

Information for pathology self-collection

# **Pathology sample** collection kits

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Introducing TDLs range of pathology self-collection kits

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Carl Crass

From October 2024

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HPV COLLECTION KIT

SEXUAL HEALTH COLLECTION KIT

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# Introduction

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The TDL Self-Collect range of testing has been gathering increased and important attention for healthcare services. Self-collection is being adopted across different target areas of healthcare: sexual health screening, wellness testing, genetic conditions, lifestyle review, pre-operative work ups, etc. Self-collection sampling allows patients to collect samples at home, and together with Royal Mail Tracked postal returns, facilitates safe and effective delivery of samples throughout the UK to the laboratory.

As part of the ongoing development of the TDL selfcollection service, the sample collection kits ensure that TDL is aligned to regulatory requirement around ISO:13485 kit manufacture and UKCA marking across the UK. This requirement for UKCA marked kits also addresses the need for clinically approved stability and comparative performance. The interest being generated for this service ensures best attention, continued development, with regular review of the repertoire, and where possible more tests will be added to the available Self-Collection list. TDL kits are manufactured using high quality components and assembled within the UK, specifically using a quality system for medical device manufacture (ISO13485:2016). The TDL Self-Collect capillary blood and sample kits include a helpful range of diagnostic and screening tests. These sample collection kits are not home test kits that provide an immediate result for the patient. Samples collected at home are all returned to the laboratory for testing, using Royal Mail Tracked 24 postal services. Results are returned directly to the healthcare organisation, doctor or healthcare professional – not to the patient. Self-Collect kits need to be UKCA marked (or dual marked with UKCA/CE) to represent the product claims that kits are being used for the collection of samples in a non-clinic setting.

The Self-Collect kit itself allows for combinations of sample types (urine, stool, swabs) – and the range of UKCA marked kits are listed on page 2. Instructions for sample collection are enclosed in each collection kit. The best results are obtained by patients who closely follow the instructions that are provided, and by collecting enough blood drops to sufficiently fill the microtainer tube(s) in their kit. A request form or specially provided tube label must be returned with the collected sample. It is exciting that the scope of this service, together with its performance and quality standards, will be revised, developed, and updated on a regular basis.

For more details relating to this service, please email UKCAkits@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

We recommend that all healthcare organisations and healthcare professionals using our TDL Tiny<sup>™</sup> 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's range of kits**

### **Respiratory virus PCR**

## KIT CODE KIT TYPE KT293 Respiratory Virus Swab Collection Kit (2mL)

Oropharyngeal and Nasal swab

SAMPLE TYPE

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KIT CODE	КІТ ТҮРЕ	SAMPLE TYPE
KT353	Capillary Blood Collection Kit (SST)	Capillary blood (SST)
KT354	Capillary Blood Collection Kit (EDTA)	Capillary blood (EDTA)
KT466	Capillary Blood Collection Kit (Plain Red)	Capillary blood (Plain)
KT384	Capillary Blood Collection Kit (SST x2)	Capillary blood (SST x 2)
KT355	Capillary Blood Collection Kit (SST and EDTA)	Capillary blood (SST and EDTA)
KT423	Capillary Blood Collection Kit (SST x2 and EDTA)	Capillary blood (SST x 2 and EDTA)
KT445	Capillary Blood Collection Kit (Plain Red and SST)	Capillary blood (Plain and SST)

### **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 swab x2
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 swab x2
KT424	Sexual Health Collection Kit (Blood, Vaginal, Throat and Rectal)	Capillary blood and Aptima multisite swab x3
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 swab x2
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 swab x3
KT429	Sexual Health Collection Kit (Blood, Urine, Vaginal, Throat and Rectal)	Capillary blood, Aptima urine and Aptima multisite swab x3

