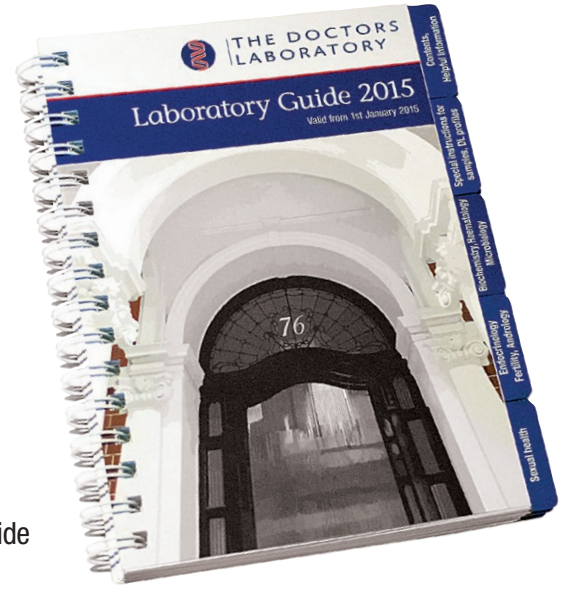
TDL Laboratory Guide 2015

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 originating 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 extended A–Z test reference for **Genetic Tests**. For advice or information about any tests, please contact the laboratory on **020 7307 7373**.

The successful introduction of **tabs** last year has been repeated to help you navigate to the various disciplines, and for all sample takers, the laboratory guide gives details of sample types, with coloured dots to match the colour of the vacutainer top A B C F G H K

CHANGES FOR NEW TESTS, UPDATES AND TDL PROFILES ARE WITH EFFECT FROM 1ST JANUARY 2015

SERVICE: NEW, UPDATES AND CHANGES

NEW – Patient Reception at 76 Wimpole Street

We have moved our Patient Reception from 55 Wimpole Street to 76 Wimpole Street. This purpose-designed conversion accommodates Patient Reception and TDL Andrology. The Waiting Area and the design of the 8 Phlebotomy Rooms and 4 Collection Rooms for Andrology will make a significant difference to all patients attending for samples to be taken.

There is nothing that can be done to a waiting room or sample taking centre that can completely eliminate anxiety for patients. The environment is not the main source of the stress; the visit is. But we hope that the comfort, signage, accessibility, colours and seating arrangements will contribute positively to their visit to Patient Reception.

UPDATE for receiving results

We continually review and update the methods for receiving requests and reporting results electronically between practices and the laboratory. A number of innovative report formats are available.

Hard Copy
Results are posted out on the day they are reported.

Autofax
As tests are authorised, results are faxed electronically in real time.

Email
Results can be sent in encrypted format to any number of predetermined email addresses.

Secure Link
Bidirectional electronic requests can be delivered from the practice to the laboratory and results downloaded from the laboratory to the practice through integrated practice systems or practice software that accepts data in an HL7 format.

TDL e-View
Registered users can **view all their results online**. This is a secure Login/Password protected look-up system, with a cumulative results reporting function. This can be accessed any time, from anywhere, through the internet. **Results that are not yet available show as 'PENDING'.**

BIOCHEMISTRY: NEW, UPDATES AND CHANGES

UPDATE: – Lp-PLA2 (PLAC®) Test

page 18

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, which serves as an independent coronary marker, would 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, it would seem that individuals with high levels of Lp-PLA2 might 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 CVD 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
- Metabolic Syndrome/Chronic Kidney Disease
- High Cholesterol
- High blood pressure
- Diabetes
- Smoking
- On lipid lowering treatment
- High saturated fat diet/physical inactivity
- Obesity
- Gender/Age (male>45/female>55)

An elevated PLAC test is an actionable tool, 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. Knowing there is active disease, rather than just risk, may generate a greater sense of urgency in patients to become more compliant with treatment recommendations.

