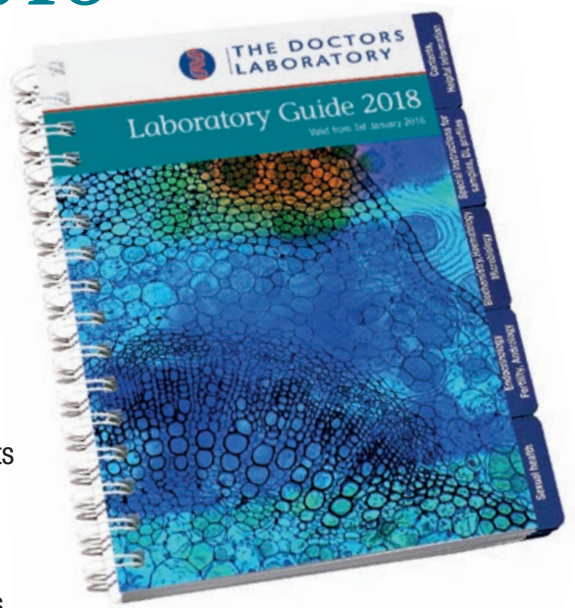
TDL Laboratory Guide 2018



Every year we review requesting patterns, frequency of use, new best practice, and include new and relevant assays into the test menu. We also try to incorporate the changes that have originated from feedback received over the past year. This helps us to keep profiles and test menus as up to date and relevant as possible. The developments in diagnostic pathology are very exciting and we hope this new guide captures some of the important trends.

Sample types and turnaround times have been updated throughout in the Laboratory Guide. **We have increased the number of tests from 1000 to 1500 by incorporating the tests that were listed in TDL Specialist Tests** and this gives a much more accessible A–Z test reference to show availability and turnaround times for the more esoteric tests. This includes an updated A–Z reference for **Genetic Tests**. For advice or information about any of the tests that are listed – and particularly if you cannot find the test you are looking for – please contact the laboratory on **020 7307 7373**, and if you need information and advice about Genetic testing please call **020 7307 7409**.

The **Tabs** will help you navigate to the various disciplines, and for sample takers, the inside back cover of the laboratory guide gives details of sample requirements, with coloured dots to match the colour of the BD vacutainer top (A B C F G H K).

REFERENCES TO NEW TESTS, CHANGES AND UPDATES ARE WITH EFFECT FROM 1ST JANUARY 2018

NEW: TDL AT THE HALO BUILDING – A new home for TDL and Sonic Healthcare UK

The Halo Building, is located on the Euston Road in central London opposite the British Library, with nearby Euston and King's Cross stations – all departments, including TDL Collect are now in one building.

The Doctors Laboratory (TDL), The Halo Building
1 Mabledon Place, London WC1H 9AX

Deliveries 24/7 to rear entrance

Patient Reception remains at 76 Wimpole Street, London W1G 9RT with **no change** to opening times:

7.00am to 7.00pm Monday to Friday

9.00am to 5.00pm Saturdays

NEW HIV Rapid RNA HIV-1 **QUALITATIVE – Results in 4 Hours** **page 77**

NEW HIV Rapid RNA HIV-1 **QUANTITATIVE – Results in 4 Hours** **page 77**

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

Sample must be received in the laboratory within 24 hours of sample taking

NEW 2018

TAT 4 HOURS

LHIV

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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)

Sample must be received in the laboratory within 24 hours of sample taking

NEW 2018

TAT 4 HOURS

RHIV

A

NEW: Fungal Cultures page 34

Adoption of PCR methods for the detection of dermatophyte fungal cultures

The detection of Dermatophyte fungal cultures has now evolved to using High Sensitivity PCR testing, replacing the Mycoline slide culture method. This reduces the overall turnaround time by up to three weeks, and increases the detection of fungal infection compared to combined microscopy and culture. Furthermore the specific targeting pathogens associated with superficial fungal infection is increased which assists in preventing the over reporting of insignificant fungi that are contaminants.

