates rapid testing and measurement of blood plasma HIV-1 RNA concentration (HIV viral load/40 copies/ml). This is the established standard of care in assessing HIV-positive patient prognosis and response to antiretroviral therapy. Assessment of viral load levels is a strong predictor of the rate of disease progression either by itself or in combination with CD4 T-cell counts.

RAPID XPERT HIV-1 RNA QUALITATIVE EARLY DETECTION FROM 10 DAYS	
HIV-1 RNA	
EDTA sample must be received in the laboratory within 24 hours of sample taking	
	TAT 4 HOURS
LHIV	

A

RAPID XPERT HIV-1 RNA VIRAL LOAD RAPID TESTING FOR HIV-POSITIVE PATIENT PROGNOSIS AND RESPONSE TO ANTIRETROVIRAL THERAPY	
HIV-1 RNA VIRAL LOAD (40 copies/ml)	
EDTA sample must be received in the laboratory within 24 hours of sample taking	
	TAT 4 HOURS
RHIV	

A

Sexual Health – TDL Profiles

STD1 M/F STD QUAD (Urine and Serology)

Serology
HIV 1&2/p24 Antigen
Syphilis IgG/IgM

Urine
Chlamydia
Gonorrhoea

TAT
2
DAYS

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

TAT
4
DAYS

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

TAT
2
DAYS

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

TAT
4
DAYS

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

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

STD6

B

STD8 VAGINITIS/BV PROFILE USING CULTURE & PCR SWAB

Candida species
Gardnerella vaginalis by PCR
Trichomonas vaginalis by PCR

TAT
3
DAYS

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

STD9

PCR

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

Mycoplasma genitalium
Macrolide Resistance Test (M.gen)*
Ureaplasma urealyticum/parvum

*If Mgen is positive, reflex testing for macrolide resistance will be carried out, using the same sample

TAT
2
DAYS

MUPC

FCRU OR PCR Swab OR TPV

HIV/HBV/HCV SCREEN (HIV1/HIV2/HBV/HCV by PCR/NAAT)

HIV1 and HIV2 (RNA)
Hepatitis B Virus (HBV DNA)
Hepatitis C Virus (HCV RNA)
Samples must be received in the laboratory within 2 days of sample taking

TAT
3
DAYS

STDX

A 10mls or 2x4mls

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

HIV1 and HIV2 (RNA)
Hepatitis B Virus (HBV DNA)
Hepatitis C Virus (HCV RNA)
Syphilis IgG/IgM
Samples must be received in the laboratory within 2 days of sample taking

TAT
3
DAYS

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
Macrolide Resistance Test (M.gen)*
Ureaplasma
Trichomonas vaginalis
Gardnerella vaginalis
Herpes Simplex I/II

All tests can be requested individually
*If Mgen is positive, reflex testing for macrolide resistance will be carried out, using the same sample

TAT
2
DAYS

DL12

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

TAT
2
DAYS

CCGT

FCRU OR PCR Swab OR TPV

Mycoplasma genitalium (MGEN) by NAAT/PCR and Macrolide Resistance Testing (M.Gen)

Mycoplasma Genitalium (M.Gen)

M.gen is an important sexually transmitted pathogen detectable only by NAAT. M.gen has limited treatment options. It spontaneously develops resistance to antimicrobials. BASHH recommends treatment with Resistance Guided Therapy – testing for M.gen with macrolide resistance determination. M.gen cannot be cultured for diagnostic testing. M.gen prevalence is higher than GC, and in some populations can be similar to CT. M.gen risk factors are similar to CT and consideration should be given to testing for M.gen in all males with non-GC urethritis and all individuals with signs or symptoms of PID, cervicitis, endometritis, associated infertility, ano-rectal condition or epididymo-orchitis. Partner testing is advised for current partners only. Rectal infections are common, and appear to be an important reservoir for resistance. BASHH guidance – all patients must return for test of cure at 3-5 weeks.

Macrolide Resistance Testing (M.gen)

Prevalence of M.gen in men and women in the general population is 1-2%. *Mycoplasma genitalium* has been implicated as a cause of acute and chronic non-chlamydial non-gonococcal urethritis in males and post coital bleeding, cervicitis, endometritis and pelvic inflammatory disease in females. It is a sexually transmitted, fastidious microorganism that is extremely difficult to culture – with nucleic acid amplification testing (NAAT urine or swab) being the only method available for routine *M. genitalium* detection. Macrolides are generally considered the first-line treatment for *M. genitalium* infections. However, **resistance to macrolides** seems to be increasing worldwide typically exceeding > 40% in male patients who are detected positive for M.gen at screening.

Testing Options for *Mycoplasma Genitalium*

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Mycoplasma genitalium	MGEN	FCRU / PCR swab / TPV	2 days
Mycoplasma genitalium/Ureaplasma	MUPC	FCRU / PCR swab / TPV	2 days
Included in the 7 STI PCR Screen	DL12	FCRU / PCR swab / TPV / Semen	2 days

NEW

Macrolide Resistance Testing (M.gen) will be undertaken **from the same sample** if M.gen is detected. Turnaround time 5-7 days.