*DiaDexus Bibliography (http://www.plactest.com/healthcare/index.html). http://www.plactest.com/healthcare/annotated-bibliography.html

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

ENDOCRINOLOGY: NEW, UPDATES AND CHANGES

UPDATE – Antimullerian Hormone (AMH) 4 Hour Turnaround Time

page 34

From the **3rd November 2014** TDL introduced the fully automated **Roche Elecsys AMH Assay**. Values are expected to be **25% lower** than those obtained from the Beckman Coulter Gen II assay. **For direct comparison between the two methods all results prior to the 3rd November should be multiplied by 0.75 (x 0.75)**. The need to make this calculation when comparing a patient's new result to a previous result will be clearly shown in each report. The new Roche assay will be run as standard.

Important Benefits:

- Results will be available within **4 Hours** of receipt of sample
- Reference intervals will now be **Age related** – see right.

Age related reference intervals in women:
The reference intervals below are derived from a population of apparently healthy women not taking any contraceptive medication. The reference intervals represent the 10th – 90th percentile values for the women in each age bracket.

Age Range	Elecsys AMH (pmol/L)
20 – 29 years	13.1 – 53.8
30 – 34 years	6.8 – 47.8
35 – 39 years	5.5 – 37.4
40 – 44 years	0.7 – 21.2
45 – 50 years	0.3 – 14.7

* Samples can be taken, at any time during a patient's monthly cycle. Ambient, unspun sample stability has been validated for up to 5 days. Postal samples are therefore acceptable, and samples can also be collected and posted using TDL TINIES.

UPDATE – Tackling troublesome turnaround times

TEST	CODE	PREVIOUS TAT	NEW TAT FOR 2015
Free Testosterone	FTES	5 days	2 days
Pregnenolone	PREN	3 weeks	6 days
Reverse T3	RT3	2 weeks	5 days
Oestrone	E1	10 days	4 days
Oestriol	E3	10 days	4 days

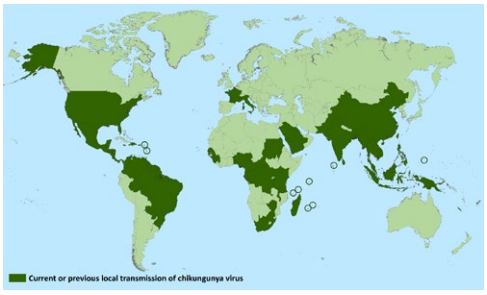
TROPICAL IMMUNOLOGY: NEW, UPDATES AND CHANGES

UPDATE – Chikungunya

Chikungunya Virus (CHKV) is a mosquito-borne, dengue-like virus common in parts of Asia but until one year ago there had been no cases reported in Europe, USA, South and Central America. International travel stands out as one of the major risk factors for the rapid global spread of the disease. It is transmitted through day-biting mosquitos.

- Symptoms
- High fever
- Possible conjunctivitis
- Wide spread rash
- Nausea, vomiting
- Persistent/incapacitating joint pain similar to rheumatoid arthritis

Since December 2013 however, at least 850,000 people have contracted the virus in the Caribbean region. No vaccine exists to prevent chikungunya virus infection or disease.



Countries and territories where chikungunya cases have been reported (as of December 2014) http://www.cdc.gov/chikungunya/geo/index.html

TEST	CODE	SAMPLE REQS	TAT
Chikungunya (Arbo) IgG/IgM Positive IgG/IgM will reflex, to confirmation by PCR	CHIK	**1ml Serum**	2 weeks

Please provide details of patient's Travel History

IMMUNOLOGY: NEW, UPDATES AND CHANGES

UPDATE – Calprotectin page 53

http://guidance.nice.org.uk/DG11: Diagnostics guidance, DG11 – Issued: October 2013

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.

Faecal calprotectin is primarily used to provide an indication for which patients require follow up studies such as colonoscopy. The test is also used in determining disease activity and monitoring response to treatment in patients with ulcerative colitis and Crohn's disease. Treatment with NSAIDs may increase a patient's faecal calprotectin by approximately twofold

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.