New fungal test codes

	Investigation of Superficial Fungal Infection	Investigation of Non-Superficial Fungal Infection
Test Code	DERM*	FUN*
Sample type	Nail, Hair, Skin.	All specimens other than Skin, Hair and Nail.
Turnaround time	72 hours for interim PCR report, and 7 days for final culture (unless the fungal culture needs to be extended for significant growth).	7 days (non-sterile e.g. ear swab) and 3 weeks (sterile i.e. CSF).
Notes	• Dermatophyte PCR is replacing microscopy for Nails, Hair and Skin (72 hour TAT). • Non-dermatophyte culture will take 7 days rather than 3 weeks. • Microscopy will be used to confirm significance of rare fungi that may cause infections. • There is no change in the price of this test.	• Non-sterile specimen fungal cultures are performed on Sabouraud's agar plates for 7 days with no microscopy. • Sterile specimen fungal cultures have microscopy (Calcafluor) reported on the day of processing and culture on a Sabouraud's agar slope, incubated for 21 days.

**Please add the codes DERM and FUN to your practice system's test menu if you request electronically.*

NEW: Enteric Pathogens by PCR, OCP and Culture pages 34-35

New stool test codes

The traditional culture method has been replaced by Real Time PCR for enteric pathogen testing. The benefits are increased sensitivity and a higher detection rate. Once received and processed in the microbiology lab, negative results will be available within 24 hours. Positive results will be followed up with culture and sensitivities for final reporting.

STOOL OCP AND CULTURE

Sample Type	Current test & method (SPAR)	New method – change of Test Code from SPAR to **PENT.** Please request as **PENT****	Comments
Stool	Stool for Ova, Cysts & Parasites (OCP) Microscopy and Culture	Serosep EntericBio PCR **Bacteria/Bacterial Toxins** • Salmonella • Campylobacter • Shigella • VTEC **Parasites** • Cryptosporidium • Giardia	All stool samples will be tested for UK Pathogens. Overseas pathogens will only be tested if requested and travel history and clinical details are provided. Samples that are positive for the bacterial pathogens will be cultured to provide sensitivities and, if indicated, for PHE referral. Samples will be kept for 7 days after receipt to allow for additional testing if required.

***Please add the code PENT to your practice system's test menu if you request electronically.*

STOOL FOR OCP

Sample Type	Current test & method (OCP)	New method – Test code remains unchanged: **OCP**	Comments
Stool	Stool for Ova, Cysts & Parasites (OCP)	Requests for OCP only will include testing for cryptosporidium and giardia by PCR.	Overseas pathogens will only be tested if requested and travel history and clinical details are provided.

***C. DIFFICILE* DETECTION**

Sample Type	Current test & method (CLOS)	New method – Test code remains unchanged: **CLOS**	Comments
Stool	Alere Techlab Duo Card (GDH & Toxin combo)	Serosep Enteric Bio PCR (GDH) Alere Techlab EIA (Toxin)	Change to PCR and Elisa methods. Two tier GDH & Toxin *c. diff* screening based on PHE guidance. Improved sensitivity and specificity for both targets tested. Primary *c. diff* gene screening using Enteric Bio PCR. Secondary sequential testing using Alere EIA to confirm Toxin.

GASTRO VIRUS DETECTION (INCLUDING ROTAVIRUS)			
Sample Type	**Current test & method (ROTA)**	**New method – Test code remains unchanged: ROTA**	**Comments**
Stool	Launch Meridian Rotavirus Immunocard Bioconnection Rotavirus Immunocard	Multiplex Gastro PCR • Rotavirus • Pan Adenovirus • Adenovirus Type F Improved sensitivity and specificity for combined rotavirus and adenovirus targets using PCR.	Change to PCR method for improved sensitivity and specificity. Additional PCR panel for Norovirus 1&2 is also available (request as NORO).

