TDL Sexual Health 2014

Overall trends in diagnoses in England*

Numbers of new diagnoses of sexually transmitted infections (STIs) in England increased by 5% between 2011 and 2012. The year before it was 2%. Increases were noted in:

- Gonorrhoea (up 21%)
- Infectious syphilis (up 1%)
- Genital herpes (up 2%)
- Trichomoniasis (up 6%)
- Non-specific genital infection (fell 3%)
- Genital warts (fell 2%)
- Chlamydia

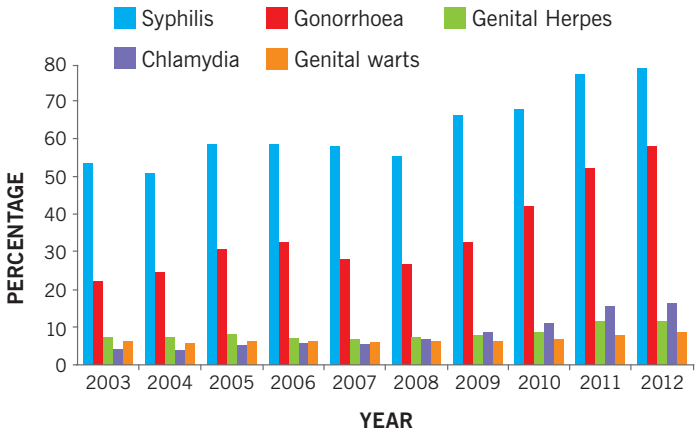
Genital chlamydia trachomatis ('chlamydia') is the most commonly reported bacterial sexually transmitted infection (STI) in the UK. Over 186,000 new cases were diagnosed in 2011, with sexually active young adults remaining at highest risk of infection. Chlamydia often has no symptoms but can lead to a wide range of complications, including pelvic inflammatory disease (PID), ectopic pregnancy and tubal factor infertility (TFI) in women and epididymitis in men, and represents a substantial public health problem.

* Health Protection Report Vol 7 No. 23 –7 June 201

STI Update

- There were approximately 450,000 STI diagnoses made in England in 2012.
- Genital chlamydial infection was the most commonly diagnosed STI, accounting for almost 46% of diagnoses.
- New diagnoses of gonorrhoea rose to over 25,000 continuing the sharp rise in cases seen in the previous year.
- Continued rise in STI diagnoses among MSM (more testing at extra-genital sites, and high levels of unsafe sex among MSM).

Proportion of men who have sex with men among all male STI diagnoses, GUM clinics, 2003–2012, England



Rates in Increase of Infection

- Increases in Sexual Health screening and testing
- Continued high levels of unsafe sexual behaviour
- Changes in sexual behaviour
- Increased asymptomatic screening of extra-genital sites in MSM
- Improved detection of gonococcal and chlamydial infections in MSM
- More sensitive and specific methodologies for testing (PCR/NAAT testing)
- Increased patient access to screening clinics
- Self-collected postal samples (test kits sent to individuals requested through mail out, telephone, website)
- Education
- Travelling – 20 to 40 percent of international travellers seen in STI clinics had sex with a new partner while abroad, and the risk of acquiring an STI is 3 times more likely in travellers who have casual sex. Use of alcohol or recreational drugs during travel increases the chance of a risky sexual encounter.

HIV in the UK (2013): HIV testing is a priority if HIV prevention efforts are to be improved

By the start of 2012, an estimated 96,000 people were living with HIV in the UK (compared with 86,500 in 2009, 91,500 in 2010 and a 58% increase since 2002); **with a consistent 25% of people unaware of their infection**. The majority of new infections are thought to be acquired in the UK (compared to only 27% in 2002). Rates of HIV diagnosis and HIV prevalence continue to be significantly higher in London than elsewhere in the UK. People diagnosed late have a 10 fold increased risk of dying within a year of diagnosis.

National Aids Trust recommendation*

- MSM should test at least once a year for STI's and HIV.
- MSM should test every 3 months if they are having unprotected sex with new or casual partners.
- HIV negative MSM diagnosed with an STI need to consider HIV as a serious risk.

* (Health Protection Agency (HPA).