Specific indications for measuring faecal calprotectin allow for:

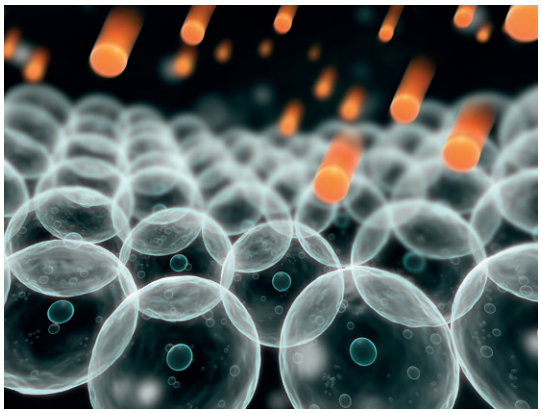
- Distinguishing inflammatory bowel disease (IBD) from functional bowel disease (IBS)
- Assessing efficacy of IBD treatments
- Predicting relapses or flares of IBD.

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

UPDATE – Oxidative Stress in Semen (ROS) and Male Infertility page 42

Almost 50% of all cases of infertility may be associated with a male factor. Although a semen analysis has classically been use as the gold standard for determining a man's fertility, this test may not detect abnormalities at the molecular level. These abnormalities may contribute to the 25% of infertility cases that remain unexplained

There is growing evidence to support a link between oxidative stress and male infertility. Reactive oxygen species (ROS) are generated by human sperm as part of their normal metabolism. At low levels ROS enhance sperm performance and are maintained at low levels by effective anti-oxidant pathways. However, if the production of ROS overwhelms the capacity of these anti-oxidant pathways, then oxidative stress occurs, leading to pathological effects. For further information please contact **Dr Sheryl Homa**: **andrology@tdlpathology.com**



TUMOUR MARKERS: NEW, UPDATES AND CHANGES

*Early*CDT®-LUNG – a blood test for earlier detection of lung cancer page 48

30% of lung cancer patients die early in the UK. Earlier diagnosis and being able to identify patients at the very early stage contribute significantly to patient survival rates.

UK public education campaigns in 2012 urged patients with a cough lasting more than 3 weeks to visit their doctor. As a result of this campaign, there were statistically significant increases in unprompted awareness of cough/hoarseness and persistent/prolonged cough.

***Early*CDT®-Lung is a blood test to aid in the early detection of lung cancer which:**

- Has 5x better Positive Predictive Value (PPV) performance than Computed Tomography (CT)
- Has 7x fewer false positives than CT
- Detects all types and all stages of lung cancer, including Stage I and II
- Is non-invasive, with no radiation risk for the patient

Results of an *Early*CDT-Lung test

There are three possible test results: 7 Autoantibodies are reported as one of the following:

• HIGH Level	meaning one or more is above the high cutoff value
• MODERATE Level	meaning one or more is above the low cutoff value
• LOW Level	

Tobacco smoking is estimated to cause around 90% of all cases in men and 80% in women, with nearly all other lung cancers caused by environmental exposure.

The latency period for lung cancers attributable to smoking is at least 20 years, which accounts for why 85% of cancers are found symptomatically in people aged 60 and over. These cancers are often detected by a chest X-ray, when they are usually advanced and the chances of long term survival are low. Early detection is key for improved survival by identification of patients with lung cancer in earlier, more curable stages.

- The earlier diagnosed the better – the five-year survival rate for early stage is 43-73%, while for later stage disease it is 2-13%
- The five-year survival rates for men and women diagnosed with lung cancer are 7.3% and 8.7% respectively

***Early*CDT-Lung** is a blood test developed to measure a panel of 7 autoantibodies, associated specifically with lung cancer. In the early stages of solid tumour cancer, autoantibodies are produced in response to tumour antigens. Autoantibodies are present, and remain measureable, in all stages.

The ***Early*CDT-Lung** test can be used in conjunction with diagnostic imaging such as X-Ray or CT scan, to further assess the risk of lung cancer being present where indeterminate lung nodules have been detected, but which may or may not be a sign of cancer.

