TDL Laboratory Guide 2012

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 relevant feedback received over the past year, to keep profiles and test menus as updated as possible. The developments in diagnostic pathology are exciting. 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. If you are not able to find the test or service you are looking for, do please contact the laboratory on 020 7307 7373 for more information.

The TDL website A–Z test list and offers additional reference at www.tdlpathology.com.

References for NEW Tests and Profiles are with effect from 1st January 2012

Hepatitis C – Hepatitis C Virus Core Antigen (HCV Ag) Page 46

Hepatitis C is a blood borne infection caused by the Hepatitis C virus. Routes of transmission are:

PERCUTANEOUS

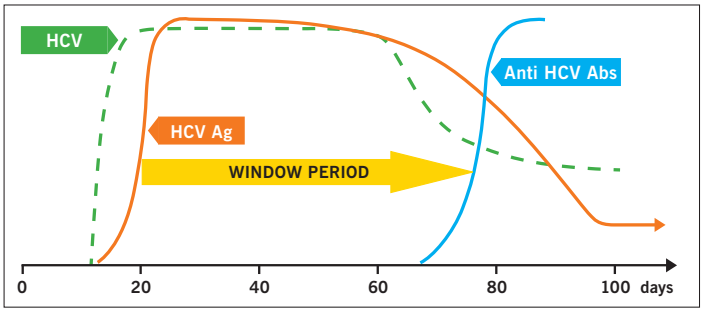
- Contaminated needlestick, tattooing, body piercing
- Haemodialysis
- Unscreened blood products

PERMUCOSAL

- Sexual intercourse/blood transfer
- Infant born to HCV infected mother

INCIDENCE/PREVALENCE

- Worldwide there may be more than 170 million chronic carriers of HCV



HCV Ag is detectable in the majority of PCR +ve, and HCV Ab +ve patients, and is considered useful to confirm HCV in untreated patients at any time.
HCV Ag will be undertaken for confirmatory testing when HCV Abs are detected.

HCV Ag is detectable well before the occurrence of antibodies against HCV. Active HCV infection, acute or chronic, is characterized by the presence of HCV antigen. The sero diagnostic window (the time when the virus is present but antibodies are not) may last, on average 70 days (but maybe as long as 180 days). HepC Antibodies are useful as an indicator of past HCV infection but do not indicate current viraemia, or elimination of virus from the patient. A negative antibody test does not rule out an HCV infection in the early incubation phase. HCV Ag is a direct marker for the diagnosis of suspected HCV infection and this test can be used for:

- confirmation of active disease from 10 days
- screening of patients at high risk for HCV infection (e.g dialysis patients, IV drug users, patients from areas of high HCV prevalence)
- quantitative adjunct in therapy monitoring
- monitoring the status of infected individuals
- reflex testing for HCV Ab positive samples of HCV

HCV Antibody	DETECTION
HCV Antigen	DETECTION/QUANTITATION
HEPC RNA (Viral Load)	DETECTION/CONFIRMATION
HCV Genotyping	DETERMINATION

HCV Ag will be undertaken for CONFIRMATORY TESTING when HCV Abs are detected.

HCV Ag has now been included with HepC Antibodies in:

Please contact the laboratory if you would like to include HCV Ag in personal profiles which contain HepC Antibodies

SEXUAL HEALTH

Introduction of STD QUAD (STDQ)

page 32

TEST	CODE	SAMPLE REQS	TAT
STD Quad Profile	STDQ	B, FCRU	2 days
Syphilis IgG/IgM HIV 1&2/p24 Antigen Chlamydia (Urine) Gonorrhoea (urine)			

TESTING FOR HIV

HIV-1 Qualitative Real Time PCR DNA/RNA using Dried Blood Spot

In 2009/2010, there were an estimated 90,000 people living with HIV (both diagnosed and undiagnosed) in the UK and a quarter of HIV-infected people were thought to be unaware of their infection.

