

Information for pathology self-collection

# Pathology sample collection kits

Introducing TDLs range of pathology self-collection kits



The Doctors Laboratory (TDL) is the largest UK independent provider of routine and highly specialised diagnostic laboratory services to clinicians (GPs and specialists), hospitals, community health services, and their patients.





# Introduction

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The self-collection of pathology samples is growing to become an important part of our diagnostic services. Self-collection is utilised extensively across areas such as sexual health screening, wellness services, hospital pre-operative screening, and we have seen the extensive use of self-collection of respiratory sampling for the COVID-19 pandemic.

In each scenario, sample self-collection has enabled patients to collect samples at home, at a convenient time. The Royal Mail Tracked postal return systems across the UK have developed to facilitate fast and effective delivery of samples to the laboratory.

As part of the ongoing development of the TDL self-collection service the kit manufacture of the TDL Tiny™ and TDL Self-Collect range ensure that TDL is aligned to the developing regulatory requirements around ISO:13485 kit manufacture and UKCA and CE marking across the UK and EU.

This process has given TDL the opportunity to refine and improve the TDL self-collection kit range and we are pleased to provide details of the kits which are now available and pathology services they support.

All TDL Self-Collect samples are returned to accredited TDL laboratories who undertake the required testing.

**TDL kits are manufactured using high quality components and assembled within the UK, specifically using a quality system for medical device manufacture (ISO13485:2016).**



# Peace of mind

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The TDL Tiny™ capillary blood and TDL Self-Collect sample kits cover a wide range of diagnostic and screening tests. These sample collection kits are not at-home test kits. TDL kits facilitate samples to be collected at home and returned to the laboratory for testing using Royal Mail Tracked 24 postal service. Results are returned directly to the healthcare organisation, doctor or managing healthcare professional, not to the patient.

TDL Tiny™ blood samples can be combined with other TDL Self-Collect sample types (urine, stool and swabs). Tests with available UKCA marked kits are listed on page 5 and this range will be updated on a regular basis.

Different tests require varying amounts of sample volume, or special handling, which means that although certain tests can be carried out from capillary tubes, many tests simply cannot be achieved from these smaller sample volumes. Additionally, out of range, abnormal or positive test results should be confirmed with a confirmatory venous sample.

The TDL Tiny™ capillary blood collection kits are designed to collect samples from skin puncture using lancets. Sample type colour coded microtainers show the 600 microlitres upper fill line. Upon receipt in the laboratory these samples are centrifuged and provide a volume of c.250 – 300 microlitres of serum/plasma (depending on the tube type used).

Instructions for sample collection are enclosed in each collection kit. The most successful outcomes are collected by patients who give best attention to the instructions provided, and who collect blood drops sufficient to fill the microtainer tube(s) in their kit.

A completed request form, or specially provided tube labels must be returned with the collected sample. Results will always be sent to the requesting healthcare organisation, doctor or managing healthcare professional.

If you are new to this service, please email **UKCAkits@tdlpathology.com**

Your TDL account manager will discuss the service with you, and provide you with an order form that includes your Source Code.

For repeat bulk orders, please email a completed order form (ensuring that the form includes your Source Code) to **supplies@tdlpathology.com**.

## Quality is key

- **Components:** verified for the specific intended use of the kit and linked to the accredited tests performed in the laboratory.
- **Instructions:** monitored for ease of use, version controlled, with regular feedback for ongoing improvement.
- **Quality:** Management of technical files, regulatory submissions and manufactured to the required ISO:13485 medical device manufacturing standards.
- **Supply:** Assembled within the UK. Both individual kit fulfilment services and larger size kit orders are available.
- **Security:** Test kits are security sealed.
- **Accompanying information:** Request forms cannot be inserted into the sealed kits. An accompanying envelope (TDL will provide) or other clearly visible method must be sent with each kit to clearly display the request form.
- **Laboratory testing:** Verified diagnostic tests performed in an ISO:15189 accredited clinical laboratory



TDL's UKCA marked self-collection kits are made with all consideration given to quality standards, with sample testing undertaken in an ISO:15189 accredited clinical laboratory.



TDL's self-collection kits have an outer sleeve designed with product and regulatory information, tamper proof seal and tear-off strip.