This is not a genetic test for predisposition – a positive test may indicate the presence of the disease and an increased risk of malignancy.

A High or Moderate Level test result means there is increased risk for lung cancer. Follow-up, which may include CT imaging, would be indicated and should take into account risk factors, symptoms and other relevant patient history, if available. A High or Moderate Level test result does not definitively mean that lung cancer is present. This test is referred to Oncimmune Ltd (www.oncimmune.com)

MOLECULAR/PCR: NEW, UPDATES AND CHANGES

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 beinappropriately 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*

GENETICS: NEW, UPDATES AND CHANGES

UPDATE – BRCA: two turnaround times/price options page 80

Breast or ovarian cancer caused by inherited mutations in the BRCA1 or BRCA2 genes account for 5-10% of all breast/ovarian cancers – and are characterised by early onset (before age 45 years) and extensive family history (generally 3 or more 1st/2nd degree relatives with breast/ovarian or prostate cancer in men). BRCA1 & BRCA2 mutations are dominant and have high lifetime penetrance, so single cases within a family are unusual when there is an inherited mutation present.

TEST	CODE	SAMPLE REQS	TAT	PRICE
Breast/Ovarian Cancer – BRCA1 + BRCA2 full screening + deletions/duplications	GENE	A A [9,11]	3 weeks	£800.00
Breast/Ovarian Cancer Gene Screening (Extended) – full sequencing + deletion/duplication testing for the following 39 genes: APC, ATM, ATR, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, CTNNB1, EPCAM, FANCC, HOXB13, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PALLD, PMS2, PTEN, RAD50, RAD51, RAD51C, RAD51D, SMAD4, STK11, TP53, VHL, XRCC2, XRCC3	GENE	A A [9,11]	6 weeks	£1550.00

There are serious implications of detecting a BRCA gene mutation for both the patient and immediate family members; a thorough medical evaluation of family history and counselling are strongly recommended.

UPDATE – Pan-Ethnic Carrier Screening for Common Diseases page 90

The RECOMBINE CarrierMap™ is the most comprehensive genetic carrier screen for all ethnic backgrounds. It examines 2000+ mutations across more than 250 diseases including Cystic Fibrosis, Sickle Cell Disease, Thalassaemia, Spinal Muscle atrophy and Fragile X Syndrome.

CarrierMap™ can be filtered to report diseases common to the Jewish population such as Bloom Syndrome, Canavan Disease, Gaucher Syndrome, Niemann-Pick and Tay Sachs Disease.

Indications for Use: Pre-pregnancy screening for couples to check if they are silent carriers for a disease that would have serious implications for the future of any children.

For patients who are concerned about a family history of a particular disease where the common mutation detection rate is very high (such as Sickle Cell or Tay Sachs).

The report gives an extensive synopsis of any disease for which a mutation is found including prognosis, treatment and mode of inheritance, risk assessment (based on ethnicity and family history) and recommendations for further testing. The test only examines very specific common diseases and mutations. A normal result cannot rule out the possibility that the patient carries a rare mutation not detectable by this particular assay so for this reason it is not appropriate to use a direct prenatal screen.

Contact TDL Genetics for the full list of diseases covered by this test.

DIABETES: NEW, UPDATES AND CHANGES

TEST UPDATE: Diagnosis of Type 2 Diabetes with HbA1c page 21

Key Messages for Diagnosing Diabetes using HbA1c

- To test for diabetes, use HbA1c instead of fasting plasma glucose or glucose tolerance testing EXCEPT in pregnancy, or presence of acute symptoms
- Diabetes is confirmed with HbA1c ≥48mmol/mol (6.5%), on two occasions in an asymptomatic individual
- If symptomatic, a single HbA1c test will suffice if 48mmol/mol (6.5%) or above
- Diabetes can be diagnosed using HbA1c