ENTERIC ORGANISM RAPID DETECTION			
Sample Type	**Current test & method (EORD)**	**No change – Test Code remains unchanged: EORD**	**Comments**
Stool	xTAG® Gastrointestinal Pathogen Panel Luminex 200	Multiplex PCR SImultaneous Detection of 15 nucleic acids from multiple gastroenteritis causing Viruses, Parasites and Bacteria.	This profile includes the following: **Bacteria and Bacterial Toxins:** *Salmonella, Shigella, Campylobacter, Clostridiium difficile Toxin A/B, Enterotoxigenic E. Coli (ETEC) LT/ST, E. coli 0157, Shiga-like Toxin Producing E. coli (STEC) stx 1/stx 2, Vibrio cholera, Yersinia entericolitica* **Viruses:** *Adenovirus 40/41, Rotavirus A, Norvirus G1/G11* **Parasites:** *Gardia, Entamoeba histolytica, Cryptosporidium*

UPDATE: Testing for ZIKA Virus pages 66, 81

In 2007 the epidemic potential of Zika virus became apparent, followed by several epidemics in the Pacific Ocean Region including outbreaks in 2013-2014 with thousands of confirmed cases in French Polynesia. In 2015 the first cases of Zika virus infection were confirmed in Brazil, which indicated the beginning of the largest outbreak record with vector-borne transmission now documented in more than 70 countries worldwide. Although it is still widely believed that most Zika virus infections in humans are asymptomatic or mild with self-limiting clinical manifestations, Zika virus infections can lead to microcephaly and other serious brain abnormalities, major complications, including congenital birth defects, neurologic disorders, and prolonged risk for sexual transmission of this virus.

The global risk assessment has not changed. Zika virus continues to spread geographically to areas where effective vectors are present. Healthcare professionals are now faced with a population of children with congenital Zika virus syndrome and a broad spectrum of clinical and radiological presentations with an as yet unknown clinical course. Zika virus is particularly of concern in pregnant women.

How Zika spreads

- Through mosquito bites
- From a pregnant woman, even without symptoms, to her unborn child
- Through sex, and probably blood transfusion

There is no vaccine – protection against bites is the only prevention at the moment.

Diagnosis is based on a person's recent travel history, symptoms and test results. Blood or Urine testing can confirm a Zika infection. Symptoms of Zika are similar to other illnesses through mosquito bites (like dengue and chikungunya).

Couples with a partner who lives or has travelled to an area with risk of Zika, especially those who are pregnant or planning to become pregnant should take steps to protect during sex. Zika can stay in semen for months after infection (even without symptoms) and can spread to partners during that time. Symptomatic female partners should wait at least 8 weeks after symptoms started, or 6 months after symptoms started in the male partner. A man infected with Zika can spread the virus during sex with a pregnant women and the virus can pass to the fetus. Condoms must be used every time for vaginal, anal or oral sex.

Interpretation of Zika virus test results

Detection of Zika virus RNA in any sample is diagnostic of infection with this virus. If Zika virus RNA is not detected in a patient's samples, this does not exclude previous infection with this virus.

Detection of Zika virus Antibodies IgM, with or without Zika virus IgG, in a serum sample from an individual who has had recent symptoms, will usually indicate recent Zika virus infection. Detection of Zika virus Antibodies IgG, with or without IgM, in a serum sample from an individual who has had recent symptoms, will often reflect recent Zika virus infection. This is because Zika virus IgM is frequently not detectable in individuals who have previously had dengue virus infection. Sometimes it is not possible to determine whether a positive Zika virus IgG result (without IgM) is due to recent Zika virus infection, past Zika virus infection, cross-reactivity from another flavivirus infection or non-specific reactivity. In such cases, it is usually appropriate to manage the patient as if they may have had recent Zika virus infection.