## **Culture/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 x 2
KT422	MRSA Collection Kit (Nose, Groin and Axilla)	Purple liquid Amies swab x 3
KT366	GBS Collection Kit (Vaginal and Rectal)	Blue gel Amies swab x 2
KT441	Vaginitis Collection Kit (Vaginal – Culture and PCR)	Aptima multisite swab and Blue gel Amies swab
KT385	Urinalysis Collection Kit (Chemistry and Microscopy)	Urine (Universal)
KT386	Urinalysis Collection Kit (Chemistry, Microscopy and Culture)	Urine (Universal & Boric)

### Gastrointestinal

KIT CODE	КІТ ТҮРЕ	SAMPLE TYPE
KT362	QFIT Collection Kit	QFIT sample collection device
KT363	Faecal Collection Kit	Stool/faecal container
KT430	Faecal Collection Kit (QFIT and Stool x2)	QFIT sample collection device and stool/faecal container x2

# **TDL test repertoire A-Z**

TEST	CODE	SAMPLE REQS	TAT	KIT CODE
7 STI Profile by PCR (7 tests from 1 Sample)	DL12	Aptima urine or multisite swab	2 days	KT356 or KT357
ALEX <sup>2</sup> Allergy Test 300 allergen panel, from single sample, supplemented by Total IgE, which includes pollens, mites, cat and dog, fur, insect venoms, moulds, yeasts, food and latex.	ALEX	(TDL Tiny)	3-4 days	KT353
Amenorrhoea Profile (LH, FSH, PROL, TEST, TOES, SHBG, FAI) CHANGE LH, FSH, PROL, TEST, TOES and SHBG now also available individually from a (F) (TDL Tiny) sample.	TAME	(TDL Tiny)	1 day	KT466
Amylase	AMY	(TDL Tiny)	1 day	KT353
Antimullerian Hormone (AMH)	AMH	(TDL Tiny) or (F) (TDL Tiny)	1 day	KT353 or KT466
Apolipoprotein A1 NEW	APOA	(TDL Tiny)	3 days	KT353
Apolipoprotein B NEW	APOB	(TDL Tiny)	3 days	KT353
C Reactive Protein	CRP	(TDL Tiny)	1 day	KT353
C Reactive Protein (High Sensitivity)	HCRP	(TDL Tiny)	1 day	KT353
CA 125	C125	(TDL Tiny)	1 day	KT353
Calprotectin	CALP	QFIT sample collection device	5 days	KT362 or KT430
Calprotectin/QFIT Profile (Combined)	QCAL	QFIT sample collection device	5 days	KT362 or KT430
Carbohydrate Deficient Transferrin (CDT)	CDT	(TDL Tiny)	3 days	KT353
Chlamydia/Gonorrhoea – Rectal	RSCG	Aptima multisite swab	2 days	KT426
Chlamydia/Gonorrhoea – Throat	TSCG	Aptima multisite swab	2 days	KT425
Chlamydia/Gonorrhoea – Urine	CCG	Aptima urine	2 days	KT356
Chlamydia/Gonorrhoea – Vaginal	SCG	Aptima multisite swab	2 days	KT357
Cortisol	CORT	(TDL Tiny)	1 day	KT353
COVID-19 (SARS-CoV-2) RNA by PCR Contact Laboratory.	NCOV	Aptima multisite swab of nose/throat	1 day	KT293
COVID-19 (SPIKE) Antibodies	SCOV	(TDL Tiny)	1 day	KT353
Creatinine (including eGFR)	CREA	(TDL Tiny)	1 day	KT353
DHEA Sulphate	DHEA	(TDL Tiny) or (F) (TDL Tiny)	1 day	KT353 or KT466
DL12 7 STI Profile by PCR (7 PCR tests from 1 Sample)	DL12	Aptima urine or multisite swab	2 days	KT356 or KT357
Elastase	ELAS	Stool/faecal container	5 days	KT363
Enteric Organism Rapid Detection	EORD	Stool/faecal container	2 days	KT363 or KT430
Female Hormone Profile (LH, FSH, PROL, TOES)	TFIP	(TDL Tiny) and (TDL Tiny)	1 day	KT445
Ferritin	FERR	(TDL Tiny)	1 day	KT353
Free T3	FT3	(TDL Tiny)	1 day	KT353
Free T4	FT4	(TDL Tiny)	1 day	KT353
FSH	FSH	(TDL Tiny) or () (TDL Tiny)	1 day	KT353 or KT466
Full Blood Count* (Haemoglobin, White Cell Count, Red Cell Count, Platelets) NEW *Mix sample on collection.	TFBC	(TDL Tiny)	1 day	KT354
Gastrointestinal Pathogen Profile by PCR	EORD	Stool/faecal container	2 days	KT363 or KT430
Gliadin Antibodies (IgG) (deamidated)	AGAB	(TDL Tiny)	2 days	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.