# TDL's range of kits

## Respiratory virus PCR

KIT CODE	KIT TYPE	SAMPLE TYPE
KT293	Respiratory Virus Swab Collection Kit (2mL)	Oropharyngeal and Nasal swab

## Capillary blood

KIT CODE	KIT TYPE	SAMPLE TYPE
KT353	Capillary Blood Collection Kit (SST)	Capillary Blood (SST)
KT384	Capillary Blood Collection Kit (SST x2)	Capillary Blood (SST x2)
KT354	Capillary Blood Collection Kit (EDTA)	Capillary Blood (EDTA)
KT355	Capillary Blood Collection Kit (SST and EDTA)	Capillary Blood (SST and EDTA)
KT423	Capillary Blood Collection Kit (SST x 2 and EDTA)	Capillary Blood (SST x 2 and EDTA)

## Sexual health

KIT CODE	KIT TYPE	SAMPLE TYPE
KT356	Sexual Health Collection Kit (Urine)	Aptima Urine
KT357	Sexual Health Collection Kit (Vaginal)	Aptima multisite swab
KT358	Sexual Health Collection Kit (Blood and Vaginal)	Capillary Blood and Aptima multisite swab
KT359	Sexual Health Collection Kit (Throat and Rectal)	Aptima multisite swabs
KT360	Sexual Health Collection Kit (Blood and Urine)	Capillary Blood and Aptima Urine
KT361	Sexual Health Collection Kit (Blood, Urine, Throat and Rectal - MSM)	Capillary Blood, Aptima Urine and Aptima multisite swabs
KT424	Sexual Health Collection Kit (Blood, Vaginal, Throat and Rectal)	Capillary blood and Aptima multisite swabs
KT404	Sexual Health Collection Kit (Oral lesion)	Oral swab
KT405	Sexual Health Collection Kit (Genital lesion)	Genital swab
KT421	Sexual Health Collection Kit (Urine, Throat and Rectal - MSM)	Aptima urine and multisite swabs
KT425	Sexual Health Collection Kit (Throat)	Aptima multisite swab
KT426	Sexual Health Collection Kit (Rectal)	Aptima multisite swab
KT428	Sexual Health Collection Kit (Vaginal, Throat and Rectal)	Aptima multisite swabs

## Microbial/Viral screening

KIT CODE	KIT TYPE	SAMPLE TYPE
KT364	HPV Swab Collection Kit	Qvintip swab
KT365	MRSA Collection Kit (Nose and Groin)	Purple liquid Amies swab x2
KT422	MRSA Collection Kit (Nose, Groin and Axilla)	Purple liquid Amies swab x3
KT366	GBS Collection Kit (Vaginal and Rectal)	Blue gel Amies swab x2
KT385	Urinalysis Collection Kit (Chemistry and microscopy)	Urine (Universal)

## Gastrointestinal

KIT CODE	KIT TYPE	SAMPLE TYPE
KT362	QFIT Collection Kit	QFIT faecal collection tube
KT363	Faecal Collection Kit	Universal faecal container

# TDL test repertoire by specialty

Allergy					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>ALEX<sup>2</sup> Allergy Test</b>	ALEX	<b>B</b> (TDL Tiny)	3-4 days	No special instructions	KT353
The ALEX <sup>2</sup> test allows for IgE multiplexing of c300 allergens (extracts and molecular allergens) from a small volume serum sample. The panel includes pollen, mites, cat and dog fur, insect venoms, moulds and yeasts, food or latex, supplemented with total IgE.					
<b>Allergy - Individual Allergens</b>	ALLE	<b>B</b> (TDL Tiny)	2 days	Specify allergen.	KT353
<b>ISAC Panel</b>	ISAC	<b>B</b> (TDL Tiny)	3 days	No special instructions	KT353
Simultaneous measurement in a single test of specific antibodies to more than 100 allergen components from more than 50 preselected allergen sources.					
Biochemistry					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Amylase</b>	AMY	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Antimullerian Hormone (AMH Plus)</b>	AMH	<b>B</b> (TDL Tiny)	1 day	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.	KT353
<b>C Reactive Protein</b>	CRP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>C Reactive Protein (High Sensitivity)</b>	HCRP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Calcium</b>	CA	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Calcium + Vitamin D</b>	CALD	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Elastase, Faecal</b>	ELAS	Universal faecal container	5 days	No special instructions	KT363
<b>Ferritin</b>	FERR	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>HbA1c</b>	GHB	<b>A</b> (TDL Tiny)	1 day	No special instructions	KT354
<b>Iron (TIBC included)</b>	FE	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Iron Status Profile</b>	ISP	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
Iron, Total Iron Binding Capacity, Ferritin, Transferrin Saturation					
<b>Lipase</b>	LIPA	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Lipid Profile</b>	LIPP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
Triglycerides, Cholesterol, HDL Cholesterol, LDL Cholesterol, Non-HDL Cholesterol					
<b>Lipoprotein (a)</b>	LPOA	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Liver Function Tests</b>	LFT	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
Bilirubin, ALT, AST, Total Protein, Alkaline Phos, Albumin, Globulin, Gamma-GT					