If Zika virus antibodies are not detected in a serum sample collected at least 2 weeks after the onset of an acute viral illness featuring fever, rash, arthralgia or conjunctivitis in a pregnant woman, appropriate investigations for alternative causes including parvovirus, rubella, CMV, dengue and chikungunya infections must be carried out, if not already performed. If no firm diagnosis is made, the patient should be individually discussed with a Consultant Virologist, and contact with PHE for further advice considered.

If Zika virus antibodies are not detected in a serum sample collected 4 or more weeks* after the last possible travel-associated or sexual exposure, then recent Zika virus infection is highly unlikely. Therefore, pregnant women with negative antibody results for such samples do not require further extra fetal ultrasound follow-up, unless there are additional concerns.

Public Health England: Zika virus (ZIKV): clinical and travel guidance, 17 November 2017.

*This period of 4 or more weeks is derived by adding together 14 days, representing the estimated upper limit of the incubation period for Zika virus, and a further 14 days representing a maximum time for the appearance of Zika antibodies after symptom onset (although available evidence indicates that antibodies usually appear much earlier than this).

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Zika Virus RNA by PCR	ZIKU	**Urine**	5-10 days
Zika Virus Antibodies IgM and IgG	ZKAB	B SST/Serum	5-7 days

UPDATE: Enhanced Liver Fibrosis (ELF) Test page 18

ELF stands for Enhanced Liver Fibrosis. The ELF™ Blood Test is a routine blood test used to assess the severity of liver fibrosis. Liver fibrosis is the scarring process that represents the liver's response to injury or disease. Chronic liver disease can lead to liver fibrosis, liver cancer and death. Cirrhosis and liver cancer are now among the top ten causes of death worldwide, and in many developed countries, liver disease is now one of the top 5 causes of death in middle age. There are three main causes of fibrosis:

- Fatty liver disease associated with obesity
- Type 2 Diabetes/Metabolic Syndrome
- Viral hepatitis B and C
- Alcohol Abuse

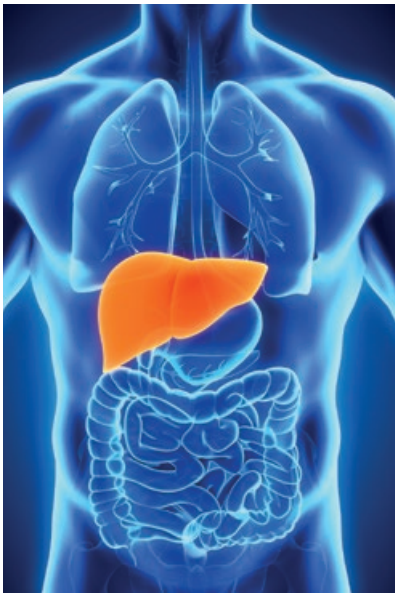
The ELF Blood Test combines three serum biomarkers, which, when correlated, are able to identify a quantifiable level of liver fibrosis. The extent of liver damage is determined by a score based on the measurement of three substances:

- Hyaluronic acid (HA)
- Procollagen III amino terminal peptide (PIIINP)
- Tissue inhibitor of metalloproteinase 1 (TIMP-1)

The algorithm of these three markers creates an ELF Score. This ELF score has been proven to correlate to the level of fibrosis assessed by liver biopsy. The spectrum of liver disease can range from simple steatosis, to cirrhosis and may be present for many years in **the absence of abnormal liver function tests** – mild to moderate liver fibrosis can exist without symptoms, which in itself supports its use for early detection and assessment.