MYCOPLASMA BY PCR
 (Urine, Swab or Thin Prep)

Mycoplasma genitalium Macrolide Resistance Test (M.gen)*	TAT 2 DAYS
*If Mgen is positive, reflex testing for macrolide resistance will be carried out, using the same sample	
MGEN	
FCRU OR PCR Swab OR TPV	

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

Mycoplasma genitalium Macrolide Resistance Test (M.gen)* Ureaplasma urealyticum/parvum	TAT 2 DAYS
*If Mgen is positive, reflex testing for macrolide resistance will be carried out, using the same sample	
MUPC	
FCRU OR PCR Swab OR TPV	

DL12 7 STI PROFILE BY PCR
 (7 PCR TESTS FROM 1 SAMPLE)

Chlamydia trachomatis N. Gonorrhoea Mycoplasma genitalium Macrolide Resistance Test (M.gen)* Ureaplasma Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II	TAT 2 DAYS
*If Mgen is positive, reflex testing for macrolide resistance will be carried out, using the same sample	
DL12	
FCRU OR PCR Swab OR TPV OR Semen	

All tests can be requested individually

STI and Screening for HIV for Men who have Sex with Men (MSM) BASHH guidelines

What STIs should MSM be tested for?

MSM should be offered testing for:

Chlamydia

Gonorrhoea

Hepatitis B

Hepatitis C*

HIV

Syphilis

Hepatitis A may occur in local epidemics affecting MSM but routine vaccination is not currently recommended.

*Consider if there is sex associated with trauma or injury, history of recreational drug use/chem sex, known to be HIV positive, or rectal lymphogranuloma venereum.

How frequently should STI testing be offered to MSM?

All sexually active MSM should be tested for STIs at least annually. MSM at high risk of STIs should be tested every 3 months. High risk includes:

- any unprotected sexual contact (oral, genital or anal) with a new partner
- following the diagnosis of a new STI
- drug use may be a marker of high risk behaviour and a detailed sexual history is required in this group

STI Profile: MSM1

HIV 1&2/p24 Ag
Syphilis IgG/IgM
Urine for CT/GC
Throat Swab CT/GC
Rectal Swab CT/GC

TAT
2
DAYS

MSM1

B FCRU PCR Swab Throat PCR Swab Rectal

STI Profile: MSM2

HIV 1&2/p24 Ag
Syphilis IgG/IgM
7 STI by PCR Screen
Throat Swab CT/GC
Rectal Swab CT/GC
Macrolide Resistance Test (M.gen)*

Hep B sAg
Hep C Abs

TAT
3
DAYS

MSM2

B FCRU PCR Swab Throat PCR Swab Rectal

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 (screening from 28 days)		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 87)		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 Macrolide Resistance Test (M.gen)* Ureaplasma genitalium Trichomonas vaginalis Gardnerella vaginalis Herpes Simplex I/II		PP12 PP12 PP12 PP12		Thin Prep Vial or First Catch Urine or PCR Swab		2 days 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 2 x 4mls	3 days	

*If Mgen is positive, reflex testing for macrolide resistance will be carried out, using the same sample

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 reporting of individual 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@tdpathology.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.

Mycoplasma genitalium: New guidelines are recommending testing for antimicrobial resistance. Macrolide resistance status will determine whether Azithromycin should be prescribed. In all cases where M. gen is detected, reflex testing will be carried out from the same sample direct treatment pathways.

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 GONN	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	5 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 2-3 days 2-3 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 2-3 days 2-3 days
Syphilis/Herpes	Bacterial/ Viral Whenever active lesions are present	Symptomatic Lesion	Syphilis/Herpes Lesion Profile	STD9	PCR Swab	7 days

NEW: Lymphogranuloma venereum (LGV)

LGV is a type of chlamydia bacteria that attacks the lymph nodes. It is seen predominantly in gay and bisexual men, and very rarely seen in the UK in heterosexual men and women.

Nearly all LGV infections seen in the UK in recent years have been in the rectum. Within a few weeks of becoming infected, most people get painful inflammation in the rectum with bleeding, pus, constipation or ulcers, sometimes with fever, rash and groin, armpit or neck swelling. Left untreated, LGV can cause lasting damage to the rectum that may require surgery. LGV in the penis might cause a discharge and pain

when urinating, with swollen glands in the groin. LGV in the mouth or throat is rare but can cause swollen glands in the neck.

Investigation for possible LGV symptoms is by PCR swab taken from the rectum and penis. If LGV infection is suspected in female patients, cervical and vaginal PCR swabs should be taken. Samples are first tested for chlamydia and if chlamydia is detected, if LGV is suspected, swabs can be further tested, if requested, for LGV as an additional test, using the same swab samples. Sexual contact partners should also be checked.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
NEW: Lymphogranuloma Venerium (LGV)	LGVP	PCR*42	1-2 weeks

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.

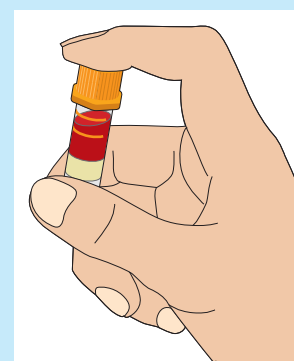
Up to 4 blood tests can be taken from one TDL TINY

- 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 offering this self-collection service.



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 and is the reason why HR-HPV testing will be fully implemented as a **first line test** in the UK during 2019. 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 one **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 reporting of **all subtypes individually**: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

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