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TEST Group B Strep – Vaginal and Rectal	GBSX	SAMPLE REQS	TAT	KIT CODE KT366
	HBAG	Blue gel Amies swab x2 Stool/faecal container	3-5 days	
H. pylori Antigen – Stool HbA1c	GHB	-	3 days	KT363 or KT430
	-	(TDL Tiny)	1 day	KT354
HCG (Quantitative)	QHCG	(TDL Tiny)	1 day	KT353
Hepatitis B Immunity (IgG)	THBI	(TDL Tiny)	1 day	KT353
Hepatitis B Surface Antigen	THBA	B (TDL Tiny)	1 day	KT353
Hepatitis C Antibodies	THCV	B (TDL Tiny)	1 day	KT353
Hepatitis C Antigen (Early detection)	TCAG	B (TDL Tiny)	1 day	KT353
Herpes Simplex (HSV) 1 & 2 – Genital lesion	HERS	Aptima multisite swab	5 days	KT405
Herpes Simplex (HSV) 1 & 2 – Oral lesion	HERS	Aptima multisite swab	5 days	KT404
HIV 1 & 2 Abs/p24Ag	THIV	(TDL Tiny)	1 day	KT353
HPV (19 high risk DNA subtypes, reported as types 16, 18 or Others)	HPVY	Qvintip vaginal swab	3 days	KT364
HPV (Individually typed high risk DNA subtypes)	HPVZ	Qvintip vaginal swab	3 days	KT364
ISAC Panel 112 allergen panel from single sample which includes components from 48 preselected allergen sources	ISAC	(TDL Tiny)	3 days	KT353
Lipase	LIPA	(TDL Tiny)	1 day	KT353
Lipid Profile	LIPP	(TDL Tiny)	1 day	KT353
Lipoprotein (a)	LPOA	(TDL Tiny)	1 day	KT353
Liver Function Tests (Excluding AST)	TLFT	(TDL Tiny) and (TDL Tiny)	1 day	KT445
Luteinising Hormone (LH)	LH	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Lymphogranuloma Venerium (LGV) – Rectal	LGVP	Aptima multisite swab	1-2 weeks	KT426
* This test can be configured to be automatically reflexed as required.				
Menopausal Profile (FSH, LH, TOES, TSH, FT4)	TMEN	(TDL Tiny) and (TDL Tiny)	1 day	KT445
MPOX (Virus) – Lesion	MPXV	Aptima multisite swab	2 days	KT405
MRSA Culture	MRW2	Purple liquid Amies swab x2	2 days	KT365
MRSA Culture	MRW3	Purple liquid Amies swab x3	2 days	KT422
MRSA PCR	MRS2	Purple liquid Amies swab x2	1 day	KT365
MRSA PCR	MRS3	Purple liquid Amies swab x3	1 day	KT422
Mycoplasma genitalium by PCR – Urine and Vaginal	MGEN	Aptima urine or multisite swab	2 days	KT356 or KT357
Mycoplasma genitalium Resistance – Urine or Vaginal	MGR	Aptima urine or multisite swab	1-2 weeks	KT356 or KT357
Oestradiol-17-Beta	TOES	(TDL Tiny)	1 day	KT466
Omega 3/Omega 6	OMG3	(TDL Tiny)	5 days	KT354
PEth (Phosphatidylethanol)	PETH	(TDL Tiny)	5-7 days	KT354
PLAC Test (Lp-PLA2)	PLA2	(TDL Tiny)	2 days	KT353
Progesterone	PROG	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Prolactin	PROL	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Prostate Specific Antigen (Total)	PSPA	(TDL Tiny)	1 day	KT353
QFIT/Calprotectin Profile (Combined)	QCAL	QFIT sample collection device	5 days	KT362 or KT430