## TDL test repertoire by specialty

Please post self-collected samples on the same day they are taken, avoid posting over weekends and bank holidays.

PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Uric Acid (Serum)</b>	UA	B (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Vitamin B12 (Active)</b>	B12	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Vitamin D (25-OH)</b>	VITD	B (TDL Tiny)	1 day	No special instructions	KT353

### Endocrinology

PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Antimullerian Hormone (AMH Plus)</b>	AMH	B (TDL Tiny)	1 day	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.	KT353
<b>Cortisol</b>	CORT	B (TDL Tiny)	1 day	TAT from time of receipt in the laboratory.	KT353
<b>DHEA Sulphate</b>	DHEA	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Female Hormone Profile</b> LH, FSH, Prolactin, Oestradiol (17-Beta)	FIP	B (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Free T3</b>	FT3	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Free T4</b>	FT4	B (TDL Tiny)	1 day	No special instructions	KT353
<b>FSH</b>	FSH	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Luteinising Hormone</b>	LH	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Oestradiol (E2)</b>	OEST	B (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Progesterone</b>	PROG	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Prolactin</b>	PROL	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Sex Hormone Binding Globulin</b>	SHBG	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Testosterone</b>	TEST	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Thyroid Profile 1</b> FT4, TSH	TF	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Thyroid Profile 3</b> FT3, FT4, TSH	TF3	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Thyroxine (T4)</b>	T4	B (TDL Tiny)	1 day	No special instructions	KT353
<b>TSH</b>	TSH	B (TDL Tiny)	1 day	No special instructions	KT353

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Immunology					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Calprotectin, Faecal</b>	CALP	Universal faecal container	5 days	No special instructions	KT363
<b>Endomysial Antibodies (IgA)</b>	AEAB	<b>B</b> (TDL Tiny)	2 days	No special instructions	KT353
<b>Gliadin Antibodies (IgG) (deamidated)</b>	AGAB	<b>B</b> (TDL Tiny)	2 days	No special instructions	KT353
<b>Syphilis IgG/IgM</b>	TSYP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Tissue Transglutaminase IgA (Coeliac)**</b>	TAA	<b>B</b> (TDL Tiny)	2 days		KT353

\*\* If Tissue Transglutaminase (TAA) is regulated and is LOW (<0.1U/ml) total IgA will be reflexed. If total IgA is low (<0.1g/L) deamidated gliadin IgG will be reflexed. If Tissue Transglutaminase (TAA) is HIGH (>10 U/ml), endomysial IgA will be reflexed as confirmatory test.

Viral Serology					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Hepatitis B Immunity (IgG)</b>	THBI	<b>B</b> (TDL Tiny)	1 Day		
<b>Hepatitis B Surface Antigen</b>	THBA	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Hepatitis C Antibodies</b>	THCV	<b>B</b> (TDL Tiny)	1 Day		KT353
<b>HIV 1 &amp; 2 Abs/p24Ag</b>	THIV	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353

Tumour markers					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>CA 125</b>	C125	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Prostate Specific Antigen (Total)</b>	PSPA	<b>B</b> (TDL Tiny)	1 day	No special instructions.	KT353

Lifestyle					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Omega 3/Omega 6</b>	OMG3	<b>A</b> (TDL Tiny)	4 days	No special instructions.	KT354
<b>Vitamin B9 (Folic acid) - Serum</b>	FOLA	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Vitamin B12 (Active)</b>	B12	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Vitamin D (25-OH)</b>	VITD	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353

COVID-19					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>COVID-19 (SARS-CoV-2) RNA by PCR</b>	NCOV	Throat and nose swab	48 hours	Contact Laboratory	KT293
<b>COVID-19 (SARS-CoV-2) Roche Elecsys Anti-SARS-CoV-2 S (SPIKE)</b>	SCOV	<b>B</b> (TDL Tiny)	24 hours	No special instructions.	KT353

