TDL Laboratory Guide 2016

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 now also includes the 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 for genetic tests **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)

REFERENCES TO CHANGES, UPDATES AND NEW TESTS ARE WITH EFFECT FROM 1ST JANUARY 2016.

SERVICE: NEW, UPDATES AND CHANGES

NEW TEST: 5th Generation HIV – Individual reporting of HIV-1, HIV-2, p24 antigen pages 66-67

The focus given to testing for HIV continues. HIV is one of the fastest growing serious health conditions in the UK. A total of 6151 people were newly diagnosed with HIV in the UK during 2014. 55% were among men who have sex with men (MSM). The challenge for the UK lies in timely diagnosis in order to start treatment. 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.*

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)*

TDL has introduced a next generation HIV assay with the Bio-Rad BioPlex 2200 HIV Ag-Ab assay. This is the first commercial screening assay to be able to distinguish between HIV-1 antibodies, HIV-2 antibodies and HIV-1 p24 antigen in 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. HIV-1 and HIV-2 are the two types of HIV, with HIV-1 being the most widespread worldwide. The two viruses are similar but distinct and different, which means that tests targeted to one type, will not detect the other.

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 OR (B) TDL Tiny™	24 hours

UPDATE: HIV Positive Patient Monitoring pages 66-67

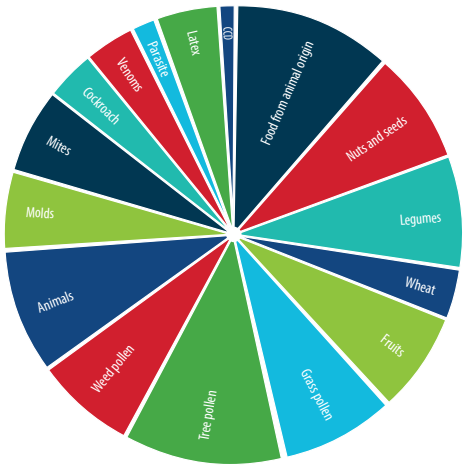
Efficient diagnostic and analytical platforms for screening and monitoring of HIV positive patients have revolutionised the treatment of HIV infection. The introduction of CD4 count, and viral load tests and antiretroviral therapy virtually ensures that HIV positive patients are able to live a normal life style. These laboratory tests are integral for the monitoring of HIV disease and of the investigation and treatment of symptoms

UPDATED ASSAY: Immunocap ISAC

Page 101

From November 2015, the updated microarray, for Immunocap ISAC is now available. Very small amounts (30 microlitres) of serum or plasma are needed for multiplex measurement of IgE antibodies to a fixed panel of 112 allergen components from 51 sources in a single test. Results are presented in a structured report which include guiding comments to help with interpretation.

ISAC testing seems to be helpful for complex cases, such as multi-sensitised patients or for those where there has been unsatisfactory response to treatment. Most allergic patients have positive test results to numerous allergens and the true course of symptoms can be difficult to identify; ISAC testing is able to provide useful and refined information in most cases, either revealing potential risk for severe food related reactions, identifying the IgE antibody profile in patients with unsatisfactory response to treatment, or assessing patients with idiopathic anaphylaxis.

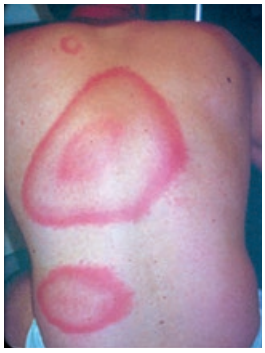


TEST	CODE	SAMPLE REQUIREMENTS	TAT
Immunocap ISAC	ISAC	(B) SST/Serum OR (B) TDL Tiny™	3 days

TEST UPDATE: Lyme Disease/*Borrelia burgdorferi*

page 53

Lyme disease, or Lyme borreliosis, is a bacterial infection spread to humans if bitten by an infected tick. The ongoing rise in Lyme disease cases in the UK – thought to be driven by climate change, leading to warmer winters – has been recognised by public health officials for some time. Reported cases in England and Wales rose from 268 in 2001 to 959 in 2011, but is probably higher. Current estimates put the actual figure at around 3,000 new cases a year in England and Wales.



