TDL Laboratory Guide 2017

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** with entries for more than 1000 of the most frequently requested tests. We have also updated the separate guide, **TDL Specialist Tests**. This provides an easy to use **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 tests – 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** help you navigate to the various disciplines, and for all sample takers, the laboratory guide gives details of sample requirements, with coloured dots to match the colour of the vacutainer top A B C F G H K and coding for other sample types.

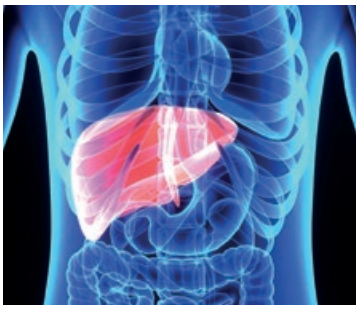
REFERENCES TO NEW TESTS, CHANGES AND UPDATES ARE WITH EFFECT FROM 1ST JANUARY 2017

UPDATE: Enhanced Liver Fibrosis (ELF) Test — pages 18, 20

Liver Disease has skyrocketed since 1970 and constitutes the third commonest cause of premature death in the UK, and is substantially higher than in other countries in Western Europe. Standard liver function tests, although helpful, do not typically include reliable markers of liver damage.

ELF stands for Enhanced Liver Fibrosis. The ELF Blood Test combines three serum biomarkers, which, when correlated, are able to identify a quantifiable level of liver fibrosis. These biomarkers include:

- Hyaluronic acid (HA)
- Procollagen III amino terminal peptide (PIIINP)
- Tissue inhibitor of metalloproteinase 1 (TIMP-1)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The algorithm of these three markers creates an ELF Score, from which a designation for fibrosis severity is determined. 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 – this in itself confirms the need for early detection and assessment.

This test offers the following benefits:

- Identification of early or significant liver disease.
- Cost effective screening and subsequent review/ follow-up response to treatment
- Blood sample vs invasive biopsy
- Easily interpretable algorithm assessing extent of liver damage/response to treatment

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NICE Guidelines: Non-Alcoholic Fatty Liver Disease: assessment and management

NICE (July 2016) recommended 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, which is 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. NAFLD is also an important determinant of clinically relevant fibrosis in a population that has a very low prevalence of viral hepatitis. There is no licensed treatment for NAFLD; early diagnosis and management are therefore important at all ages.

Whilst recognising that liver biopsy remains the gold standard for diagnosis, use of the ELF test has been established for identification of fibrosis caused by:

- Viral Hepatitis
- Type 2 Diabetes
- Metabolic Syndrome
- Alcohol
- Non-alcoholic fatty liver disease
- Smoking

Liver Fibrosis and Diabetes (Page 18 and 24)

The combination of diabetes and non-alcoholic fatty liver disease increase the risk for liver fibrosis more than fivefold. Estimates of 60-90% of Type 2 Diabetics have fatty liver disease. Most doctors think that fatty liver is benign, but it isn't. About 2-4% will develop cirrhosis and people with fatty liver are at greater risk of developing cancer. Most patients have no idea they have fatty liver disease until they develop

cirrhosis. Because the liver is able to regenerate and new therapies are in the pipeline for the treatment of NAFLD and NAFLD related fibrosis, identification of these patients is key to stopping progression of disease and reversing cirrhosis and fibrosis.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Diabetic Profile 1 (page 24) *Glucose, HbA1c*	DIAB	A G	8 hours
Diabetic Profile 2 (page 24) *Glucose, HbA1c, Microalbumin*	DIA2	A G **RU**	2 days

If ELF is being added to either of these profiles, please take 1 GOLD tube.

Liver Fibrosis and Metabolic Syndrome

Patients with greater waist circumference, high lipids, hypertension are more likely to have NAFLD than those without. If doctors have patients in whom they can identify three or four features of metabolic syndrome **and** they are diabetic, they will almost certainly have NAFLD and probably some sort of fibrosis especially if they are 50 years of age or older.