## TDL test repertoire by specialty

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PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>COVID-19 (SARS-CoV-2) Roche Elecsys Anti-SARS-CoV-2 Total Antibody</b>	TCOV	<b>B</b> (TDL Tiny)	24 hours	No special instructions	KT353
<b>Sexual health</b>					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>7 STI Profile by PCR (7 tests from 1 Sample)</b>	DL12	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
Chlamydia trachomatis, Neisseria gonorrhoea, Mycoplasma genitalium, Ureaplasma species, Trichomonas vaginalis, Gardnerella vaginalis, Herpes Simplex I/II					
<b>Chlamydia/Gonorrhoea - Rectal</b>	RSCG	Aptima multisite swab	2 days	No special instructions	KT426
<b>Chlamydia/Gonorrhoea - Throat</b>	TSCG	Aptima multisite swab	2 days	No special instructions	KT425
<b>Chlamydia/Gonorrhoea - Urine</b>	CCG	Aptima urine	2 days	No special instructions	KT356
<b>Chlamydia/Gonorrhoea - Vaginal</b>	SCG	Aptima multisite swab	2 days	No special instructions	KT357
<b>DL12 7 STI Profile by PCR (7 PCR tests from 1 Sample)</b>	DL12	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
Chlamydia trachomatis, Neisseria gonorrhoea, Mycoplasma genitalium, Ureaplasma species, Trichomonas vaginalis, Gardnerella vaginalis, Herpes Simplex I/II					
<b>Herpes Simplex (HSV) 1 &amp; 2 - Oral lesion</b>	HERS	Aptima multisite swab	5 days	No special instructions	KT404
<b>Herpes Simplex (HSV) 1 &amp; 2 - Genital lesion</b>	HERS	Aptima multisite swab	5 days	No special instructions	KT405
<b>HIV 1 &amp; 2 Abs/p24Ag</b>	THIV	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Lymphogranuloma Venerium (LGV) - Rectal*</b>	LGVP	Aptima multisite swab	1-2 weeks	* This test can be configured to be automatically reflexed as required.	KT426
<b>Monkeypox Virus - Lesion</b>	MPXV	Aptima multisite swab	2-3 days	No special instructions	KT405
<b>Mycoplasma genitalium Detection - Urine or Vaginal</b>	MGEN	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
<b>Mycoplasma genitalium Resistance - Urine or Vaginal*</b>	MGR	Aptima urine or multisite swab	2 days	* This test can be configured to be automatically reflexed as required.	KT356 or KT357
<b>STI Profile by PCR (7 tests from 1 Sample)</b>	DL12	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
Chlamydia trachomatis, Neisseria gonorrhoea, Mycoplasma genitalium, Ureaplasma species, Trichomonas vaginalis, Gardnerella vaginalis, Herpes Simplex I/II					
<b>Syphilis IgG/IgM</b>	TSYP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Trichomonas Vaginalis (TV) - Urine or Vaginal</b>	TVPC	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357

Ensure all specimens and forms are labelled with given Forename, Surname, DOB, Date and Time of collection. Turnaround times are quoted as working days from receipt in the laboratory.



## TDL test repertoire by specialty

Please post self-collected samples on the same day they are taken, avoid posting over weekends and bank holidays.

Microbiology					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Group B Strep - Vaginal and Rectal</b>	GBSX	Blue gel Amies swab x2	3-5 days	No special instructions	KT366
<b>MRSA Culture - Nose/Groin</b>	MRW2	Purple liquid Amies swab x2	2 days	No special instructions	KT365
<b>MRSA Culture - Nose/Groin/Axilla</b>	MRW3	Purple liquid Amies swab x3	2 days	No special instructions	KT422
<b>MRSA PCR - Nose/Groin</b>	MRS2	Purple liquid Amies swab x2	1 day	No special instructions	KT365
<b>MRSA PCR - Nose/Groin/Axilla</b>	MRS3	Purple liquid Amies swab x3	1 day	No special instructions	KT422
<b>Urine Chemistry and Microscopy</b>	UMIC	Urine (Universal)	1-2 days	Mid-stream urine.	KT385
<b>Urine Chemistry, Microscopy and Culture</b>	UCEM	Urine (Universal)	1-2 days	Mid-stream urine.	KT385