Presence of antibodies confirms infection with the Lyme Disease spiral bacterium (spirochaete) known as Borrelia burgdorferi by a bite from an infected tick. Patients bitten by an infected tick which is not removed within a day or so may develop Lyme disease. An expanding rash usually appears at the site of the bite within 3 to 30 days in a large proportion of those infected. The rash spreads and often develops a 'bulls-eye' appearance. Many also develop flu-like symptoms with aching joints and muscles. The disease can later affect the nervous system, joints and other body systems.

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 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.

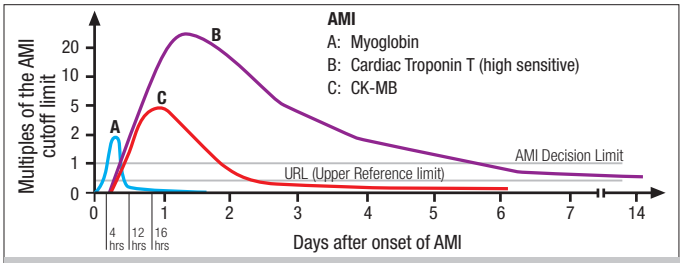
TEST	CODE	SAMPLE REQUIREMENTS	TAT
Borrelia Antibodies IgM	BORM	(B)	2 days
Borrelia Antibodies IgG/IgM	BORR	(B)	2 days
Borrelia Confirmation (Immunoblot)	BORC	(B) (provide travel history)	10 days

NEW TEST: TROPONIN T (high sensitive)

pages 22-23

The introduction of the high sensitive Troponin T assay with lower cut-off levels for diagnosing acute myocardial infarction (AMI) in patients with acute chest pain is associated with greater diagnostic accuracy. This gain in sensitivity may be particularly important in patients with a short duration from symptom onset to hospital admission. Troponin-T is a cardio-specific, highly sensitive marker for myocardial damage. A negative hsTroponin T test has a high negative predictive value, and will serve to exclude AMI in the diagnostic process.

Cardiac Troponin T (hs) increases approximately 3-4 hours after myocardial infarction, and may persist for up to 2 weeks. Use of hsTroponin testing is likely to have a major positive influence on cardiology practice in the next few years, accelerating diagnosis and potentially improving outcomes.



Kinetic Characteristics for Chest Pain Markers

	Beginning	Peak	Duration
Myoglobin	0.5–2 hours	5–12 hours	12–24 hours
Troponin T (hs)	3–4 hours	12–24 hours	14 days
CKMB	3–8 hours	10–18 hours	24–36 hours

Troponin T (high sensitive)

This assay can be used to aid in the differential diagnosis of acute coronary syndrome to identify necrosis, e.g. acute myocardial infarction. As a result of its high tissue-specificity, cardiac troponin T is a cardio-specific, highly sensitive marker for myocardial damage. Cardiac Troponin T (hs) increases approximately 3-4 hours after myocardial infarction and may persist for up to 2 weeks.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
High Sensitive Troponin-T	TROT	B	STAT
Chest Pain Profile	CPP	B	STAT