This test offers the following benefits:

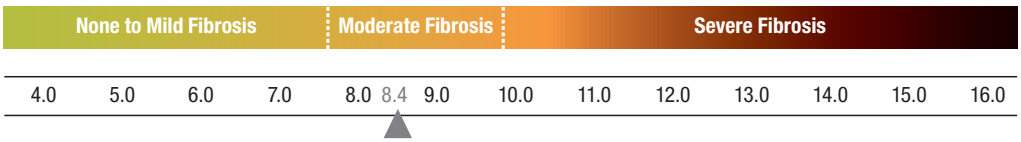
- Identification of early or significant liver disease.
- Allows for cost effective screening test and subsequent review/follow-up response to treatment
- Minimally-invasive routine serum sample vs invasive biopsy
- Mathematical algorithm to assess extent of liver damage



Interpretation of results

Interpretation of the ELF score is as follows:

< 7.7	None to mild
≥ 7.7 to <9.8	Moderate
≥ 9.8	Severe



TEST	CODE	SAMPLE REQUIREMENTS	TAT
Liver Fibrosis (Enhanced Liver Fibrosis ELF)	ELF	B SST/Serum	5-7 days

NICE Guidelines

NICE (July 2016) recommends the use of the ELF test to screen and/or monitor advanced liver fibrosis in people diagnosed with Non Alcoholic Fatty Liver Disease (NAFLD). Risk factors for NAFLD, one of the most common types of liver disease, are high and this group of patients is a primary care challenge. Primary NAFLD is a condition where there is an excess of fat in the liver, not caused by excessive alcohol or secondary causes. NAFLD has become the most chronic liver disease in children and young people in industrialised countries, mainly as a result of obesity. There is no licensed treatment for NAFLD; early diagnosis and management are therefore important at all ages.

Link to NICE Guidelines: https://www.nice.org.uk/guidance/ng49/chapter/recommendations.

UPDATE: Group B Streptococcus (GBS) Guidelines page 33

An estimated one in five pregnant women around the world carry Group B Streptococcus (GBS) bacteria which is a major, yet preventable, cause of maternal and infant ill health globally. These are the findings of a new research supplement published in the journal *Clinical Infectious Diseases*.*

Led by the London School of Hygiene & Tropical Medicine and involving more than 100 researchers from around the world, this first comprehensive study of the burden of GBS, funded by a grant from the Bill & Melinda Gates Foundation, includes data and estimates for the year 2015 from every country of the world, including outcomes for pregnant women and their babies.

Current GBS prevention focuses on giving antibiotics to women in labour, aiming to reduce disease in infants at delivery. At least 60 countries have a policy for antibiotic use in pregnancy to prevent newborn GBS disease. Of those, 35 have a policy to test all pregnant women to see if they carry GBS, and the remaining 25 countries identify women with clinical risk factors. However, implementation of these policies varies around the world. At this time there is no policy to test for GBS in the UK, but there is heightened awareness of its significance.

GBS is carried by up to a third of adults, usually with no symptoms. In women, GBS can live harmlessly in the digestive system or lower vaginal tract, from where it can be passed to the unborn baby through the amniotic fluid or to newborns during labour. Babies are more vulnerable to infection as their immature immune systems cannot fight off the multiplying bacteria. If untreated, GBS can cause serious infections, such as meningitis and septicaemia, which may lead to stillbirths, and newborn and infant deaths. If they survive, babies can develop permanent problems including hearing or vision loss, or cerebral palsy.

GBS is the most common cause of severe infection in newborn babies and of meningitis in babies under 3 months old. Most early onset GBS infections (in babies aged 0 - 6 days) can be prevented by giving intravenous (not oral) antibiotics during labour to women whose babies are at raised risk of GBS infection.

**Clinical Infectious Diseases*, Volume 65, Issue Suppl_2, 6 November 2017, Pages S89–S99

1 What should you do during a woman's pregnancy?

- Provide all pregnant women with a patient information leaflet about group B Strep. A suitable leaflet has been produced jointly by the RCOG and Group B Strep Support and from 2018 will be available from www.gbss.org.uk/RCOG.
- If a woman has had a GBS urinary tract infection (>105 cfu/ml) during her pregnancy, treat her at diagnosis with oral antibiotics, and make sure also to offer her IV antibiotics in labour.
- Treating GBS found on a vaginal or rectal swab is not recommended in pregnancy before labour starts. The woman should be offered IV antibiotics when labour starts.