Virology					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>COVID-19 (SARS-CoV-2) RNA by PCR</b>	NCOV	Throat and nose swab	48 hours	Contact Laboratory	KT293
<b>Herpes Simplex (HSV) 1 &amp; 2 - Oral lesion</b>	HERS	Aptima multisite swab	5 days	No special instructions	KT404
<b>Herpes Simplex (HSV) 1 &amp; 2 - Genital lesion</b>	HERS	Aptima multisite swab	5 days	No special instructions	KT405
<b>HPV Individually Typed High Risk DNA Subtypes</b>	HPVZ	Qvintip vaginal swab	10 days	No special instructions	KT364
<b>HPV mRNA (All High Risk Subtypes)</b>	HPVY	Qvintip vaginal swab	3 days	No special instructions	KT364
<b>Monkeypox Virus - Lesion</b>	MPXV	Aptima multisite swab	2-3 days	No special instructions	KT405
<b>Respiratory PCR Panel (COVID-19, Flu A/B and RSV)</b>	FLU4	Throat and nose swab	2 days	No special instructions.	KT293

Flu A, Flu B, Respiratory Syncytial Virus (RSV), COVID-19

## TDL test repertoire by specialty

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Gastrointestinal					
PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>Calprotectin, Faecal</b>	CALP	Universal faecal container	5 days	No special instructions	KT363
<b>Elastase, Faecal</b>	ELAS	Universal faecal container	5 days	No special instructions	KT363
<b>Gastrointestinal Pathogen PCR</b> Detection of Bacterial, Viral and Parasitic Infection by Multiplex Real-Time PCR	EORD	Universal faecal container	2 days	No special instructions	KT363
<b>H. pylori Antigen - Stool</b>	HBAG	Universal faecal container	3 days	No special instructions	KT363
<b>Quantitative Faecal Immunochemical Test (QFIT)</b>	QFIT	QFIT faecal collection tube	1 day	No special instructions	KT362

### Sample type guide

<b>A</b> (TDL Tiny)	Lavender Microtainer, EDTA anticoagulant, Top fill line: 400-500µL
<b>B</b> (TDL Tiny)	Gold Microtainer, SST, Top fill line: 400-600µL
<b>STM</b>	Orange/Blue swab for culture - swab in transport medium

We recommend that all healthcare organisations and healthcare professionals using our TDL Tiny™ and TDL Self-Collect kits are up to date with latest diagnostic testing guidelines and relevant updates, including but not limited to those published by:

- UKHSA Standards for Microbiology Investigations (SMI)
- British Association of Sexual Health and HIV Guidelines (BASHH)
- Royal College of Obstetrics and Gynaecology Guidelines (RCOG)
- NICE Evidence-based recommendations on faecal immunochemical tests (DG30)
- British Society of Haematology Evidence Based Guidance (BSH)
- Association of Clinical Biochemistry (ACB)

# TDL test repertoire A-Z

PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>7 STI Profile by PCR (7 tests from 1 Sample)</b>	DL12	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
Chlamydia trachomatis, Neisseria gonorrhoea, Mycoplasma genitalium, Ureaplasma species, Trichomonas vaginalis, Gardnerella vaginalis, Herpes Simplex I/II					
<b>ALEX<sup>2</sup> Allergy Test</b>	ALEX	<b>B</b> (TDL Tiny)	3-4 days	No special instructions	KT353
The ALEX <sup>2</sup> test allows for IgE multiplexing of c300 allergens (extracts and molecular allergens) from a small volume serum sample. The panel includes pollen, mites, cat and dog fur, insect venoms, moulds and yeasts, food or latex, supplemented with total IgE.					
<b>Allergy - Individual Allergens</b>	ALLE	<b>B</b> (TDL Tiny)	2 days	Specify allergen.	KT353
<b>Amylase</b>	AMY	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Antimullerian Hormone (AMH Plus)</b>	AMH	<b>B</b> (TDL Tiny)	1 day	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.	KT353
<b>C Reactive Protein</b>	CRP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>C Reactive Protein (High Sensitivity)</b>	HCRP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>CA 125</b>	C125	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Calcium</b>	CA	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Calcium + Vitamin D</b>	CALD	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Calprotectin, Faecal</b>	CALP	Universal faecal container	5 days	No special instructions	KT363
<b>Chlamydia/Gonorrhoea - Rectal</b>	RSCG	Aptima multisite swab	2 days	No special instructions	KT426
<b>Chlamydia/Gonorrhoea - Throat</b>	TSCG	Aptima multisite swab	2 days	No special instructions	KT425
<b>Chlamydia/Gonorrhoea - Urine</b>	CCG	Aptima urine	2 days	No special instructions	KT356
<b>Chlamydia/Gonorrhoea - Vaginal</b>	SCG	Aptima multisite swab	2 days	No special instructions	KT357
<b>Cortisol</b>	CORT	<b>B</b> (TDL Tiny)	1 day	TAT from time of receipt in the laboratory.	KT353
<b>COVID-19 (SARS-CoV-2) RNA by PCR</b>	NCOV	Throat and nose swab	48 hours	Contact Laboratory	KT293
<b>COVID-19 (SARS-CoV-2) Roche Elecsys Anti-SARS-CoV-2 S (SPIKE)</b>	SCOV	<b>B</b> (TDL Tiny)	24 hours	No special instructions.	KT353
<b>COVID-19 (SARS-CoV-2) Roche Elecsys Anti-SARS-CoV-2 Total Antibody</b>	TCOV	<b>B</b> (TDL Tiny)	24 hours	No special instructions	KT353
<b>DHEA Sulphate</b>	DHEA	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353