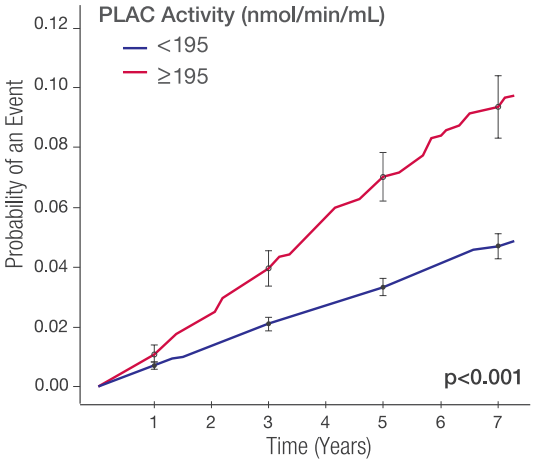
TEST UPDATE: Lp-PLA2 (PLAC®) Test

pages 17-18

The PLAC Test for Lp-PLA2 Activity gives additional prognostic information than traditional risk factors. Patients with low and moderate coronary heart disease risk may still be at risk because half of myocardial infarctions occur in individuals with normal LDL levels.

- Risk prediction for coronary heart disease in patients with no prior history of cardiovascular events
- Prognostic value independent of standard lipid profile testing
- Useful as an independent marker, in conjunction with clinical evaluation and patient risk assessment
- Easy-to-use cut off point of 195 nmol/min/mL.

Total CHD events



The PLAC test measures the amount of lipoprotein-associated phospholipase (Lp-PLA2) in blood. Lp-PLA2 is an enzyme primarily associated with low density lipoprotein (LDL). LDL carries Lp-PLA2 to the coronary artery walls where it activates an inflammatory response. If plaque is present it becomes more prone to rupture. Because this enzyme is associated with causing inflammation of coronary artery walls, high levels of Lp-PLA2 seem to indicate an increased risk of heart attack or stroke. Given that the majority of heart attacks and strokes are caused by plaque rupture and thrombosis, rather than narrowing of the arteries, individuals with high levels of Lp-PLA2 would benefit from more aggressive management with therapeutic intervention and/or lifestyle modification.

It is not intended that the PLAC Test should replace blood lipid testing or other traditional risk factors identified for cardiovascular disease. It provides an additional independent risk marker.

The PLAC test is recommended for patients with known coronary vascular disease, or for patients with moderate/intermediate risk for CVD including, but not limited, to two or more of the following risk factors:

- Family history of CVD
- Diabetes
- Obesity
- High saturated fat diet/physical inactivity
- Metabolic Syndrome/Chronic Kidney Disease
- Smoking
- Gender/Age (male>55/female>45)
- High Cholesterol
- On lipid lowering treatment
- High blood pressure

Risk Levels are reported quantitatively as **Low**, **Medium** or **High**:

Low < 151 nmol/min/ml **Medium** 152–194 nmol/min/ml **High** > 195 nmol/min/ml

An elevated PLAC test is actionable, and may indicate a need for more aggressive therapy, including treatment to lower LDL Cholesterol levels. Lipid lowering agents including statins are proven to reduce cardiovascular events.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Lp-PLA2 (PLAC®) Test	PLA2	B	2 days

NEW TEST: Phosphatidylethanol (PEth) in blood
Direct marker for Alcohol Detection

page 117

Phosphatidylethanol in Blood (PEth) is a stable, highly specific and sensitive marker for detecting chronic excessive drinking behaviour with a regular daily alcohol intake.

- PEth is found to be detectable in blood up to 28 days without alcohol.
- Sex, age, gender and body mass do not influence the normalisation rate of PEth.
- In comparison to serum CDT, PEth appears more sensitive.
- CDT is an indirect marker, PEth is a DIRECT marker.
- 99% clinical specificity when differentiating between abstainer and non-abstainer.