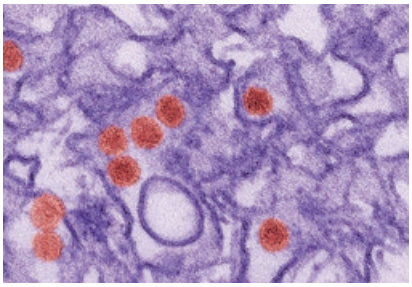
TEST	CODE	SAMPLE REQUIREMENTS	TAT
Metabolic Syndrome (page 35) *Lipids, Glucose, HbA1c, Insulin, hs-CRP, Adiponectin (provide patient's weight and height)*	METS	A B B G	9 days

If ELF is being added to this profile, please take 1 more GOLD tube.

NEW TEST: Testing for ZIKA Virus page 72

No-one could have predicted the enormity of detail and the unfolding of information and findings when in February 2016 the World Health Organisation (WHO) declared that the association of Zika infection with clusters of microcephaly and other neurological disorders constituted a Public Health Emergency of International Concern (PHEIC). At that time it had emerged in 25 countries and territories in South and Central America. By 30th September 2016, WHO declared that 71 countries and territories have reported evidence of mosquito-borne Zika virus transmission.

By the end of November 2016 WHO felt that "the Zika virus and associated consequences remain a significant enduring public health challenge requiring intense action but that (the virus) no longer represents a PHEIC". They say "we are not downgrading the importance of Zika, by placing this as a longer programme of work, we are sending the message that zika is here to stay."



Zika virus under electron microscope. CDC/ Cynthia Goldsmith

Previously considered harmless, Zika virus disease has now been profiled as a viral illness, and a global public threat, mainly because of the severe neurological complications and adverse clinical outcomes associated with the virus. Microcephaly is one of a constellation of Zika associated problems, with other defects including seizures, deafness, blindness and a range of neurological and developmental abnormalities as well as Zika related effects occurring months after a seemingly normal birth.

Previously believed to be spread only by mosquitoes, Zika virus is now known to be transmissible through sexual and non-sexual contact; sweat, tears, amniotic fluid, semen. These are still early days, and there isn't enough understanding yet how to interpret results of tests of semen or vaginal fluids. More studies are needed to determine how long semen and other bodily fluids contain infectious Zika virus. This has understandably raised questions about the need to include screening for Zika virus in the testing of semen generally, and specifically in sperm donations at fertility centres. We don't yet know how the presence of Zika virus (or level of RNA) in semen correlates to infectivity, or for how long a person might be infectious after infection with Zika virus.

When to test for reliable diagnosis of Zika Virus Infections

The most suitable method for the detection of Zika virus infection depends on the disease stage. RNA is relatively short lived typically persisting in urine for up to 14 days although seroconversion can be delayed because of individualised patient differences. In the early phase, viral RNA can be determined in blood up to one week after the onset of symptoms and in urine for up to two weeks. If the infection is older than 7 days, serum Zika IgM antibody testing should be performed. Antibodies IgM develop during the first week of illness and can be detected up to 12 weeks.

All available information should be given when ordering a test for Zika virus infection including patient travel history, travel vaccination history, pregnancy intention/status and presence of symptoms.

Zika Virus testing is recommended for:

- Pregnant women with any possible exposure to Zika virus, with our without symptoms. Possible exposure to the virus is defined as
  - Living in the area of active Zika virus transmission
  - Travelling to areas with active Zika virus transmission
  - Having sex without the use of condoms with a partner who lives in, or who has travelled to areas with active Zika virus transmission.
- Anyone who has recently experienced symptoms of Zika virus infection (fever, rash, joint pain, conjunctivitis) and lives in or has recently travelled to an area with active Zika Virus transmission.
- Anyone who has recently experienced symptoms of Zika virus infection (fever, rash, joint pain, conjunctivitis) and had sex without a condom with a partner who lived in or who recently travelled to an area with active Zika Virus transmission.