## TDL test repertoire A-Z

Please post self-collected samples on the same day they are taken, avoid posting over weekends and bank holidays.

PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>DL12 7 STI Profile by PCR (7 PCR tests from 1 Sample)</b> Chlamydia trachomatis, Neisseria gonorrhoea, Mycoplasma genitalium, Ureaplasma species, Trichomonas vaginalis, Gardnerella vaginalis, Herpes Simplex I/II	DL12	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
<b>Elastase, Faecal</b>	ELAS	Universal faecal container	5 days	No special instructions	KT363
<b>Endomysial Antibodies (IgA)</b>	AEAB	B (TDL Tiny)	2 days	No special instructions	KT353
<b>Female Hormone Profile</b> LH, FSH, Prolactin, Oestradiol (17-Beta)	FIP	B (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Ferritin</b>	FERR	B (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Free T3</b>	FT3	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Free T4</b>	FT4	B (TDL Tiny)	1 day	No special instructions	KT353
<b>FSH</b>	FSH	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Gastrointestinal Pathogen PCR</b> Detection of Bacterial, Viral and Parasitic Infection by Multiplex Real-Time PCR	EORD	Universal faecal container	2 days	No special instructions	KT363
<b>Gliadin Antibodies (IgG) (deamidated)</b>	AGAB	B (TDL Tiny)	2 days	No special instructions	KT353
<b>Group B Strep - Vaginal and Rectal</b>	GBSX	Blue gel Amies swab x2	3-5 days	No special instructions	KT366
<b>H. pylori Antigen - Stool</b>	HBAG	Universal faecal container	3 days	No special instructions	KT363
<b>HbA1c</b>	GHB	A (TDL Tiny)	1 day	No special instructions	KT354
<b>Hepatitis B Immunity (IgG)</b>	THBI	B (TDL Tiny)	1 Day		
<b>Hepatitis B Surface Antigen</b>	THBA	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Hepatitis C Antibodies</b>	THCV	B (TDL Tiny)	1 Day		KT353
<b>Herpes Simplex (HSV) 1 &amp; 2 - Genital lesion</b>	HERS	Aptima multisite swab	5 days	No special instructions	KT405
<b>Herpes Simplex (HSV) 1 &amp; 2 - Oral lesion</b>	HERS	Aptima multisite swab	5 days	No special instructions	KT404
<b>HIV 1 &amp; 2 Abs/p24Ag</b>	THIV	B (TDL Tiny)	1 day	No special instructions	KT353
<b>HPV Individually Typed High Risk DNA Subtypes</b>	HPVZ	Qvintip vaginal swab	10 days	No special instructions	KT364
<b>HPV mRNA (All High Risk Subtypes)</b>	HPVY	Qvintip vaginal swab	3 days	No special instructions	KT364
<b>Iron (TIBC included)</b>	FE	B (TDL Tiny)	1 day	No special instructions	KT353
<b>Iron Status Profile</b> Iron, Total Iron Binding Capacity, Ferritin, Transferrin Saturation	ISP	B (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353