Neither CDT or PEth have established legal cut off values.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Phosphatidylethanol Results show: Any drinking > 35 ug/L Regular excessive drinking > 210 ug/L	PETH	(A) EDTA **Whole Blood** (do not separate) OR (A) TDL Tiny™	5-7 days

CHANGE: Alcohol Profiles

page 117

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Alcohol Profile 1 LFT, Alcohol Level, CDT and MCV – now includes PEth	AP	(A)(A)(B)(G)	5-7 days
Alcohol Profile 2: LFT, Alcohol Level, CDT, MCV, Urine Ethyl Gluconaride/Ethyl Sulfate – now includes PEth	APCP	(A)(A)(B)(G) **RU**	5-7 days

CHANGE: Natural Killer Profiles

page 27

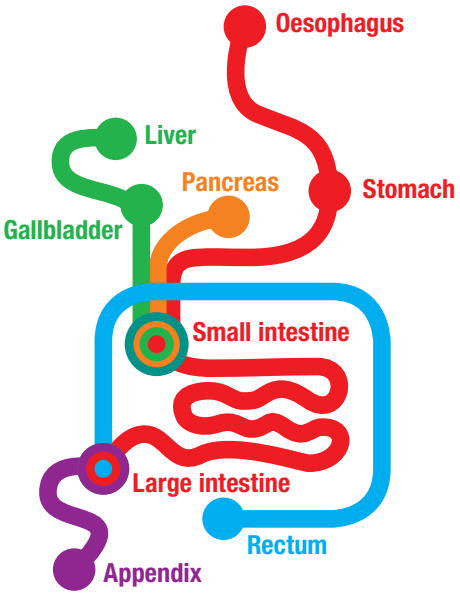
TEST	CODE	SAMPLE REQUIREMENTS	TAT
Natural Killer Profile 1 – CD16, CD56, CD69 Samples must be taken and received by 11.00am Monday to Friday. Samples cannot be received on Saturdays or Sundays.	NKP1	(H)	2 days
Natural Killer Profile 2 – CD3, CD4, CD8, CD16, CD56, CD19	NKP2	(A)	2 days

NEW and UPDATE: Gastrointestinal Tract

Oesophagus	
CA 19-9	page 71
CEA	page 71

Stomach	
CA 19-9	page 71
CEA	page 71
Gastrin	
H. Pylori Antibodies	page 54
H. Pylori Ag (stool/breath)	page 54
Pepsinogen I/II and Ratio	page 22
Vitamin B12	page 22

Pancreas	Gallbladder
Amylase	page 19
Bilirubin	page 19
CA 19-9	page 71
CEA	page 71
Elastase	page 57
Gallstone analysis	page 20
Lipase	page 21



Liver	
AFP	page 71
Alpha 1 Antitrypsin	page 19
CEA	page 71
Enhanced Liver Fibrosis (ELF test)	page 21
Ferritin	page 20
Fibrotest (Liver fibrosis)	page 21
Haemochromatosis	Page 21
Hepatitis A, B, C, D, E	Page 62
Iron Overload Profile	Page 21
Liver Function Tests	Page 21

Small Intestine	
Coeliac Disease	page 56

Large Intestine to Rectum	
CA 19-9	page 71
CA 50	page 71
Calprotectin	page 53
CEA	page 71
Cologuard	Contact the laboratory
Enteric Organism by PCR (EORD)	page 60
Faecal Occult Blood (FIT test)	page 28
Stool for o/c/p and culture	page 29

NEW Tests: Pepsinogen I/II and Ratio
Pepsinogen I/II and Ratio with Gastrin
Pepsinogen I/II and Ratio, Gastrin and H. pylori Abs

page 22

Gastric cancer is one of the most important gastrointestinal cancers. It is the fourth most common cancer and second leading cause of cancer deaths (700,000 deaths annually) worldwide. With any risk of cancer, there is always emphasis given to methods for earlier detection and for this cancer, the possibility of avoidance of invasive screening.

Serum pepsinogen is classified into two biochemically and immunologically distinct types, namely, Pepsinogen I (PG1) and Pepsinogen II (PGII). Pepsinogen levels reflect the functional and morphologic status of the stomach mucosa. If the fundic gland mucosal area reduces, the PG I levels gradually decrease, while the PG II levels remain fairly constant. From a results point of view, the **lower the PG I/II ratio, the greater the progression from normal gastric mucosa to extensive atrophic gastritis**.