2 Who should be offered antibiotics in labour?

Women should be offered antibiotics effective against GBS in labour who:

- carried GBS in a previous pregnancy (or alternatively testing – see below).
- had a previous baby who had GBS infection.
- had GBS in her urine during the pregnancy.
- had GBS found on a vaginal or rectal swab (via an NHS or other test).
- are in preterm labour (before 37 completed weeks).
- have a temperature of 38°C or greater (in which case, offer broad-spectrum antibiotics that also cover GBS).

3 When is an offer of antenatal testing appropriate?

If a woman carried GBS in a previous pregnancy and the baby did not develop GBS disease, an Enriched Culture Medium (ECM) swab test for GBS carriage at 35-37 weeks (or earlier if preterm delivery is anticipated) should be offered.

The ECM test is not the same as a standard swab for a vaginal discharge. Swabs should be taken both from the low vagina and rectum, with samples cultured using enriched culture media and processed ASAP. You should specifically state 'test for GBS' on the request form.

If positive, the woman should be offered antibiotics in labour. If negative, she can be reassured that the risk of early onset neonatal GBS disease is very low (about 1 in 5,000). If she declines the test, she should be offered antibiotics in labour.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Group B Strep (Lower vaginal and lower rectal culture swabs, collected from 35 weeks)	GBS	**GBS Collection Pack –** Includes 2 x culture swab and instructions for self-collection	3-4 days

NEW: General Data Protection Regulations (GDPR) page 10

GDPR is a new legal regime, governing how organisations handle data. It comes into force on the 25th May 2018. Fines for non-compliance for these new data protection laws can be high and this will impact on every practice, every healthcare company, every organisation.

GDPR will have a dramatic impact on every organisation. It directly affects the way all business will collect, store and process the personal details of existing patients, new patients and employees. It doesn't matter how in depth the data is, simply having a name on file or in the diary has to be stored according to regulations.

2018: TDL's Terms and Conditions as printed in the Laboratory Guide will be updated for the new GDPR requirements and sent to your practice before 31st March 2018. An introduction to changes with various processes that TDL will be adopting (including the issuing of Results, Invoices and Patient Information) will also be sent.

UPDATE: Sexual Health Profiles pages 58-59

Mycoplasma genitalium is a significant sexually transmitted pathogen that is becoming more recognised, better understood, but more complicated because of its increasing resistance to standardised treatments.

MGEN lives on and in the epithelial cells of the urinary and genital tracts of men and women. In both low and high risk populations prevalence is higher than gonorrhoea and is nearer to that of chlamydia. This in itself provides ample justification for inclusion in testing for routine STI screening. MGEN is strongly associated with non CT/GC urethritis in men and for cervicitis, pelvic inflammatory disease, preterm birth, spontaneous abortion and infertility in women, but a high proportion of cases will be asymptomatic.

Managing MGEN infection has been made more complicated by poor treatment efficacy in eradicating MGEN with doxycycline 100 mg twice a day for 7 days, or azithromycin 1g single dose, which are the current first-line treatments for non-gonococcal urethritis and cervicitis in the UK. Macrolide resistance in MGEN began in early 2000 with the increasing use of azithromycin 1g to treat STI's. Macrolide-resistant MGEN is especially recognised where azithromycin 1g is used as a first-line treatment for non-gonococcal urethritis, cervicitis, and chlamydia when testing for MGEN was either not tested or overlooked. There is a strong recommendation[1] that all patients with MGEN infection should be followed up regardless of the azithromycin regimen used. **Because macrolide resistance can emerge even with the use of extended azithromycin, all azithromycin-treated patients with MGEN should have a test of cure undertaken no sooner than three weeks after starting treatment, even if they're asymptomatic**.