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## TDL test repertoire A-Z

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PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>ISAC Panel</b> Simultaneous measurement in a single test of specific antibodies to more than 100 allergen components from more than 50 preselected allergen sources.	ISAC	<b>B</b> (TDL Tiny)	3 days	No special instructions	KT353
<b>Lipase</b>	LIPA	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Lipid Profile</b> Triglycerides, Cholesterol, HDL Cholesterol, LDL Cholesterol, Non-HDL Cholesterol	LIPP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Lipoprotein (a)</b>	LPOA	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Liver Function Tests</b> Bilirubin, ALT, AST, Total Protein, Alkaline Phos, Albumin, Globulin, Gamma-GT	LFT	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Luteinising Hormone</b>	LH	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Lymphogranuloma Venerium (LGV) - Rectal*</b>	LGVP	Aptima multisite swab	1-2 weeks	* This test can be configured to be automatically reflexed as required.	KT426
<b>Monkeypox Virus - Lesion</b>	MPXV	Aptima multisite swab	2-3 days	No special instructions	KT405
<b>MRSA Culture - Nose/Groin</b>	MRW2	Purple liquid Amies swab x2	2 days	No special instructions	KT365
<b>MRSA Culture - Nose/Groin/Axilla</b>	MRW3	Purple liquid Amies swab x3	2 days	No special instructions	KT422
<b>MRSA PCR - Nose/Groin</b>	MRS2	Purple liquid Amies swab x2	1 day	No special instructions	KT365
<b>MRSA PCR - Nose/Groin/Axilla</b>	MRS3	Purple liquid Amies swab x3	1 day	No special instructions	KT422
<b>Mycoplasma genitalium Detection - Urine or Vaginal</b>	MGEN	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
<b>Mycoplasma genitalium Resistance - Urine or Vaginal*</b>	MGR	Aptima urine or multisite swab	2 days	* This test can be configured to be automatically reflexed as required.	KT356 or KT357
<b>Oestradiol (E2)</b>	OEST	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Omega 3/Omega 6</b>	OMG3	<b>A</b> (TDL Tiny)	4 days	No special instructions.	KT354
<b>Progesterone</b>	PROG	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Prolactin</b>	PROL	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Prostate Specific Antigen (Total)</b>	PSPA	<b>B</b> (TDL Tiny)	1 day	No special instructions.	KT353
<b>Quantitative Faecal Immunochemical Test (QFIT)</b>	QFIT	QFIT faecal collection tube	1 day	No special instructions	KT362
<b>Respiratory PCR Panel (COVID-19, Flu A/B and RSV)</b> Flu A, Flu B, Respiratory Syncytal Virus (RSV), COVID-19	FLU4	Throat and nose swab	2 days	No special instructions.	KT293
<b>Sex Hormone Binding Globulin</b>	SHBG	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353

## TDL test repertoire A-Z

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PROFILE	CODE	SAMPLE REQS	TAT	SPECIAL INSTRUCTIONS	KIT CODE
<b>STI Profile by PCR (7 tests from 1 Sample)</b>	DL12	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
Chlamydia trachomatis, Neisseria gonorrhoea, Mycoplasma genitalium, Ureaplasma species, Trichomonas vaginalis, Gardnerella vaginalis, Herpes Simplex I/II					
<b>Syphilis IgG/IgM</b>	TSYP	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Testosterone</b>	TEST	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Thyroid Profile 1</b>	TF	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
FT4, TSH					
<b>Thyroid Profile 3</b>	TF3	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
FT3, FT4, TSH					
<b>Thyroxine (T4)</b>	T4	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Tissue Transglutaminase IgA (Coeliac)**</b>	TAA	<b>B</b> (TDL Tiny)	2 days		KT353
** If Tissue Transglutaminase (TAA) is regulated and is LOW (<0.1U/ml) total IgA will be reflexed. If total IgA is low (<0.1g/L) deamidated gliadin IgG will be reflexed. If Tissue Transglutaminase (TAA) is HIGH (>10 U/ml), endomysial IgA will be reflexed as confirmatory test.					
<b>Trichomonas Vaginalis (TV) - Urine or Vaginal</b>	TVPC	Aptima urine or multisite swab	2 days	No special instructions	KT356 or KT357
<b>TSH</b>	TSH	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Uric Acid (Serum)</b>	UA	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Urine Chemistry and Microscopy</b>	UMIC	Urine (Universal)	1-2 days	Mid-stream urine.	KT385
<b>Urine Chemistry, Microscopy and Culture</b>	UCEM	Urine (Universal)	1-2 days	Mid-stream urine.	KT385
<b>Vitamin B9 (Folic acid) - Serum</b>	FOLA	<b>B</b> (TDL Tiny)	1 day	Sample integrity may be compromised on received samples older than 48 hours.	KT353
<b>Vitamin B12 (Active)</b>	B12	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353
<b>Vitamin D (25-OH)</b>	VITD	<b>B</b> (TDL Tiny)	1 day	No special instructions	KT353