Days after onset of symptoms	Virus detection RT-PCR Serum Laboratory code: ZIKA	Virus detection RT-PCR Urine Laboratory code: ZIKU	Serology IgG/IgM ELISA and IIF Laboratory code: ZKAB
1 to 7 days	+	+	–/+
8 to 14 days	–	+	+
from 15 days	–	–	+

Please provide a serum sample with urine PCR as POSITIVE results will be confirmed and additionally reflexed to IgG and IgM antibodies.
If the IgG and IgM are reported as negative – and there is concern that seroconversion may not have occurred within 7-10 days, repeat serology is recommended after 2 weeks.

TEST UPDATE: Lipids – inclusion of Non-HDL Cholesterol

In response to release of NICE guidelines for Lipid assessment, TDL's Lipid profile now includes the reporting of Non-HDL Cholesterol.

Non-HDL assay has the following advantages over the LDL.

LDL calculation should require the sample to be fasting, **the calculation of non-HDL does not require a fasting sample**.

The LDL calculation is not valid for Triglyceride levels of 4.5 mmol/L or greater, the non-HDL remains valid.

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In summary the NICE guidelines recommendations are:

Before starting lipid modification therapy for the primary prevention of cardiovascular disease, a lipid sample is taken to measure a full lipid profile. This should include measurement of total cholesterol, high-density lipoprotein (HDL) cholesterol, non-HDL cholesterol, and triglyceride concentrations. A fasting sample is not needed.

Measure total cholesterol, HDL cholesterol and non-HDL cholesterol in all people who have been started on high-intensity statin treatment at 3 months of treatment and aim for a greater than 40% reduction in non-HDL cholesterol. Arrange for specialist assessment of people with a non-HDL cholesterol > 7.5 mmol/L.

TEST UPDATE: Antimullerian Hormone (AMH) page 34

AMH is considered an accurate marker of ovarian reserve. It varies less across menstrual cycles compared to other biomarkers of ovarian activity, such as FSH, and this has a number of obvious clinical advantages. AMH is associated with good accuracy when predicting ovarian response.

The reference intervals for the Roche Elecsys AMH assay have been updated as more patients have been recruited into the older age categories.

Healthy women (years)	5th Percentile (pmol/L)	Median (pmol/L)	95th percentile (pmol/L)
20 – 24	10.9	28.6	71.0
25 – 29	8.6	23.6	64.6
30 – 34	5.1	20.0	54.2
35 – 39	2.89	14.2	49.7
40 – 44	0.42	6.3	31.7
45 – 50	0.07	1.39	12.8

Effect of oral contraceptive – when to assess AMH levels

The impact of oral contraceptive is to suppress the circulating concentration of AMH. Studies indicate that AMH levels are on average about 30% lower in women using oral contraception compared to non-users, with the reduction more pronounced in long-term users.[1] After cessation of oral contraception, serum AMH levels appear to increase by a mean of 30% within two to three months.[1]

References

1 La Marca, A. How much does AMH really vary in normal women? *International Journal of Endocrinology*, Volume 20123 (12): 959487.

NEW TEST: Screening for Pre-eclampsia pages 37-39

Pre-eclampsia is a serious pregnancy complication. Screening can now be tested at any stage throughout pregnancy. If risks are identified as being high, treatment can be started early enough to prevent, or at least delay pre-eclampsia.

Pre-eclampsia is characterised by a combination of gestational hypertension and proteinuria that occur only in pregnancy, and forms the basis for diagnosis of the condition. Women with mild pre-eclampsia may not show any symptoms, and are therefore only identified during routine antenatal appointments (through standard blood pressure checks and urine samples). It affects 2%-8% of pregnancies. The exact cause of pre-eclampsia remains unknown but research indicates that genetics and the placenta could be factors in the development of the condition.

Women are more likely to suffer from pre-eclampsia if:

- their mothers and sisters have a history of pre-eclampsia
- they had pre-eclampsia in a previous pregnancy
- they are older than 40 years of age
- they are pregnant with twins or triplets
- they have high blood pressure, renal disease or diabetes.
- they have a BMI of 35 or more
- the pregnancy was medically assisted (eg IVF)

Placental Growth Factor (PIGF) has been shown to be the most discriminating biochemical marker for pre-eclampsia. In all three trimesters best results are obtained using the PIGF test with results from other markers such as maternal history and mean arterial blood pressure. The **Perkin Elmer PIGF 1-2-3 assay** is designed for use as an aid in screening for pre-eclampsia and suitable for use at every stage of pregnancy.