Testing Options for *Mycoplasma Gentalium*

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

1 *Sex Transm Infect* 2017

MYCOPLASMA BY PCR
(Urine, Swab, Thin Prep, Semen)

Mycoplasma genitalium

TAT 2 DAYS

MGEN

FCRU OR PCR Swab OR TPV OR Semen

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

Mycoplasma genitalium
Ureaplasma urealyticum/parvum

TAT 2 DAYS

MUPC

FCRU OR PCR Swab OR TPV OR Semen

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

Chlamydia trachomatis
N. gonorrhoea
Mycoplasma genitalium
Ureaplasma
Trichomonas vaginalis
Gardnerella vaginalis
Herpes Simplex I/II

TAT 2 DAYS

MGEN

FCRU OR PCR Swab OR TPV OR Semen

NEW: MSM Profiles page 60

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

NEW 2018

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

NEW 2018

TAT 4 DAYS

MSM2

B FCRU PCR Swab Throat PCR Swab Rectal

UPDATE: 5th GENERATION HIV
Individual reporting of HIV-1, HIV-2, p24 antigen

pages 76-77

TDL introduced a next generation HIV assay with the Bio-Rad BioPlex 2200 HIV Ag-Ab assay at the beginning of 2016. 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 serum or plasma samples. 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
- 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 hrs
	THV5	B TDL Tiny™	24 hrs

NEW: Polycystic Ovary Syndrome Profile SHORT

page 42

Polycystic ovary syndrome, or PCOS, is a complex hormonal condition, affecting up to around 1 in every 10 women. The causes of PCOS are not completely understood. It is likely that a genetic tendency – heredity – is involved. The diagnosis of PCOS can usually be made if a woman has any two of the following three features (provided other conditions are ruled out):

- Infrequent or absent ovulation.
- Clinical and/or biochemical signs of androgen excess.
- Polycystic ovaries detected on an ultrasound scan.

Women with PCOS can have a wide spectrum of signs and symptoms, from very mild to severe. They may include:

- Infrequent or absent menstrual periods
- Signs of androgen excess, including oily skin and acne, excessive hair growth (on the face, chest, abdomen or thighs), thinning of hair on the crown of the head
- Heavy vaginal bleeding – although infrequent or absent periods are more common, occasionally women may experience heavy bleeding
- Obesity
- Subfertility or infertility – as a result of infrequent or absent ovulation
- Acanthosis nigricans – darkening and thickening of certain areas of the skin, especially in skin folds
- Increased risk of type 2 diabetes
- Increased risk of high cholesterol
- Increased risk of metabolic syndrome – both PCOS and metabolic syndrome are associated with insulin resistance
- Increased risk of obstructive sleep apnoea
- Increased risk of diabetes in pregnancy, or gestational diabetes

POLYCYSTIC OVARY SYNDROME: SHORT

Testosterone
SHBG
FAI
FSH
LH
Glucose
Insulin
Lipid Profile
FT4/TSH

NEW 2018

TAT 4 HOURS

PCOS

B G

TEST	CODE	SAMPLE REQUIREMENTS	TAT
NEW Polycystic Ovary Profile SHORT version	PCOS	B G	4 hrs

TDL Andrology

page 47

Infertility as a couple problem is fairly common – it affects about one in seven couples which is about 15% of the population. Who is responsible? About 30% female, about 30% male and for the rest, it is both male and female.

A Comprehensive Semen Analysis looks at the count (how many) and morphology (sperm shape) and motility (their swim capability).

A meta-analysis of 185 studies* involving nearly 43,000 men from 6 continents and 50 countries showed that sperm counts more than halved between 1973 and 2011 in men from North America, Europe, Australia and New Zealand. The mean sperm count showed an overall reduction of 52.4% over the 38 years of the study – with an increase in the number of men moving to subfertile or infertile classifications.