Most Common STIs (alphabetical order)

- Anogenital warts
- Bacterial vaginosis
- Chancroid
- Chlamydia
- Gonorrhoea
- Hepatitis B
- Hepatitis C
- Herpes
- HIV
- Human papillomavirus
- Mycoplasma genitalium
- Infectious Syphilis
- Trichomoniasis

Risk factors

- Youth
- Failure to use barrier contraceptives
- Non-regular sexual relationships
- Homosexuality
- Travel and Risky Sexual Encounters
- Intravenous drug use
- African origin (Sub-Saharan Africa)
- Social deprivation
- Prostitution/Promiscuity
- Poor access to advice and treatment of STDs

TDL Sexual Health Profiles

STD1 MALE PROFILE

Urethral Micro Swab
Chlamydia/Gonorrhoea (Urine)
Syphilis IgG/IgM

TAT 2 DAYS

STD1

B STM FCRU

STD2 MALE PROFILE PLUS

HIV 1 & 2 Abs/p24 Antigen
Hep B surface Antigen
Hep C Abs
Hep C Ag (early detection)
Syphilis IgG/IgM
Chlamydia/Gonorrhoea (urine)
Herpes Simplex I/II by PCR
Urethral Swab for culture

TAT 4 DAYS

STD2

B STM FCRU

STD3 FEMALE PROFILE

Syphilis IgG/IgM
Chlamydia/Gonorrhoea (PCR Swab)
High vaginal Swab (Culture swab)

TAT 2 DAYS

STD3

B STM PCR

STD QUAD

Syphilis IgG/IgM
HIV 1&2/p24 Antigen
Chlamydia (Urine)
Gonorrhoea (urine)

TAT 2 DAYS

STDQ

B FCRU

STD4 FEMALE PROFILE PLUS

HIV 1 & 2 Abs/p24 Antigen
Hep B surface Antigen
Hep C Abs
Hep C Ag (early detection)
Syphilis IgG/IgM
Chlamydia/Gonorrhoea
Herpes Simplex I/II by PCR
High Vaginal Swab for culture

TAT 4 DAYS

STD4

B STM PCR

STD5 BLOODS ONLY

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

TAT 4 HOURS

STD5

B

STD6 BLOODS ONLY

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

TAT 4 HOURS

STD6

B

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

Positive findings will be reflexed for individual qualitative confirmatory testing using the Roche Cobas Ampliscreen

HIV1 and HIV2 (RNA)
Hepatitis B Virus (HBV DNA)
Hepatitis C Virus (HCV RNA)

Sample must be received in the laboratory within 2 days of sample taking

TAT 3 DAYS

STDX

A 10mls or 2x4mls

STD8 VAGINITIS/BACTERIAL VAGINOSIS PROFILE

DNA Probe test for
Candida species
Gardnerella vaginalis by PCR
Trichomonas vaginalis by PCR

CHANGE 2014

TAT 3 DAY

STD8

PCR STM

STD9 SYMPTOMATIC LESION SAMPLE USING PCR SWAB

Syphilis by PCR
Herpes Simplex I/II by PCR
(from single swab)

TAT 7 DAYS

STD9

PCR

7 STD 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 5 DAYS

PP12

FCRU OR PCR Swab OR TPV OR Semen

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

Positive findings will be reflexed for individual qualitative confirmatory testing using the Roche Cobas Ampliscreen

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

Sample must be received in the laboratory within 2 days of sample taking

TAT 3 DAYS

STXX

B A 10mls or 2x4mls

*FAST*est Test Sexual Health Screening – *ahead of expected time*

FCT	*FAST* Chlamydia Urine	FSCT	*FAST* Chlamydia Swab	FTCG	*FAST* CT/NG Throat Swab
FGN	*FAST* Gonorrhoea Urine	FSGN	*FAST* Gonorrhoea Swab	FRCG	*FAST* CT/NG Rectal Swab
FCG	*FAST* CT/NG Urine	FSCG	*FAST* CT/NG Swab		