## **TDL test repertoire A-Z**

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

TEST	CODE	SAMPLE REQS	TAT	KIT CODE
Quantitative Faecal Immunochemical Test (QFIT)	QFIT	QFIT sample collection device	1 day	KT362 or KT430
Respiratory PCR Panel (COVID-19, Flu A/B and RSV)	FLU4	Aptima multisite swab of nose/throat	2 days	KT293
Selenium (Serum)	SELE	(TDL Tiny)	4 days	KT353
Sex Hormone Binding Globulin	SHBG	(TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
STI Profile by PCR (7 tests from 1 sample)	DL12	Aptima urine or multisite swab	2 days	KT356 or KT357
STI Profile: MSM1 (Blood + Urine/Throat/Rectal Swabs)	MSM1	(TDL Tiny) / Aptima Urine / Aptima multisite swab x 2	2 days	KT361
STI Profile: MSM2 (Blood + Urine/Throat/Rectal Swabs)	MSM2	(TDL Tiny) / Aptima urine / Aptima multisite swab x 2	3 days	KT361
Syphilis IgG/IgM	TSYP	(TDL Tiny)	1 day	KT353
Testosterone	TEST	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Testosterone (Free)	FTES	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	3 days	KT353 or KT466
Thyroid Abs (Thyroglobulin + Thyroid Peroxidase Abs)	THAB	(TDL Tiny)	2 days	KT353
Thyroid Profile 1 (FT4/TSH)	TF	(TDL Tiny)	1 day	KT353
Thyroid Profile 3 (FT3/FT4/TSH)	TF3	(TDL Tiny)	1 day	KT353
Tissue Transglutaminase IgA (Coeliac)	TAA	(TDL Tiny)	2 days	KT353
Trichomonas vaginalis (TV) – Urine or Vaginal	TVPC	Aptima urine or multisite swab	2 days	KT356 or KT357
Triple Swab Female STI Profile (Vaginal/Throat/Rectal Swabs)	3SWA	Aptima multisite swab x 3 (label by site)	2 days	KT428
TSH	TSH	(TDL Tiny)	1 day	KT353
Urea	UREA	(TDL Tiny)	1 day	KT353
Urea/Creatinine/eGFR	TCU	(TDL Tiny)	1 day	KT353
Urine Chemistry and Microscopy	UMIC	Urine (Universal). Mid stream.	1-2 days	KT385
Urine Chemistry, Microscopy and Culture	UCEM	Urine (Universal & Boric). Mid stream.	1-2 days	KT386
Vaginitis/BV Profile using Culture & PCR Swab	STD8	Aptima multisite swab and Blue gel Amies swab	3-5 days	KT441
Viral Respiratory RNA Screen by PCR	VPR	Aptima multisite swab of nose/throat	2 days	KT293
Vitamin B12 (Active)	B12	(TDL Tiny)	1 day	KT353
Vitamin D (25-OH)	VITD	(TDL Tiny)	1 day	KT353

Sample type guide

\land (TDL Tiny)	Lavender Microtainer, EDTA anticoagulant, Top fill line: 400-500µL
追 (TDL Tiny)	Gold Microtainer, SST, Top fill line: 400-600µL
🕞 (TDL Tiny)	Red Microtainer, Plain no additive, Top fill line: 500µL