Atrophic gastritis is a precancerous change, but extensive atrophic gastritis is a high risk factor for gastric cancer. Serum pepsinogen I (PG I) and pepsinogen II (PG II) levels are known to increase in the presence of *H. pylori*-related non-atrophic chronic gastritis. The eradication of *H. pylori* provokes a significant change in serum PG values: it reduces both PG I and PG II and elevates the PG I to PG II ratio.

There are various options for non-invasive assessment of the stomach. They can be used alone or in combination to increase diagnostic potential. These, in particular, include **Gastrin**, Pepsinogen I and II and markers for *H. pylori* infection (serum IgG antibodies, stool antigen and urease activity determined by urea breath testing).

The diagnostic methods for ***H. pylori*** infection are reliable in daily clinical practice, and if positive, indicate the presence of chronic active gastritis, a condition that virtually always accompanies *H. pylori* colonisation. The actual level of antibody, antigen or urease has no relation to the severity of gastritis, nor the presence of further pathology such as ulcer disease or premalignant changes. For the latter purpose, further testing is needed.

Gastrin is a marker for gastric acid output. A decrease in acid output, either as a result of inflammation or gland loss generally, is associated with an increase in serum gastrin levels.

Serum levels of pepsinogen I and II increase as a result of gastric inflammation, particularly *H. pylori* gastritis. Gland loss due to long-standing gastritis eventually leads to a decrease of pepsinogens, particularly pepsinogen I. These phenomena can be used for non-invasive assessment of the condition of the gastric mucosa.

Positive *H. pylori* serology with increased serum pepsinogen I and II levels confirms *H. pylori* gastritis.

Positive *H. pylori* serology with decreased Pepsinogen I level and a decreased Pepsinogen I/II ratio is indicative of long-standing *H. pylori* gastritis that has led to atrophic changes.

Increased serum fasting **Gastrin** levels reflect reduced acid output as a result of loss of specialised glands.

A markedly decreased Pepsinogen I and I/II ratio, with increased **Gastrin** and negative *H. pylori* serology will be found in patients with marked atrophic gastritis either as a result of previous *H. pylori* infection or autoimmune gastritis.

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Pepsinogen I/Pepsinogen II with ratio	PEPI	B	5 days
Pepsinogen I/Pepsinogen II with Gastrin	PPRG	B	5 days
Pepsinogen I/Pepsinogen II with Gastrin and H. pylori Abs	PPGH	B B	5 days

TEST UPDATE: Cologuard

Colorectal cancer (bowel cancer) is considered the most preventable, yet least prevented cancer due to the lack of patient compliance with screening. It primarily affects people age 50 and older.

Colorectal cancer screening is effective at reducing illness and death related to colon cancer. Colorectal cancer occurs in the colon/large intestine or rectum. Most colorectal cancers start as abnormal raised or flat tissue growths on the wall of the large intestine or rectum (polyps). Some very large polyps are more likely than smaller polyps to progress to cancer.

Using a stool sample, Cologuard® detects haemoglobin, a protein molecule that is a component of blood, as well as certain mutations associated with colorectal cancer in the DNA of cells shed by advanced adenomas as stool moves through the large intestine and rectum. Patients with positive test results are advised to undergo a diagnostic colonoscopy. Cologuard sample collection packs must be used for this test. To order Cologuard stool collection instructions/packs, contact **020 7307 7409** or **orders@tdlpathology.com**

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Cologuard	COLO	Stool Sample using Cologuard Sample Collection Pack	10 days

TEST UPDATE: Calprotectin pages 53/57

Faecal calprotectin testing is recommended by NICE as an option to help doctors distinguish between inflammatory bowel diseases (such as Crohn's disease and ulcerative colitis) and non-inflammatory bowel diseases, such as irritable bowel syndrome. (http://guidance.nice.org.uk/DG11: Diagnostics guidance, DG11 – Issued: October 2013)

Chronic abdominal pain or discomfort, with diarrhoea or constipation, are common. The symptoms can be caused by several different conditions, including irritable bowel disease (IBD), of which ulcerative colitis and Crohn's disease are the most common, and irritable bowel syndrome (IBS). The majority of symptoms are associated with IBS. Symptoms caused by IBD can lead to serious complications, high risk of surgery and increased risk of colorectal cancer. It is therefore important to distinguish IBD from non IBD.