In the **1st trimester** PIGF 1-2-3 helps identify high risk pregnancies so that preventative actions may be initiated during this trimester and can be undertaken at the same time as investigations for Trisomy 21 and other first trimester screens.

In the **2nd and 3rd trimesters** the same test allows reassessment of risk to help to identify pregnancies where timely interventions can improve outcomes.

Screening for Pre-eclampsia will help to identify

Low Risk Unlikely to develop pre-eclampsia later in pregnancy, and allows for normal prenatal care.

High Risk More likely to develop pre-eclampsia, and therefore alerts for possible signs and symptoms of pre-eclampsia and to start the necessary form of treatment early.

The object of early screening is to identify the high risk group that may benefit from therapeutic intervention that reduce the prevalence of pre-eclampsia. The prophylactic use of low dose aspirin is particularly effective in the prevention of preterm, rather than term, pre-eclampsia.

For further information about sample taking and screening for pre-eclampsia please contact TDL Genetics: pre-eclampsia@tdlpathology.com or telephone 020 7307 7409.

NEW TEST: Drug Allergy Testing pages 114-117

Testing for clinical allergy to anaesthetic, therapeutic and prescription drugs requires a specialist testing facility, and this new service is being undertaken for TDL by RefLab ApS, Copenhagen, Denmark (ISO 17025 accredited).

The drug induced basophil activation test (BaHRT) is based on allergen induced induced histamine release from patients own cells. Each drug is tested in titration and in 12 concentrations, with results expressed as a threshold value (mg/mL or µg/mL or ng/mL) of the drug, indicating the level of sensitivity. A healthy control is always included as reference for unspecific release. With positive detection at 70%[1], a POSITIVE test result will confirm sensitization. **A negative result does not exclude possible drug allergy. A drug allergy challenge test in a specialised allergy centre is indicated for EACH negative drug allergy results to achieve a definitive diagnosis.**

The range of drug availability is listed in the Laboratory Guide on pages 115-117. If a specific drug is not seen in this listing, please contact TDL to check availability – in most cases it will be possible to carry out testing, as drug availability is increasing and specialty drugs can be tested upon request. The drug itself can be sent with the sample to RefLab in Denmark.

1 Fernando Pineda, Adriana Arisa, Cristobalina Mayorga, Francisca Arribas, Rosaria González-Mendiola, Natalia Blanca-López, Galicia Davila, Nieves Cabañes, Gabriale Canto, José Julio Laguna, Carlos Senent, Per Stahl-Skov, Ricardo Palacios, Miguel Blanca, María José Torres.Role of Histamine Release Test for the Evaluation of Patients with Immediate Hypersensitivity Reactions to Clavulanic Acid. Int Arch Allergy Immunol 2015; 168:233-240.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
NEW **Single drug allergy** – please specify drug	RSD	(H)(H)	3 days

Samples must be taken on Mondays, Tuesdays and Wednesday and received by noon in the laboratory.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
NEW **Allergy to Perioperative Anaphylaxis Panel** *Atracurim, Metoclopramide, Mivacurim, Morphine, Ondansetron, Pancuronium, Propofol, Remifentanil, Rocuronium, Suxamethonium, Vecuronium*	RDP1	(H)(H)	3 days

Samples must be taken on Mondays, Tuesdays and Wednesday and received by noon in the laboratory.