- **Simultaneous RT-PCR detection of both CT and Dual Target NG**
- **Sample Adequacy and Process Controls for every sample tested**
- **The *FASTEST* Results: HIV/HBV/HCV/ Syphilis and CT/NG in 4 hours***
- **Runs on: Cepheid GeneXpert® System CE IVD**

FAST SSC Fast Screen *SHORT*

NEW 2014

HIV 1&2/p24 Ag
Syphilis IgM/IgG
FAST Urine CT/NG

TAT 4 HOURS*

FSSC

1x SST/Serum + Urine

FAST USC Fast Screen *URINE*

NEW 2014

HIV 1&2/p24 Ag
Hep B sAg
Hep C Abs
Hep C Ag
Syphilis IgG/IgM
FAST Urine CT/NG

TAT 4 HOURS*

FUSC

1x SST/Serum + Urine

FAST SSC Fast Screen *SWAB*

NEW 2014

HIV 1&2/p24 Ag
Hep B sAg
Hep C Abs
Hep C Ag
Syphilis IgG/IgM
FAST Swab CT/NG

TAT 4 HOURS*

FSWS

1x SST/Serum + Urine

7 STDs – Sexual Health Profile by PCR

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

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

Choice of Sample types

Urine	✓
PCR Swab	✓
Cytyc Thin Prep Vial	✓
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	Cytyc Vial	Semen
Chlamydia trachomatis	**CPCR**	✓	✓	✓	✓
N.gonorrohea	**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

7 STD 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 5 DAYS

PP12

FCRU OR PCR Swab OR TPV OR Semen

TDLTinies for Self Collection Blood Samples

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 pack

- HIV/p24 Antigen
- Hep B sAg
- Hep C Abs
- Hep C Antigen for early detection
- Syphilis IgG/IgM

Because of sample volume limitations, reactive samples need to be followed up with a venous sample for confirmatory sample.

For information and packs, please contact Annette Wilkinson on **020 7307 7343** or email **tinies@tdlpathology.com**

Self-Collection HPV Test

NEW 2014

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; this cannot be done with a pap smear. There is well documented high level of concordance between the HPV DNA results from self-collected and clinician-collected specimens. This concordance indicates that the self-obtained samples are representative of the HPV types which infect the cervix. The likely explanation is either the presence of viral particles, or viral DNA fragments, in the vagina due to exfoliation of infected cells from the cervix or that the vaginal epithelium itself is infected with HPV, or both.

The **Self-Collection HPV Test** is validated, using a Rovers® Evalyn Brush Sampler, CE marked for vaginal cell collection. This sample is then sent to the laboratory for processing of HPV DNA subtypes. A negative result means that 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 provides 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 the high risk DNA subtypes individually
- Personal Preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears
- Self-collection for HPV increases acceptability and coverage rate of cervical cancer prevention

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 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**

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 table on page 46) Early detection at 10 days	HCAG	B	4 hours

EARLY DETECTION PROFILES BY PCR	INCUBATION PERIOD	SAMPLE SITE	TEST	TEST CODE	SAMPLE TYPE	TAT
7 STDs by PCR	One sample for 7 STD 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**	5 days 5 days 5 days
HIV/HBV/HCV	Early Detection Screen by PCR Multiplex HIV/HCV at 10 day	Blood	**HIV 1&2 RNA** **Hepatitis B (HBV DNA)** **Hepatitis C (HCV RNA)**	STDX	A 10mls or 2x4mls	3 days

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.

HPVY	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 high risk 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