September 2011: estimates of 100,000 people in the UK will have HIV by 2012. The actual numbers are likely to be far higher: some reports estimate that around a quarter of people with the virus are unaware they have it. HIV testing is a priority if HIV prevention efforts are to be improved.

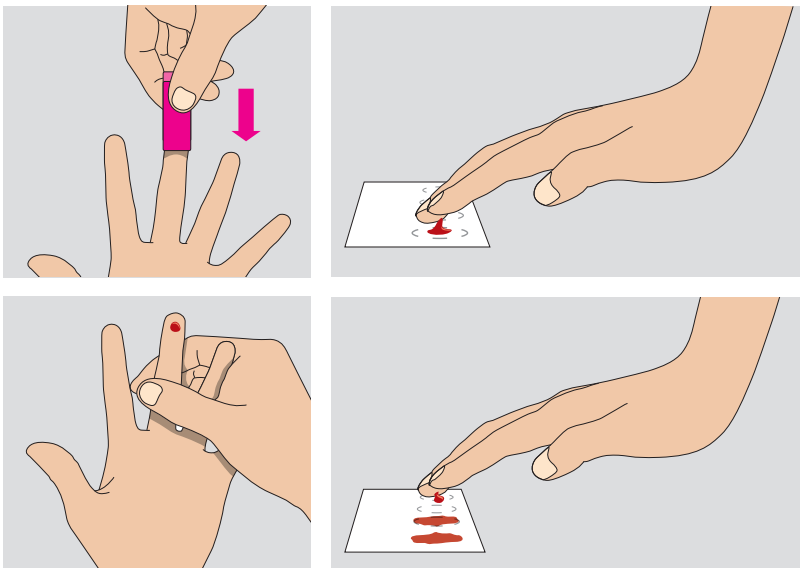
Dried Blood Spot (DBS) Test

page 50

HIV-1 QUALITATIVE REAL TIME PCR DNA/RNA

- Sample Stability: 12 weeks/ambient temperatures
- Home Sample Collection/postal sample
- CE marked
- Early Detection/10 days post exposure
- Qualitative result – detected/not detected
  LOD 2500 copies/ml in whole blood
- Detects: Group M Subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, Subtype H and Group N, Group O.

Developed by Abbott Molecular, this is a new CE marked, qualitative PCR-based HIV-1 test that produces highly accurate results from dried blood spot specimens.



Contact the Laboratory for information and to request Dried Blood Spot Postal Packs

Screening for Drugs of Abuse and Alcohol

page 94

Drugs of Abuse

Drugs of Abuse with Alcohol

Drugs of Abuse (large panel)

Drugs of Abuse with Chain of Custody

Drugs of Abuse from Hair

Drugs of Abuse from Blood

Alcohol Profile with CDT (measuring alcohol intake for 2–4 weeks)

Alcohol Profile with CDT with Urine Ethyl Gluconaride (EtG) and Urine Ethyl Sulfate (EtS) for binge drinking

NUTRITION/VITAMINS

Red Cell Mineral Screen page 75

Bone Screen (bloods only) page 9

4 Hour Turnaround for Vitamin D (25 OH) page 8

HIGH RISK HUMAN PAPILLOMAVIRUS (HR-HPV)

Introducing Triage and Test of Cure

page 92

Cervical cancer prevention is in transition, from a cytology only based screening programme to a model that incorporates testing for Human papillomavirus (HPV).

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

HPV Triage and T**est of Cure** are being introduced across the NHS Cervical Screening Programme and implementation in the NHS will follow national protocols. All women in the screening age range of 25–64 are eligible for HPV Triage and Test of Cure.

For details see Page 92

TDL is introducing a HR-HPV Assay that is an NHS approved qualitative assay, able to ***collectively*** test for 14 high risk HPV subtypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) and provide a genotype result for types 16 and 18 when present. This assay provides the minimum necessary information for patient stratification.