Allergy to Penicillin

Research shows that although 10% of inpatients claim to have a penicillin allergy, only about 10% of those show an intolerance on testing, and even fewer are actually allergic. The down side of claims like this is that without testing, patients are unnecessarily given broad-spectrum second-line antibiotics. A better understanding of penicillin-allergic patients would help improve the prescribing of antibiotics in hospitals. Several studies have shown that patients who have a penicillin allergy documented in their health record have longer hospital stays and less success with antibiotics, which puts them at risk for adverse effects. More effective drugs would decrease hospital stays. Testing and ensuring that results on patient records are accurate would dramatically decrease the use of second-line antibiotics. It is a significant health risk to carry an unconfirmed penicillin allergy.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
NEW **Allergy to Penicillin Antibiotic Panel** *Amoxicillin, Amoxicillin/Clavulanic acid, Benzylpenicillin, Cefuroxime, Clavulanic acid, Phenoxymethylpenicillinkalium*	RDP2	(H)(H)	3 days

Samples must be taken on Mondays, Tuesdays and Wednesday and received by noon in the laboratory.

NEW TEST: Gluten Allergy Profile page 58

A **Gluten Allergy IgE** test can now be requested either as a single allergen or when a patient is being tested for Coeliac Disease and has had negative results on Coeliac specific antibody tests. An allergy test can also be ordered prior to Coeliac testing to rule out Gluten Allergy as a likely cause for a person's symptoms.

This test is used to determine if a person has an allergic reaction to **gluten**, a protein found in wheat, barley, and rye. An IgE test looks for antibodies which develop in a person who has a particular allergy. Gluten Allergy can display symptoms similar to other conditions such as **Coeliac Disease**. Unlike an allergy, Coeliac Disease can do permanent harm to the body if left untreated. Allergy testing when a person is experiencing symptoms can help identify or rule out an allergy as the cause.

Gluten Allergy is typically less severe than other Gluten related conditions like Coeliac Disease. People with Gluten Allergy will often experience abdominal discomfort, bloating, gas, constipation, or diarrhoea when they eat products containing gluten. These symptoms usually stop when a person cuts gluten out of their diet.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
NEW **Gluten Allergy Profile** *Gluten single IgE Allergen, Endomysial Abs IgA, Reticulin Abs IgA, Gliadin Abs IgA and IgG, Tissue Transglutaminase IgA, HLA DQ2/DQ8, Total IgA*	GLUT	(A)(B)(B)	10 days

CHANGE: Sexual Health Profiles pages 52-53

Sexual Health – made easier: Change of content for profiles STD1, STD2, SDT3, 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					FEMALE TESTING				
STD1 BASIC	=	Block 1	+	Block 3	**STD3 BASIC**	=	Block 1	+	Block 5
STD2 MORE	=	Block 2	+	Block 4	**STD4 MORE**	=	Block 2	+	Block 6

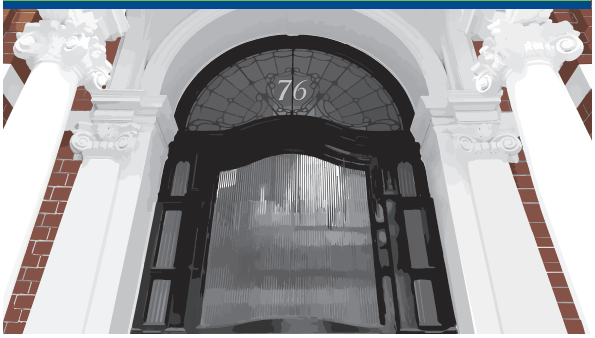
Add additional swabs (culture or NAAT/PCCR) as needed.

2 New groups – Important STIs

TEST	CODE	SAMPLE REQUIREMENTS	TAT
NEW **Mycoplasma/Ureaplasma by NAAT/PCR** *Mycoplasma genitalium, Ureaplasma*	MUPC	**FCRU** or **PCR Swab** or **TPV**	2 days
NEW **CT/GC/Trichomonas vaginalis by NAAT/PCR** *Chlamydia, Gonorrhoea, Trichomonas*	CCGT	**FCRU** or **PCR Swab** or **TPV**	2 days

NEW SERVICE: Semen Analysis – Appointments online page 42

Semen analysis



It is **very important** to make an appointment for all semen analyses. To book an **online appointment** please go to

www.tdlpathology.com/andrologybooking

To book a telephonic appointment and/or confirm instructions for sample collection please call