Type 2 Diabetes Mellitus (T2DM) Risk Factors

- Age – over 40 years or 25 years for Afro-Caribbean/South Asian/Chinese
- Ethnicity – Afro-Caribbean/South Asian/Chinese are 5 times more likely to have diabetes
- Family history of diabetes in a first degree relative – the closer the relative, the higher the risk
- History of heart attack or stroke, poor blood circulation
- BMI & waist circumference
- PMH of hypertension (over 140/90)

HbA1c is not appropriate for diagnosis of diabetes for:

- ALL children and young people
- Patients of any age suspected of having Type 1 diabetes
- Patients at high diabetes risk who are acutely ill (e.g. those requiring hospital admission)
- Patients taking medication that may cause rapid glucose rise e.g. steroids, antipsychotics
- Patients with acute pancreatic damage, including pancreatic surgery
- In pregnancy
- Presence of genetic, haematologic and illness-related factors that influence HbA1c and its measurement – see Annex 1 from WHO report

SEXUAL HEALTH: NEW, UPDATES AND CHANGES

FASTest TEST for CT/GC – Urine, PCR swab and Thin Prep Vial

page 48

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

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

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

FAST SSC
Fast Screen *SHORT*

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

TAT 4 HOURS*

FSSC

B FCRU

FAST USC
Fast Screen *URINE*

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

TAT 4 HOURS*

FUSC

B FCRU

FAST SSC
Fast Screen *SWAB*

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

TAT 4 HOURS*

FSWS

B FCRU

SERVICE: NEW, UPDATES AND CHANGES

UPDATE – TDL TINIES for self collection blood samples

tinies@tdlpathology.com

Using postal packs for sending samples is well known and well used for off-site, or home sample collection tests.

TDL TINIES provide an option for patients to self-collect blood samples or for healthworkers to collect blood samples without phlebotomy training. This option using postal packs with full instructions, can be supplied directly to doctors or healthcare companies for their online or practice patients.

Sample taking instruction video:

www.tdlpathology.com/test-information/test-service-updates/tdl-tinies

This video can be personalised to practice, company or clinic.

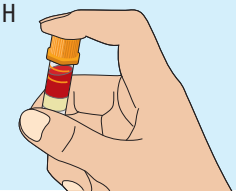
1 **TDL TINIES** are for home sample taking, NOT point of care testing (PoCT).

2 **TINY** samples are processed using the same laboratory platform/assays as venous bloods.

3 **Results from TINIES and POSTAL PATHOLOGY are always sent directly to the healthcare company or doctor, not to the patient**.

Suggestions for TDL TINY Testing

HbA1c	HE4
Omega 3/6	CA 125
Lipid Profile	Hep B Immunity
Hormones	AMH
TF	
Vitamin D	
Iron Status	
PSA	



The qualifying factors for TINY TESTS are

1 tests that can be processed in the laboratory from small sample volumes

2 their suitability for postal pathology.

SEXUAL HEALTH: NEW, UPDATES AND CHANGES

UPDATE – Using TDL TINIES for Sexual Health testing: up to 4 tests from one TDL TINY

Up to 4 tests can be processed from one TDL TINY sample

• HIV 1&2/p24 Antigen • Hep B sAg • Hep C Abs • Hep C Antigen for early detection • Syphilis IgG/IgM

Packs can also be made up for urine, swabs and TINY (e.g. MSM self-collection packs are made up for self-sample collection for:

TINY	URINE	PCR SWABS
HIV 1&2/p24	CT/GC	Rectal
Syphilis		Pharyngeal

Reactive samples must be followed up with a venous sample for confirmatory testing.

SERVICE: NEW, UPDATES AND CHANGES

UPDATE – Self-Collection HPV Test

The Self Collection HPV Test provides women with the option to self-collect a vaginal specimen that is then sent to the laboratory for testing; a PAP smear cannot be self-collected. There is well documented high level of concordance between the HPV DNA results from self-collected and clinician-collected specimens confirming that the self-obtained samples are representative of the HPV types which infect the cervix.