Any request for Cervical Cytology (PAPT) that is received by TDL without a specific request for HPV testing, but is reported with either borderline or mild changes will automatically reflex to this HR-HPV DNA test. The cost of this reflexed test is INCLUDED in the price of the cervical cytology. There is no additional charge. For women whose cytology findings are more abnormal than borderline or mild, the recommendation for referral for colposcopy will be given, as standard.

The primary benefit of HPV testing lies in its high sensitivity and high negative predictive value, but HPV DNA testing, on its own, cannot identify progression from transient to a transforming infection or oncogenic activity. This is when an HPV infection has transformed from merely being present and insignificant, to become an integrated infection. The expression of viral oncoproteins E6 and E7, which affect cell cycle control, initiate the cervical cancer process. The detection of E6/E7 mRNA confirms the persistent expression of viral oncoproteins in human cells.

TEST	CODE	SAMPLE REQS	TAT	PRICE
HPV DNA	HPV	TPV	2 days	No Charge

High Risk Types reported collectively (negative/positive)

If a result for cervical cytology shows borderline or mild changes, and the PAPT has been requested without HPV, this HPV DNA test will be undertaken at no additional charge. HPV subtypes are reported collectively, with typed 16 and 18 only, if present.

The benefit of a negative HPV result is its negative predictive value – meaning a negative result indicates that a patient is at very low risk of developing cervical disease. The Negative Predictive Value (NPV) for both DNA and mRNA is the same. DNA based tests detect presence of virus only, whilst the mRNA-based test detects the persistence of viral oncogenic expression from subtypes 16, 18, 31, 33 and 45. mRNA testing can be undertaken from Cytyc Thin Prep samples only.

NEW

HPV/PAPT Combined Report
Where an HPV result is reported with Cervical Cytology, a recommendation for patient management will be given, based on the combined findings.

HPV with SUBTYPES testing options page 92

FERTILITY

Reproductive Immunology bloods for St Helier, Carshalton and Rosalind Franklin Laboratory, Chicago page 18

4 Hour Semen Analysis with morphology to follow page 26

Gastrointestinal Pathogen Panel: Enteric Organism Rapid Detection Bacterial, Viral and Parasitic Infection by Real-Time PCR Multiplex page 44

This is a qualitatative molecular multiplex diarrhoea test intended for the simultaneous detection and identification of multiple gastrointestinal pathogens including bacteria, viruses, and parasites. Because the symptoms from viral, bacterial and parasitic agents are often the same it is often difficult to differentiate them – hence 80% of all cases of diarrhoea are currently unidentified, and antibiotics are often inappropriately used.

This is the first panel available that is able to cover 15 major gastrointestinal pathogens in a single test:

15 PATHOGENS IN THE PANEL

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*
- *Cryptosporidium*

A culture is not included and a separate sample and request would need to be made for stool o/c/p and culture.

TDL UPDATES

HE4	Earlier Detection/Ovarian Cancer. HE4 has shown an increased sensitivity and specificity for detection of ovarian cancer over that of CA125 alone – **24 hour turnaround**.	**page 51**
CURT	Histamine Releasing Urticaria Test for detection of autoreactive urticaria.	**page 79**
HIV2	HIV-2 RNA by PCR.	**page 50**
STDX	The 2nd Gen assay reports each virus individually. The early detection PCR multiplex for HIV/HBC/HCV **now needs 10mls only of EDTA whole blood**.	**page 32**
VITD	Vitamin D (25 OH) **4 hour** turnaround.	**page 8**
CMV	Both Cytomegalovirus IgG and IgM **4 hour** turnaround.	**page 52**
TFAM	Toxoplasma IgG/IgM **4 hour** turnaround	**page 52**
SPER	Comprehensive Semen Analysis with a **4 hour** turnaround with the morphology to follow.	**page 26**
ALLE	All single allergens are now listed with their specific Phadia Code and by Category.	**page 83**
PAPT	HPV and Cervical Cytology: Combined reports.	**page 92**
BON2	Osteoporosis, Bone Screen (blood only by regular request).	**page 9**

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