Allergy				
TEST	CODE	SAMPLE REQS	TAT	KIT CODI
ALEX <sup>2</sup> Allergy Test 300 allergen panel, from single sample, supplemented by Total IgE, which includes pollens, mites, cat and dog, fur, insect venoms, moulds, yeasts, food and latex.	ALEX	(TDL Tiny)	3-4 days	KT353
ISAC Panel 112 allergen panel from single sample which includes components from 48 preselected allergen sources	ISAC	(TDL Tiny)	3 days	KT353
Biochemistry				
TEST	CODE	SAMPLE REQS	TAT	KIT COD
Amylase	AMY	(TDL Tiny)	1 day	KT353
Apolipoprotein A1 NEW	APOA	(TDL Tiny)	3 days	KT353
Apolipoprotein B NEW	APOB	(TDL Tiny)	3 days	KT35
C Reactive Protein	CRP	(TDL Tiny)	1 day	KT35
C Reactive Protein (High Sensitivity)	HCRP	(TDL Tiny)	1 day	KT35
Calprotectin	CALP	QFIT sample collection device	5 days	KT362 or KT43
Calprotectin/QFIT Profile (Combined)	QCAL	QFIT sample collection device	5 days	KT362 or KT43
Carbohydrate Deficient Transferrin (CDT)	CDT	(TDL Tiny)	3 days	KT35
Creatinine (including eGFR)	CREA	(TDL Tiny)	1 day	KT35
Elastase	ELAS	Stool/faecal container	5 days	KT36
Ferritin	FERR	(TDL Tiny)	1 day	KT35
HbA1c	GHB	(TDL Tiny)	1 day	KT35
Lipase	LIPA	(TDL Tiny)	1 day	KT35
Lipid Profile	LIPP	(TDL Tiny)	1 day	KT35
Lipoprotein (a)	LPOA	(TDL Tiny)	1 day	KT35
Liver Function Tests (Excluding AST)	TLFT	(TDL Tiny) and 🕒 (TDL Tiny)	1 day	KT44
PEth (Phosphatidylethanol)	PETH	(TDL Tiny)	5-7 days	KT35
PLAC Test (Lp-PLA2)	PLA2	(TDL Tiny)	2 days	KT35
Urea	UREA	(TDL Tiny)	1 day	KT35
Urea/Creatinine/eGFR	TCU	(TDL Tiny)	1 day	KT35
Vitamin B12 (Active)	B12	(TDL Tiny)	1 day	KT35
Vitamin D (25-OH)	VITD	(TDL Tiny)	1 day	KT35

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

Endocrinology				
TEST	CODE	SAMPLE REQS	TAT	KIT CODE
Amenorrhoea Profile (LH, FSH, PROL, TEST, TOES, SHBG, FAI) CHANGE LH, FSH, PROL, TEST, TOES and SHBG now also available individually from a 🕞 (TDL Tiny) sample.	TAME	(TDL Tiny)	1 day	KT466
Antimullerian Hormone (AMH)	AMH	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Cortisol	CORT	(TDL Tiny)	1 day	KT353
DHEA Sulphate	DHEA	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Female Hormone Profile (LH, FSH, PROL, TOES)	TFIP	(TDL Tiny) and 追 (TDL Tiny)	1 day	KT445
Free T3	FT3	(TDL Tiny)	1 day	KT353
Free T4	FT4	(TDL Tiny)	1 day	KT353
FSH	FSH	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
HCG (Quantitative)	QHCG	(TDL Tiny)	1 day	KT353
Luteinising Hormone (LH)	LH	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Menopausal Profile (FSH, LH, TOES, TSH, FT4)	TMEN	(TDL Tiny) and 🕒 (TDL Tiny)	1 day	KT445
Oestradiol-17-Beta	TOES	(TDL Tiny)	1 day	KT466
Progesterone	PROG	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Prolactin	PROL	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Sex Hormone Binding Globulin	SHBG	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Testosterone	TEST	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	1 day	KT353 or KT466
Testosterone (Free)	FTES	🕒 (TDL Tiny) or 🕞 (TDL Tiny)	3 days	KT353 or KT466
Thyroid Abs (Thyroglobulin + Thyroid Peroxidase Abs)	THAB	(TDL Tiny)	2 days	KT353
Thyroid Profile 1 (FT4/TSH)	TF	(TDL Tiny)	1 day	KT353
Thyroid Profile 3 (FT3/FT4/TSH)	TF3	(TDL Tiny)	1 day	KT353
TSH	TSH	(TDL Tiny)	1 day	KT353