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

STDs can be caused by virus, fungus, parasite or bacteria. Anyone who is sexually active may be at risk of acquiring an STD. 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	**Chlamydia**	CPCR	**First Catch Urine**	2 days
			Cervix/Vagina	**Chlamydia**	SPCR	**PCR Swab**	2 days
			Cervix/Vagina	**Chlamydia**	TPCR	**Thin Prep Vial**	5 days
Gonorrhoea GC	Bacterial	2–7 days, up to 1 month	Urine	**Gonorrhoea by PCR**	CGON	**First Catch Urine**	2 days
			Cervix/Vagina	**Gonorrhoea by PCR**	SGON	**PCR Swab**	2 days
			Cervix/Vagina	**Gonorrhoea by PCR**	TGON	**Thin Prep Vial**	5 days
			Cervix/Vagina	**Gonorrhoea by CULTURE**	GONN	**Culture swab**	2-3 days
CT/GC Combined	Bacterial	1–3 weeks, up to 6 weeks	Urine	**CT/GC**	CCG	**First Catch Urine**	2 days
			Cervix/Vagina	**CT/GC**	SCG	**PCR Swab**	2 days
			Cervix/Vagina	**CT/GC**	TCG	**Thin Prep Vial**	5 days
			Rectum	**CT/GC**	RSCG	**PCR Swab**	2 days
			Throat	**CT/GC**	TSCG	**PCR Swab**	2 days
Mycoplasma genitalium	Bacterial	Symptoms develop at 1–3 weeks	Urine	**Mycoplasma genitalium by PCR**	MGEN	**First Catch Urine**	5 days
			GU Site	**Mycoplasma genitalium by PCR**	MGEN	**PCR Swab**	5 days
			Cervix/Vagina	**Mycoplasma genitalium by PCR**	MGEN	**Thin Prep Vial**	5 days
Ureaplasma urealyticum	Bacterial	Symptoms develop at 1–3 weeks	Urine	**Ureaplasma by PCR**	UGEN	**First Catch Urine**	5 days
			GU Site	**Ureaplasma by PCR**	UGEN	**PCR Swab**	5 days
			Cervix/Vagina	**Ureaplasma by PCR**	UGEN	**Thin Prep Vial**	5 days
Trichomonas vaginalis	Parasitic	4–28 days, many patients are asymptomatic carriers	Urine	**Trichomonas vaginalis by PCR**	TVPC	**First Catch Urine**	5 days
			GU Site	**Trichomonas vaginalis by PCR**	TVPC	**PCR Swab**	5 days
			Cervix/Vagina	**Trichomonas vaginalis by PCR**	TVPC	**Thin Prep Vial**	5 days
Gardnerella vaginalis	Bacterial	Imbalance of normal flora	Urine	**Gardnerella vaginalis by PCR**	GVPC	**First Catch Urine**	5 days
			GU Site	**Gardnerella vaginalis by PCR**	GVPC	**PCR Swab**	5 days
			Cervix/Vagina	**Gardnerella vaginalis by PCR**	GVPC	**Thin Prep Vial**	5 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	**Herpes by PCR**	HERS	**PCR Swab**	5 days
			PCR swab	**Herpes by PCR**	HERD	**First Catch Urine**	5 days
Human Papillomavirus	Viral	HPV is the most common sexually transmitted infection – usually asymptomatic	Cervical cells	**HPV DNA/mRNA**	HPVT	**Thin Prep Vial**	5 days
			Cells/papilloma from site (throat/penile/anal)	**HPV Typed DNA**	HP20	**PCR Swab**	5 days
				HPV Typed DNA	HP20	**Cells/Papilloma**	5 days
Genital warts	Viral	Weeks/months after exposure	GU Warts	**HPV Typed DNA**	HPVT	**Thin Prep Vial**	5 days
				HPV Typed DNA	HP20	**PCR Swab**	5 days
				HPV Typed DNA	HP20	**Cells/Papilloma**	5 days
Syphilis/Herpes	Bacterial/ Viral	Whenever active lesions are present	Symptomatic Lesion	**Syphilis/Herpes Lesion Profile**	STD9	**PCR Swab**	7 days

High Risk Human Papillomavirus (HR-HPV) Introducing Triage and Test of Cure

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 cancer.

HPV testing in conjunction with cervical cytology is important for determining which women need to be referred for further evaluation or treatment. Treatment is aimed at women who are at risk of developing cervical cancer, and extended screening intervals are becoming more confidently accepted after a negative HPV test.

There are over 100 subtypes of HPV, all are given a number, and most do not cause significant disease but some (notably types 16 and 18 which account for 70% of all cervical cancer cases worldwide) have been identified and confirmed as causal agents for cervical cancer. These are known as High Risk HPV (HR-HPV) types. Although most women will have at least one HPV infection at some time in their lives, the majority of HPV infections are transient and are cleared by the immune system without treatment. A small but still significant number of HPV infections do not clear spontaneously and it is in these women that there is an increased risk of developing cervical intraepithelial neoplasia (CIN) and cervical cancer. Because it is recognised that almost 100% of cervical cancers contain HPV DNA, women with no evidence of HR-HPV infection are extremely unlikely to develop cervical cancer in the short to medium term.