020 7025 7940

Appointment times available for semen sample collections:

Monday to Friday: 7.00am to 7.00pm

Saturday: 9.00am to 5.00pm

TEST UPDATE: 5th GENERATION HIV – Individual reporting of HIV-1, HIV-2, p24 antigen pages 68-69

The focus given to testing for HIV continues. HIV is one of the fastest growing serious health conditions in the UK. Approximately 6000 people were newly diagnosed with HIV in the UK during 2015. 55% were among men who have sex with men (MSM). The challenge for the UK lies in finding it early. Two out of five people newly diagnosed had late stage HIV. Being diagnosed late is associated with a tenfold risk of death within one year of diagnosis*.

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
- 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

**Public Health England (PHE)*

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

TEST UPDATE: Lyme Disease/*Borrelia burgdorferi* page 55

When it comes to laboratory testing for Lyme disease, it is important to understand when diagnostic testing is most effective, or even whether to test at all. If a patient has a classic rash presentation alongside appropriate exposure history, testing may not be needed, or recommended, as the lesion is in itself diagnostic. Serological testing at this stage has a low sensitivity and could provide a confusing false-negative result. Testing is ideally positioned for patients who have symptoms associated with Lyme disease and an exposure history. Serology is the recommended testing method for the diagnosis of Lyme disease.

Borrelia Antibodies IgM [BORM] Detectable after 2-3 weeks increasing up to 6 weeks.

Borrelia Antibodies IgG/IgM [BORR] Detectable after several weeks increasing to maximum at 4-6 months and may remain at high levels for many years.

Borrelia Confirmation (Immunoblot) [BORC] The ELISA test is sensitive but has a well-documented and well understood high false positive rate giving positive results in conditions such as glandular fever, rheumatoid arthritis and other autoimmune conditions. If the IgG/IgM or IgM result is positive, then testing by Immunoblot will confirm a diagnosis by Lyme disease. IgM and IgG antibodies are tested separately with this test. Results from the serology need to be given with a request for the Immunoblot test.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Borrelia Antibodies IgM	**BORM**	B SST/Serum	2 days
Borrelia Antibodies IgG/IgM	**BORR**	B SST/Serum	2 days
Borrelia Confirmation (Immunoblot) Provide clinical/travel history	**BORC**	B SST/Serum	10 days

TEST CHANGE: Quantiferon-TB Gold PLUS (QFT®-PLUS) page 57

4 Specialised blood tubes OR 1 x Lith Hep

This test is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluations. TB is a communicable disease caused by infection with *M. tuberculosis* complex organisisms. Most infected people remain well. The purpose of testing for Latent TB infection (LTBI) is to consider whether treatment is needed.

QFT-Plus will now use **FOUR specialised blood collection tubes** (previously 3) to collect whole blood. Alternatively, blood may be collected in a **single generic Lith Hep tube** (green top) which on receipt in the laboratory needs to be transferred to the four QFT-Plus tubes.

Samples should be incubated as soon as possible and not later than 16 hours after sample collection. On receipt in the laboratory, the samples are incubated for 16-24 hours, after which the four tubes need to be centrifuged, plasma removed and testing carried out.

TEST UPDATE: HARMONY in the UK – NIPT in 3-5 days pages 101-102

TDL Genetics offers a cost-effective NIPT service – **Harmony™ in the UK** – which has been validated for pregnant women of all ages and all risk categories. NIPT is becoming an increasingly important, as the UK National Screening Committee has recently released its recommendation for incorporating it into the national screening programme for women with higher risk results, and for evaluating its impact on current screening.

harmony™
PRENATAL TEST
performed in the UK

The Harmony™ in the UK Prenatal Test is available for:

- The detection of trisomy 21, 18, and 13.
- All singleton and twin pregnancies from 10 weeks.
- All IVF pregnancies using own or donor eggs.
- Optional X and Y chromosome aneuploidy, or analysis for monosomy X only for singleton pregnancies, if appropriate.
- There is an additional option for fetal sexing for twin pregnancies, if appropriate.
- Results include fetal fraction (cell-free DNA percentage), which in line with the recommendation from the International Society of Prenatal Diagnosis (ISPD).
- Results are available within 3-5 days from receipt of samples

Test Limitations:

- The Harmony test cannot be performed on multiple pregnancies other than twins.
- The Harmony test cannot be performed on vanishing twin pregnancies
- Despite its accuracy, NIPT is a screening test and an invasive diagnostic test would be required to receive a definitive diagnosis.