Haematology				
TEST	CODE	SAMPLE REQS	TAT	KIT CODE
Full Blood Count* (Haemoglobin, White Cell Count, Red Cell Count, Platelets) NEW	TFBC	(TDL Tiny)	1 day	KT354

\*Mix sample on collection.

#### Immunology

TEST	CODE	SAMPLE REQS	TAT	KIT CODE
COVID-19 (SPIKE) Antibodies	SCOV	(TDL Tiny)	1 day	KT353
Endomysial Antibodies (IgA)	AEAB	(TDL Tiny)	2 days	KT353
Gliadin Antibodies (IgG) (deamidated)	AGAB	(TDL Tiny)	2 days	KT353
Tissue Transglutaminase IgA (Coeliac)	TAA	(TDL Tiny)	2 days	KT353

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

Culture/Viral Screening				
TEST	CODE	SAMPLE REQS	TAT	KIT CODE
Group B Strep – Vaginal and Rectal	GBSX	Blue gel Amies swab x2	3-5 days	KT366
H. pylori Antigen – Stool	HBAG	Stool/faecal container	3 days	KT363 or KT430
MRSA Culture	MRW2	Purple liquid Amies swab x2	2 days	KT365
MRSA Culture	MRW3	Purple liquid Amies swab x3	2 days	KT422
MRSA PCR	MRS2	Purple liquid Amies swab x2	1 day	KT365
MRSA PCR	MRS3	Purple liquid Amies swab x3	1 day	KT422
Quantitative Faecal Immunochemical Test (QFIT)	QFIT	QFIT sample collection device	1 day	KT362 or KT430
Urine Chemistry and Microscopy	UMIC	Urine (Universal). Mid stream.	1-2 days	KT385
Urine Chemistry, Microscopy and Culture	UCEM	Urine (Universal & Boric). Mid stream.	1-2 days	KT386