### Sample type guide

<b>A</b> (TDL Tiny)	Lavender Microtainer, EDTA anticoagulant, Top fill line: 400–500µL
<b>B</b> (TDL Tiny)	Gold Microtainer, SST, Top fill line: 400–600µL
<b>STM</b>	Orange/Blue swab for culture – swab in transport medium

We recommend that all healthcare organisations and healthcare professionals using our TDL Tiny™ and TDL Self-Collect kits are up to date with latest diagnostic testing guidelines and relevant updates, including but not limited to those published by:

- UKHSA Standards for Microbiology Investigations (SMI)
- British Association of Sexual Health and HIV Guidelines (BASHH)
- Royal College of Obstetrics and Gynaecology Guidelines (RCOG)
- NICE Evidence-based recommendations on faecal immunochemical tests (DG30)
- British Society of Haematology Evidence Based Guidance (BSH)
- Association of Clinical Biochemistry (ACB)

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# Additional information

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## Distribution

TDL's UKCA marked kits are registered with the MHRA and for distribution in the UK only. Kits required for distribution to Northern Ireland (NI) and the European Union (EU) would need to be CE marked under European legislation and are required to be registered with the Competent Authority responsible for each territory. This is a requirement for both direct, distributed and online sales. Any requirements for distribution to other non-EU territories should consider and follow the required medical device legislation on a region by region basis.

As part of TDL's distribution to clients or direct fulfilment to patients, TDL will keep a record of kit lot number. In the event of a faulty component and the need for a product recall this provides full traceability of kits and their respective components. Clients performing their own fulfilment distribution are required to manage their own onward lot number traceability.

## Transport Compliance

TDL's kits utilise primary, secondary and outer packaging combinations which are compliant with UN3373, PI650 and ADR transport regulations, including pressure test compliance to 95KPa.

## Multi-lingual translations

In the UK depending on the region of operation, it may be necessary to provide kits with a language translation. Consideration should be given to ethnic minority communities where English is not a first language and translation may help to support sample collection.

In addition, in particular for UK devolved nations where there is active legislation across public bodies to ensure the ongoing protection and use of local languages (the Welsh Language Act 1993 and Welsh Language Measure 2011).

If kit distribution is required within the EU, there is a requirement for the translation of labelling, instructions for use, packaging and user manuals into their designated language(s). Typically, sections of documentation and critical information related to safety must be translated.

## Warnings and precautions

As part of each kit's instructions for use there is a warnings and precautions section which details important information for both the managing healthcare organisation and healthcare professional, and the end patient user. This includes relevant safety information, contraindications for use and laboratory acceptance criteria. Please familiarise yourself with the warning and precautions section of the relevant kits.

## Envelope for request form and additional information

TDL will provide with each kit an 'Important Documents' envelope. This envelope will primarily be used to contain the patient's request form. If any further documentation is offered such as client-specific instructions for online kit activation, it can be provided to TDL to be included in this envelope at the fulfilment stage.

## Sustainability

The Doctors Laboratory, as part of Sonic Healthcare's global network of diagnostic laboratories are committed to reducing carbon emissions, waste and investing in renewable energy. Underpinning social and environmental sustainability is a strong corporate governance framework and a culture of Medical Leadership that promotes integrity and ethical behaviour.

Sustainability within our TDL Self-Collect range is important to us and an area for continuous review and improvement. Our self-collect kit boxes are manufactured from a mixture of recycled corrugated paperboard with a virgin outer layer and our kit boxes and sleeves are fully recyclable and use water based inks. TDL's biological waste is disposed using regulated pathways for medical waste management.



The Doctors Laboratory  
The Halo Building  
1 Mabledon Place  
London  
WC1H 9AX

T +44 (0)20 7307 7373  
E [tdl@tdlpathology.com](mailto:tdl@tdlpathology.com)  
[www.tdlpathology.com](http://www.tdlpathology.com)