**Human Reproduction Update*, Volume 23, Issue 6, 1 November 2017, Pages 646–659

Guidelines for producing Semen Samples

It is important to **make an appointment** for all semen samples **020 7025 7940**

Ideally samples should be produced on site at TDL Andrology, 76 Wimpole Street, W1G 9RT. Ideally patients should abstain from ejaculation for 2-3 days prior to testing – no less than 2 days and no longer than 5 days. Ideally two separate semen analyses should be performed before any diagnosis is made.

TDL Andrology Page 48 shows details of services for:

- **Sperm DNA Fragmentation**
- **Sperm Aneuploidy**
- **Oxidative Stress in Semen**

UPDATE: Breath Testing resumed for testing for *Helicobacter Pylori* Infection page 62

Patients with new peptic ulcer disease should have a breath test (C 13 Urease), or they may need an investigation for stool antigens.

Stool 98% specific 94% sensitive
Results that are positive in the initial stages of infection can be used to detect eradication after treatment

Breath test Concentration of carbon is high in breath only when urease is present in the stomach – a reaction only with *H. pylori* infection.

Serology >90% specific and > 90% sensitive
Useful for detecting a newly infected person but not helpful as a follow up of treatment patients because the results do not indicate present infection. Antibody titres may remain elevated for a long time after *H. pylori* eradication. False positive results are age related and increases with age.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
H. pylori stool collection	HBAG	**1 x stool sample** (bean sized sample)	3 days
H. pylori Breath Test	HBQT	**1 x breath collection kit (pre and post breath samples)** Sample collection Instructions are provided in each kit	5 days
H. pylori Antibodies	HBPA	B SST/Serum	2 days

SMALL BUT NOTEWORTHY

- Helicobacter Breath Tests – breath test kits are now available again.
- Reporting of Protein electrophoresis now includes Immunoglobulins.
- Standard GTT's cover three time points only (fasting baseline 0, baseline + 60 mins, baseline + 120 mins).
- Malarial Abs IgG Elisa includes species of *P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale* and *P. knowlesi*.

DISCONTINUED SERVICES

- Reticulin Antibodies are no longer included in Coeliac Profiles.
- Andrology Services/Semen Analysis no longer available in Manchester.

Service email addresses, who to contact to make arrangements

addons@tdlpathology.com	Request **ADDITIONAL TESTS** from a sample in the laboratory	see page 8
andrology@tdlpathology.com	Arrange an **APPOINTMENT FOR SEMEN ANALYSIS (Tel: 020 7025 7940)**	see page 7
couriers@tdlpathology.com	Contact couriers as an alternative to **ONLINE BOOKING**	see page 8
eview@tdlpathology.com	Arrange secure Login / Password to **VIEW RESULTS ONLINE**	see page 10
finance@tdlpathology.com	Contact credit control for **INVOICE RELATED QUERIES**	see page 10
homevisits@tdlpathology.com	**ARRANGE FOR A HOME VISIT** for your London based patients	see page 8
logo@tdlpathology.com	Include your **LOGO** (GIF format) for all emailed results	see page 10
patientreception@tdlpathology.com	Email ahead to make **SPECIAL ARRANGEMENTS** for your patients	see page 6
phlebotomy@tdlpathology.com	Email to make **SPECIAL ARRANGEMENTS** for your patients	see page 6
queries@tdlpathology.com	**SPECIAL INSTRUCTIONS** for the laboratory for samples that have been sent or received by TDL	
supplies@tdlpathology.com	**ORDER PATHOLOLOGY SUPPLIES/POSTAL PACKS** for TDL samples (Supplies Reorder Form – see inside back cover)	see page 10
tdl@tdlpathology.com	**GENERAL ENQUIRIES**	

TDL's Laboratory Guide 2018 is designed to give you an easy to use reference, for the most regularly requested tests and profiles. If you need help or advice in finding information about tests or services, please contact the laboratory on 020 7307 7373 or email tdl@tdlpathology.com. We continue to develop clinically relevant diagnostic services and our aim is to offer commitment to customer service, strong working relationships and help and support to doctors and their practises.

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