### **Sexual Health**

TEST	CODE	SAMPLE REQS	TAT	KIT CODE
7 STI Profile by PCR (7 tests from 1 Sample)	DL12	Aptima urine or multisite swab	2 days	KT356 or KT357
Chlamydia/Gonorrhoea – Rectal	RSCG	Aptima multisite swab	2 days	KT426
Chlamydia/Gonorrhoea – Throat	TSCG	Aptima multisite swab	2 days	KT425
Chlamydia/Gonorrhoea – Urine	CCG	Aptima urine	2 days	KT356
Chlamydia/Gonorrhoea – Vaginal	SCG	Aptima multisite swab	2 days	KT357
Hepatitis B Surface Antigen	THBA	(TDL Tiny)	1 day	KT353
Herpes Simplex (HSV) 1 & 2 – Genital lesion	HERS	Aptima multisite swab	5 days	KT405
Herpes Simplex (HSV) 1 & 2 – Oral lesion	HERS	Aptima multisite swab	5 days	KT404
HIV 1 & 2 Abs/p24Ag	THIV	(TDL Tiny)	1 day	KT353
HPV (19 high risk DNA subtypes, reported as types 16, 18 or Others)	HPVY	Qvintip vaginal swab	3 days	KT364
HPV (Individually typed high risk DNA subtypes)	HPVZ	Qvintip vaginal swab	3 days	KT364
Lymphogranuloma Venerium (LGV) – Rectal * This test can be configured to be automatically reflexed as required.	LGVP	Aptima multisite swab	1-2 weeks	KT426
MPOX (Virus) – Lesion	MPXV	Aptima multisite swab	2 days	KT405
Mycoplasma genitalium by PCR – Urine and Vaginal	MGEN	Aptima urine or multisite swab	2 days	KT356 or KT357
Mycoplasma genitalium Resistance – Urine or Vaginal	MGR	Aptima urine or multisite swab	1-2 weeks	KT356 or KT357
STI Profile by PCR (7 tests from 1 sample)	DL12	Aptima urine or multisite swab	2 days	KT356 or KT357
STI Profile: MSM1 (Blood + Urine/Throat/Rectal Swabs)	MSM1	(TDL Tiny) / Aptima Urine / Aptima multisite swab x 2	2 days	KT361
STI Profile: MSM2 (Blood + Urine/Throat/Rectal Swabs)	MSM2	<ul> <li>(TDL Tiny) / Aptima urine</li> <li>/ Aptima multisite swab x 2</li> </ul>	3 days	KT361
Syphilis IgG/IgM	TSYP	(TDL Tiny)	1 day	KT353
Trichomonas vaginalis (TV) – Urine or Vaginal	TVPC	Aptima urine or multisite swab	2 days	KT356 or KT357
Triple Swab Female STI Profile (Vaginal/Throat/Rectal Swabs)	3SWA	Aptima multisite swab x 3 (label by site)	2 days	KT428
Vaginitis/BV Profile using Culture & PCR Swab	STD8	Aptima multisite swab and Blue gel Amies swab	3-5 days	KT441

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.

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

Tumour Markers/Sites				
TEST	CODE	SAMPLE REQS	TAT	KIT CODE
CA 125	C125	(TDL Tiny)	1 day	KT353
Prostate Specific Antigen (Total)	PSPA	(TDL Tiny)	1 day	KT353

Virology				
TEST	CODE	SAMPLE REQS	TAT	KIT CODE
COVID-19 (SARS-CoV-2) RNA by PCR	NCOV	Aptima multisite swab	1 day	KT293
Contact Laboratory.		of nose/throat		
Gastrointestinal Pathogen Profile by PCR	EORD	Stool/faecal container	2 days	KT363 or KT430
Hepatitis B Immunity (IgG)	THBI	(TDL Tiny)	1 day	KT353
Hepatitis B Surface Antigen	THBA	(TDL Tiny)	1 day	KT353
Hepatitis C Antibodies	THCV	(TDL Tiny)	1 day	KT353
Hepatitis C Antigen (Early detection)	TCAG	🕒 (TDL Tiny)	1 day	KT353
Herpes Simplex (HSV) 1 & 2 – Genital lesion	HERS	Aptima multisite swab	5 days	KT405
Herpes Simplex (HSV) 1 & 2 – Oral lesion	HERS	Aptima multisite swab	5 days	KT404
HIV 1 & 2 Abs/p24Ag	THIV	(TDL Tiny)	1 day	KT353
HPV (19 high risk DNA subtypes, reported as types 16, 18 or Others)	HPVY	Qvintip vaginal swab	3 days	KT364
HPV (Individually typed high risk DNA subtypes)	HPVZ	Qvintip vaginal swab	3 days	KT364
Respiratory PCR Panel (COVID-19, Flu A/B and RSV)	FLU4	Aptima multisite swab of nose/throat	2 days	KT293
Viral Respiratory RNA Screen by PCR	VPR	Aptima multisite swab of nose/throat	2 days	KT293

## Vitamins, Nutrition and Lifestyle

TEST	CODE	SAMPLE REQS	ТАТ	KIT CODE
Omega 3/Omega 6	OMG3	(TDL Tiny)	5 days	KT354
Selenium (Serum)	SELE	(TDL Tiny)	4 days	KT353
Vitamin B12 (Active)	B12	(TDL Tiny)	1 day	KT353
Vitamin D (25-OH)	VITD	(TDL Tiny)	1 day	KT353

Sample type guide

(TDL Tiny)	Lavender Microtainer, EDTA anticoagulant, Top fill line: $400-500 \mu L$
(TDL Tiny)	Gold Microtainer, SST, Top fill line: 400-600µL
(TDL Tiny)	Red Microtainer, Plain no additive, Top fill line: 500µL

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# **Additional information**

## 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**

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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.