HPV Triage and Test of Cure have been introduced across the NHS Cervical Screening Programme and implementation in the NHS with national protocols. All women in the screening age range of 25–64 are eligible for HPV Triage and Test of Cure.

HPV Triage introduces reflex testing for HR-HPV for women whose cervical cytology shows either borderline changes normal recall borderline changes, or low grade dyskariosis. A recommendation to refer for colposcopy will be made if HR-HPV is detected. If results are negative, the recommendation will be to return to routine screening.

Test of Cure uses HR-HPV testing to assess the risk of residual or recurrent disease in women who have been treated for any grade of CIN. Women who have normal cytology and are negative for HR-HPV at the time of their follow up screening appointment are at very low risk of residual disease, and can be returned to recall every 3 years, unless advised differently by their gynaecologist. If HR-HPV is detected, further referral is needed for colposcopy and followed up in accordance with national guidelines. This strategy will not be applied to women receiving treatment for CGIN or for invasive disease.

TDL provides a HR-HPV Assay that is an NHS approved qualitative DNA assay, able to individually test for types 16 and 18 and collectively report 12 HR- HPV subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). This assay provides the minimum necessary information for patient stratification.

Any request sent to TDL for Cervical Cytology that is not accompanied by a specific request for HPV testing, but is reported with either borderline or mild changes will automatically reflex to this 16/18 and other high risk DNA test. The cost of this reflexed test is INCLUDED in the price of the cervical cytology (PAPT). There is no additional charge. For women whose cytology findings are more abnormal than borderline or mild, the recommendation for referral for colposcopy will be given, as standard.

The benefit of using HPV testing lies in its high sensitivity and high negative predictive value (NPV), meaning a negative result indicates that a patient is at very low risk of developing cervical disease. However, HPV DNA testing, on its own, cannot identify progression from transient to a transforming infection or oncogenic activity. This is when an HPV infection has transformed from merely being present and insignificant, to become an integrated infection. The expression of viral oncoproteins E6 and E7, which affect cell cycle control, initiate this cervical cancer process. The detection of E6/E7 mRNA confirms the persistent expression of viral oncoproteins in human cells.

TEST	CODE	SAMPLE REQS	TAT
HPV DNA (Reflex at no charge)	HPV	**TPV**	2 days
High Risk Types reported collectively (negative/positive) If a result for cervical cytology shows borderline or mild changes, and there has been no accompanying request for HPV testing with this request, this HPV DNA test will be undertaken at no additional charge. This result shows individual reporting of subtypes 16 and 18 and collective reporting of other high risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).			
HPV DNA	HPV	**TPV**	2 days
This result shows individual reporting of subtypes 16 and 18 and collective reporting of other high risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).			
HPV Typed DNA	HP20	**TPV/PCR**	5 days
20 HPV DNA subtypes will all be reported individually (5 low risk and 15 high risk).			
HPV Typed DNA/mRNA	HPVT	**TPV**	5 days
mRNA testing can be undertaken from Cytyc Thin Prep samples only. 20 HPV DNA subtypes will all be reported individually (5 low risk and 15 high risk) If one or more of High Risk types 16, 18, 31, 33 or 45 are positive, reflex testing for expression of E6/E7 oncoproteins will be undertaken.			
HPV mRNA only	HPVR	**TPV**	3 days
Usually requested by laboratories who have undertaken DNA testing, this option confirms expression of E6/E7 oncoproteins.			

The benefit of a negative HPV result is its negative predictive value (NPV) and this is the same for both DNA and mRNA. DNA based tests detect presence of virus only, whilst the mRNA-based test detects the persistence of viral oncogenic expression from subtypes 16, 18, 31, 33 and 45. Note: mRNA testing can be undertaken from Cytyc Thin Prep samples only.

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