The symptoms of lower gastrointestinal disorders (including IBD and IBS) can be sufficiently similar to sometimes make diagnosis difficult. Tests are often carried out to exclude conditions rather than to diagnose them, leading to repeat visits and investigations. Faecal calprotectin is primarily used to provide an indication of which patients require follow up studies such as colonoscopy.

Levels of faecal calprotectin are HIGH, or VERY HIGH in patients with inflammatory bowel disease and NORMAL, within range in patients with irritable bowel syndrome, even if they are symptomatic.

Specific indications for measuring faecal calprotectin allow for:

- Distinguishing inflammatory bowel disease (IBD) from functional bowel disease (IBS).
- Assessing efficacy of IBD treatments.
- Predicting relapses or flares of IBD.

NICE accredited
www.nice.org.uk/accreditation

TEST	CODE	SAMPLE REQUIREMENTS	TAT
Calprotectin (Stool packs can be requested from supplies@tdlpathology.com Stool samples are stable for 7 days and can be posted to the laboratory.)	CALP	Small Stool Sample	5 days

TEST UPDATE: Gastrointestinal Pathogen/Diarrhoea Panel – Enteric Organism Rapid Detection (Bacterial, Viral and Parasitic Infection) page 60

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* 0157
- 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 Stool packs can be requested from supplies@tdlpathology.com Stool samples are stable for 7 days and can be posted to the laboratory.	EORD	Small Stool Sample	2 days

NEW: HARMONY in the UK – NIPT in 3-5 days pages 91-92

Ariosa's Harmony test is now being undertaken by TDL Genetics. This validated transfer of technology ensures the same performance and accuracies but brings a welcomed reduction in turnaround time of 3-5 days. Worldwide interest and adoption of the Harmony test has been growing steadily. The Harmony test is now available in more than 100 countries and has been used to guide clinical care in more than 600,000 pregnancies worldwide.

- Harmony test is clinically validated to assess the risk of Trisomies 21, 18 and 13, in pregnant women of **any age or risk category**
- Harmony reduces false-positives by more than 90-fold, compared to First Trimester Screening
- The performance of the Harmony test was shown to be far superior to that of traditional first trimester screening for the detection of trisomy 21 in the general pregnancy population.

Non-invasive prenatal testing allows for analysis of cell free DNA from the mother's blood, from 10 weeks' gestational age, enabling the detection of trisomies 21, and other common chromosomal conditions (trisomies 18 and 13) and X and Y chromosome options) with exceptional accuracy. The test identifies in singleton pregnancies more than 99% of fetuses with trisomy 21, 97% with trisomy 18 and 94% with trisomy 13 and 96% of fetuses with Turner Syndrome. X and Y analysis provides >99% accuracy for fetal sex.

The test can be requested for any singleton or twin pregnancy, including those conceived naturally or by IVF using the patient's own or donor egg. Whilst fetal sexing can now be undertaken for twin pregnancies, sex chromosomes cannot be analysed in twin pregnancies.

This test is non-invasive; it involves taking a venous blood sample from the mother. The pregnancy is not put at risk of miscarriage well documented to be associated with invasive procedures. The number of women required to have a CVS or amniocentesis is less than 1%. A high risk result does not definitely mean that the fetus has one of these conditions, although it is highly likely. For this reason, in the event of a high risk (or positive) result, follow up testing by an invasive procedure is strongly recommended.