## UKCA Kit Order Form



Source Code:

Date of Order: Requested by: Delivery address: Postcode: If urgent, required by: Contact phone number:

TAP5065E/12-06-24/V19

Purchase Order/Order Reference:

Must be supplied if organisation operates a No PO No Pay policy

Clinical Category	Kit Code	Кіт Туре	Unit Price	Quantity	Total
Respiratory Virus	KT293	Respiratory Virus Swab (2mL)	£3.50		£0.00
	KT353	SST (Gold)	£3.50		£0.00
	KT354	EDTA (Purple)	£3.50		£0.00
	KT355	SST (Gold) & EDTA (Purple)	£3.50		£0.00
Capillary Blood	KT466	PLAIN (Red)	£3.50		£0.00
	KT384	SST (Gold) x 2	£3.50		£0.00
	KT423	SST (Gold) x 2 & EDTA (Purple)	£3.50		£0.00
	KT445	SST (Gold) & Plain (Red)	£3.50		£0.00
	KT356	Urine (STI only)	£3.50		£0.00
	KT357	Vaginal Swab (PCR)	£3.50		£0.00
	KT359	Throat & Rectal Swabs (PCR x 2)	£3.50		£0.00
	KT428	Vaginal, Throat & Rectal Swabs (PCR x 3)	£3.50		£0.00
	KT421	Urine, Throat & Rectal Swabs (PCR x 3)	£3.50		£0.00
	KT358	Blood (SST, Gold) & Vaginal Swab (PCR)	£3.50		£0.00
Sexual Health	KT360	Blood (SST, Gold) & Urine (STI ony)	£3.50		£0.00
	KT361	Blood (SST, Gold), Urine, Throat & Rectal Swabs (PCR x 2) – MSM	£3.50		£0.00
	KT424	Blood (SST, Gold), Vaginal, Throat & Rectal Swabs – TRANS (PCR x 3)	£3.50		£0.00
	KT404	Oral Lesion Swab (PCR)	£3.50		£0.00
	KT405	Genital Lesion Swab (PCR)	£3.50		£0.00
	KT425	Throat Swab (PCR)	£3.50		£0.00
	KT426	Rectal Swab (PCR)	£3.50		£0.00
	KT362	QFIT sample collection device	£0.00		£0.00
Stool	KT363	Stool/Faecal Kit (Tube x 1)	£3.50		£0.00
	KT430	QFIT sample collection device/Stool (Tube x 2)	£3.50		£0.00
	KT364	HPV	£3.50		£0.00
	KT365	MRSA Swabs (Culture x 2)	£3.50		£0.00
	KT422	MRSA Swabs (Culture x 3)	£3.50		£0.00
Microbiology	KT366	GBS Swabs (Culture x 2)	£0.00		£0.00
	KT385	Urine Microscopy & Chemistry	£3.50		£0.00
	KT386	Urine Microscopy, Chemistry & Culture (Universal & Boric Tubes)	£3.50		£0.00
	KT441	Vaginitis Swabs (Culture & PCR)	£3.50		£0.00
	•		Total ex VAT		£0.00
			VAT @ 20%		£0.00
			Total to Pay		£0.00

#### You will receive an invoice for your kit orders at the beginning of the next month Email completed form to <u>Supplies@tdlpathology.com</u>

For TDL Use			
Fulfilled by		Date fulfilled	
Forward order for invoicing to	billing@tdlpathology.com		

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