TDL Genetics provide Harmony sample-taking packs including:

- Request forms
- Patient information and consent forms
- Specific blood collection tubes
- Packaging and/or postage material

See page 92 in the Laboratory Guide for more information. For further information, and to order Harmony packs, contact **TDL Genetics** on **020 7307 7409** or **NIPT@tdlpathology.com**

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Harmony NIPT	**NIPT**	Harmony Pack made up with Cell Free DNA tubes	3-5 days

TEST UPDATE: Gastrointestinal Pathogen/Diarrhoea Panel – Enteric Organism Rapid Detection (Bacterial, Viral and Parasitic Infection) page 62

This is a qualitatative molecular multiplex diarrhoea test intended for the simultaneous detection and identification of multiple gastrointestinal pathogens including bacteria, viruses, and parasites. Each test is reported individually. Symptoms from viral, bacterial and parasitic agents are often the same, and it is often difficult to differentiate them and antibiotics may be inappropriately prescribed. This panel tests for 15 of the main gastrointestinal pathogens in a single test from a small stool sample.

A positive is reflexed for culture and sensitivities where possible. If stool culture is needed, please send a separate sample/request.

Bacteria and bacterial toxins

- *Salmonella*
- *Shigella*
- *Campylobacter*
- *Clostridium difficile* Toxin A/B
- Enterotoxigenic *E. coli*
- *E. coli* O157
- Shiga-like Toxin producing *E. coli*
- *Vibrio cholerae*
- *Yersinia enterocolitica*

Viruses

- Adenovirus 40/41
- Rotavirus A
- Norovirus GI/GII

Parasites

- Giardia
- *Entamoeba histolytica*
- *Cryptosporidum*

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Enteric Organism Rapid Detection by PCR	EORD	**Small stool sample**	3 days

Stool packs can be requested from supplies@tdlpathology.com. Stool samples are stable for 7 days and can be posted to the laboratory.

TEST UPDATE: Self-Collection HPV Test pages 141-142

The **Self Collection HPV Test** provides women with an option to self-collect their own vaginal specimen that is then sent to the laboratory for testing. Concordance between the HPV DNA results from self-collected vs clinician-collected specimens is high, and well documented, confirming that self-obtained vaginal samples are representative of the HPV types which infect the cervix.

The **Self-Collection HPV Test** is validated, using a CE marked vaginal sampler. A negative HPV result means that high-risk subtypes HPV were not detected and the patient is at extremely low risk of developing high-grade cervical disease before their next routine visit. A positive HPV result might indicate an increased risk of developing cervical cancer. The laboratory report provides the doctor/healthcare organisation requesting the test with 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.
- Personal preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears

Even though self-collected by the patient, results will always be sent directly 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.

DISCONTINUED SERVICES

- COLOGUARD
- Semen Analysis in Manchester
- 15RF – replaced by Endometrial Immune Profiling 23RF (see page 33)
- BacT/Alert (Biomerieux blood culture bottles will be replaced by Bectec (BD) bottles during December 2016

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**	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 samples on their way to TDL	see page 4
supplies@tdlpathology.com	**ORDER PATHOLOLOGY SUPPLIES/POSTAL PAC KS** for TDL samples	see page 10
tdl@tdlpathology.com	**ANY QUERY, ANY TIME**	

TDL's Laboratory Guide 2017 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.

The Doctors Laboratory, 60 Whitfield Street, London W1T 4EU Tel: 020 7307 7373 Fax: 020 7307 7374
E-mail: tdl@tdlpathology.com Website: www.tdlpathology.com TAP3331/27-11-16/V4