The Self-Collection HPV Test is validated, using a Rovers® Evelyn Brush Sampler, CE marked for vaginal cell collection. The self taken sample processed for HPV DNA subtypes. A negative result means that high-risk subtypes HPV were not detected and the patient is at extremely low risk of developing high-grade cervical disease before their next routine visit. A positive HPV result might indicate an increased risk of developing cervical cancer. The laboratory report provides a clear recommendation for follow-up/colposcopy.

The value of HPV DNA testing in cervical cancer screening and disease detection has been proven over and over again. Self-collection of specimens for HPV testing is not intended to replace existing patient management pathways but allows for:

- Those who wish to test following a change of sexual partner
- Option for identifying the high risk DNA subtypes
- Personal preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears

The Self Collection HPV Test provides women with the option to self-collect a vaginal sample that is then sent to the laboratory for testing. Results will always be sent to the requesting clinician, clinic or healthcare organisation.

The Self Collection HPV Test provides women with the option to self-collect a vaginal sample that is then sent to the laboratory for testing. Results will always be sent to the requesting clinician, clinic or healthcare organisation.

HPVY Self-Collected HPV DNA with individual reporting of subtypes 16, and 18 and 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.

SERVICE: NEW, UPDATES AND CHANGES

UPDATE – ONLINE COURIER BOOKING

TDL COLLECT is one of the most recognisable and successful, same day, trained medical despatch operators in London, carrying out in excess of 1700 collections every day.

The new courier management software, with GPS and hand held technology, allows for live vehicle tracking, customer web booking, auditable job trails with electronic signature capture, and live job progress updates using email or SMS. Practices can either telephone for collections using their **unique customer account number** – or **BOOK ONLINE** through **www.tdlcollect.com**.
For your practice's Username and Password, please contact Chris Tanalega on 020 7307 9447 or email chris.tanalega@tdlpathology.com

GENETICS: NEW, UPDATES AND CHANGES

COMING: Technology Transfer for Harmony Test Non-Invasive Prenatal Testing

As from the **1st December**, the price for Ariosa's Harmony test will be **£275.00**. This lower price will be set for all practices and clinics.

NIPT allows for analysis of cell free DNA from the mother's blood, enabling the detection of trisomies 21, 18 and 13 with an exceptional accuracy of greater than 99% (with a false positive rate of less than 0.1%) within a general screening population. It can also detect and sex chromosome anomalies if required.

The Harmony test is well positioned for both high and low risk women, with singleton, twin, IVF, donor or self-donor egg pregnancies. Turnaround times will become shorter, whilst technology transfer TDL Genetics. This will allow us to offer the Harmony test from London next year.

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

For further information or Harmony packs, contact **TDL Genetics** on **020 7307 7409** or **NIPT@tdlpathology.com**

COMING: Cologuard Q1 2015

After a comprehensive evaluation, Cologuard was recently approved by the US FDA as a non-invasive stool-based colorectal cancer screening test. Cologuard detects multiple DNA methylation (2) and mutational markers (7) and the total amount of human DNA in the stool released from cells shedding from colorectal carcinomas or advanced colorectal adenomas, and faecal haemoglobin.

The clinical data came from a 10,000 patient pivotal trial comparing Cologuard and Faecal Immunochemical Testing (FIT) using colonoscopy on all patients as the reference method. (*N Engl J Med.* 2014;370:1287-129). Cologuard detected 92% of colorectal cancers and 42% of advanced adenomas; by contrast, FIT screening detected 74% of cancers and 24% of advanced adenomas. It will be more expensive than traditional stool testing. No special preparation, diet or medication is needed. Cologuard is indicated for adults who are at typical risk of colorectal cancer, of either sex, and who are 50 years of age or older. This test is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.

SERVICE: NEW, UPDATES AND CHANGES

NEW – 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 vew 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 to one of your London based patients	see page 8
logo@tdlpathology.com	Send your logo artwork (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 needs for samples on their way to the laboratory	see page 4
supplies@tdlpathology.com	Order pathology supplies/postal packs for TDL samples	see page 10
tdl@tdlpathology.com	Any query, any time	

TDL's Laboratory Guide 2015 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 TAP2578/04-12-13/V6