About the Ariosa Harmony™ Prenatal Test

DNA from the fetus circulates in the mother's blood. Cell Free DNA (cfDNA) results from the natural breakdown of fetal cells (presumed to be mostly placental) and clears from the maternal system within hours of giving birth. During a pregnancy, the cfDNA can be tested to provide the most accurate screen to estimate the risk of a fetus having a common chromosome condition, often referred to as a trisomy. This occurs when there are three copies of a particular chromosome instead of the expected two. This test looks to detect the following trisomies:

Singleton and Twin Pregnancies:

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)
- Fetal sexing

For Singleton Pregnancies only:

Sex Chromosome conditions XXX, XYY, XXYY, XXY and a missing X

harmony™ PRENATAL TEST performed in the UK

TDL Genetics will provide Harmony sample taking packs including:

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

To 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

UPDATE: Patient Self-Collection Samples – TDL Tinies™ (tinies@tdlpathology.com) pages 121-126

A list of tests that can be offered to patients for self-collection using TDL TINIES™ and Royal Mail postal packs has been given on pages 122-123 of the Laboratory Guide. Packs are supplied by TDL. These can be sent individually to patients, or supplied directly to doctors or healthcare companies with personalised request forms and artwork. Self-collection of samples by patients is not the same as point of care testing. All processing of samples is undertaken in the laboratory and results are always returned directly to the healthcare company or doctor, not to the patient.

Tests that would routinely have reflexed confirmatory testing (ie HIV, Syphilis, Hep BsAg and Hep C Abs) are reported with the recommendation for a venous sample to be taken for confirmatory testing. TDL TINY™ blood samples can be combined with other self-collected samples types (urine, stool, swabs, HPV).

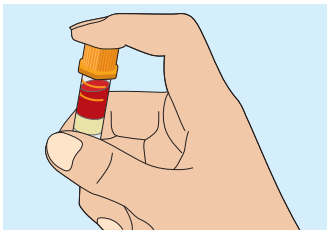
The sample volume from one TINY™ sample, when filled to the upper fill line, is **600 microlitres**. Different tests require varying amounts of sample, and this, together with analyser dead volumes, means that although certain tests can be carried out from TINY tubes, many tests simply cannot be achieved from these smaller sample volumes (refer to the list of tests on pages 122/123). TDL TINY™ microtainers are manufactured by **BD Diagnostics**. They are designed for sample collection from skin puncture. BD Microtainers come with a variety of additives for various tests, have visible fill lines, and are colour coded as for standard BD Vacutainer tubes. Tubes and Lancets are CE marked. TDL TINY™ packs are made up by TDL and contain everything needed for a patient to self-collect their blood sample.

Recommendation: most people are not experienced self-collectors of their own blood. Whilst it is certainly possible to do a number of tests from one TINY™ and it is possible to collect blood for two or three microtainers at a time, the most successful results are achieved by patients

who read the instructions given in each pack, and who collect enough sample to fill one microtainer. Instructions for sample collection are enclosed in each pack. A completed **request form** must be enclosed with the returned sample. Results will always be sent to the requesting doctor /healthcare organisation.

There is a TDL TINY™ video to assist patients with sample collection at **http://www.tdlpathology.com/test-information/test-service-updates/tdl-tinies**

This can be personalised with logo and details. For information and possible test combinations and packs, contact Annette Wilkinson on **020 7307 7343** or email **tinies@tdlpathology.com**



TEST UPDATE: Self-Collection HPV Test page 127

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

After 31st December 2015, ECG Services will no longer be available at Patient Reception, 76 Wimpole Street, or with Home Visits.

COMING SOON: Details to follow in Spring 2016

Andrology On Line – details for patients to make their own on-line appointments for semen analyses will be introduced in 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 ahead 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 PACKS** for TDL samples	see page 10
tdl@tdlpathology.com	**ANY QUERY, ANY TIME**	

TDL's Laboratory Guide 2016 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 TAP2959/26-11-15/V4A