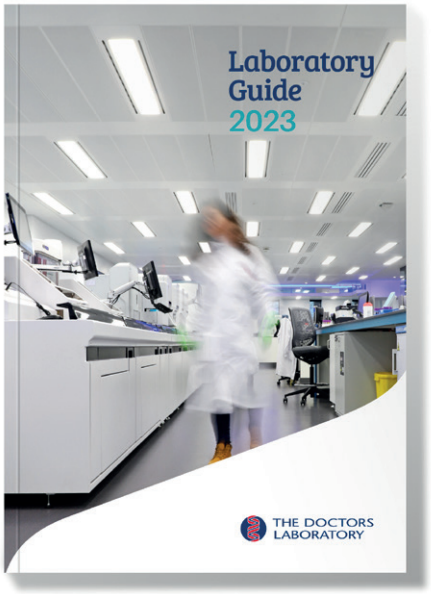
THE DOCTORS LABORATORY

TDL Laboratory Guide 2023 New, Changes and Updates



This year the Laboratory Guide looks different but every year we review requesting patterns, frequency of use, new best practice, new methods, and include new and relevant assays into the test menu. We also try to incorporate the changes that have originated from feedback received over the past year. This helps us to keep profiles and test menus as up to date and as relevant as possible. Details of nearly 1500 tests are listed in sections, by speciality, and through the **A-Z test list** in the last section of the guide. **Profiles continue to be laid out by specialty but are now listed in alphabetical order**. For advice or information about any of the tests that are listed – and particularly if you cannot find the test you are looking for, do please contact the laboratory on **020 7307 7373**. If you need information and advice about Genetic Tests please call **020 7307 7409**.

Updated Terms and Conditions of Business from 1st January 2023 now include a section relating to Supplies and Consumables provided by TDL (Clause 2). Holding a signed copy of these Terms and Conditions has become important for CQC and other inspections and audits. The updated version is shown on page 187 of the Guide. Two copies of the document have been supplied in the Pathology Pack – one to complete and file and one to complete and return to **terms@tdlpathology.com**

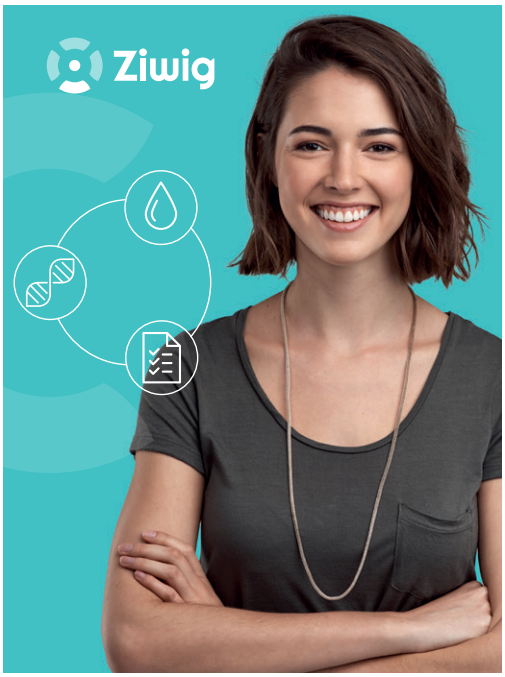
The symbols **NEW** and **CHANGE** show new test entries and changes to tests, respectively.
New tests, changes, updates and prices are effective from 1st January 2023.

What is in your Pathology Pack?

- TDL Laboratory Guide 2023
- TDL New Tests, Changes and Updates 2023
- TDL Standard Terms and Conditions 2023
- TDL Calendar 2023
- Ziwig Endotest® Information Card
- Re-order Form for lab guides and Calendars.

Ziwig Endotest® NEW

ZIWIG Endotest® is a new non-invasive diagnostic test for reliable and rapid diagnosis for all types of endometriosis. The test relies on Next Generation Sequencing of micro RNA present in saliva and on the use of Artificial Intelligence to process the very large volume of data generated. Ziwig Endotest® is an in vitro diagnostic test for diagnosis of endometriosis on salivary samples with reliability close to 100%.



About 10% of all women are affected by endometriosis with average times for diagnosis of around 8 years. Patients not infrequently see up to 10 doctors before being diagnosed with endometriosis (MRI, pelvic ultrasound, laparoscopy). Ziwig Endotest® is able to detect all types of endometriosis, mild and advanced. Endometriosis is not infrequently mistaken for other conditions that can cause pelvic pain, such as pelvic inflammatory disease (PID) or ovarian cysts. The effects of endometriosis range from asymptomatic, often identified during investigations for infertility, to chronic or progressively severe symptomatic related conditions. Once diagnosed, optimised clinical management of endometriosis would apply.

Laparoscopy is the gold standard for diagnosis of endometriosis but is relatively expensive, invasive, and requires an anaesthetic. The saliva sample required for the test is straight forward to collect and non-invasive and provides a definitive diagnosis even in the most complex cases. It has been validated by one of the largest clinical studies in the world.

Ziwig Endotest® provides a Bioinformatics Approach to microRNA sequencing analysis, from saliva.

For access to scientific publications visit: **https://ziwig.com/en/science/**

- Clear Positive/Negative result
- Definitive diagnosis for all forms of endometriosis
- Non-invasive, saliva sample
- Cost contained single test outcome

For information about this test and to order kits please contact **endotest@tdlpathology.com**

The quality of the saliva sample collection is important. Samples should be collected under supervision.

TEST	CODE	SAMPLE REQS	TAT
Ziwig Endotest® NEW For information about this test and to order kits please contact endotest@tdlpathology.com. The quality of the saliva sample collection is important. Samples should be collected under supervision.	ENDT	Endotest saliva collection kit	25 days

ALEX² Allergy Test NEW

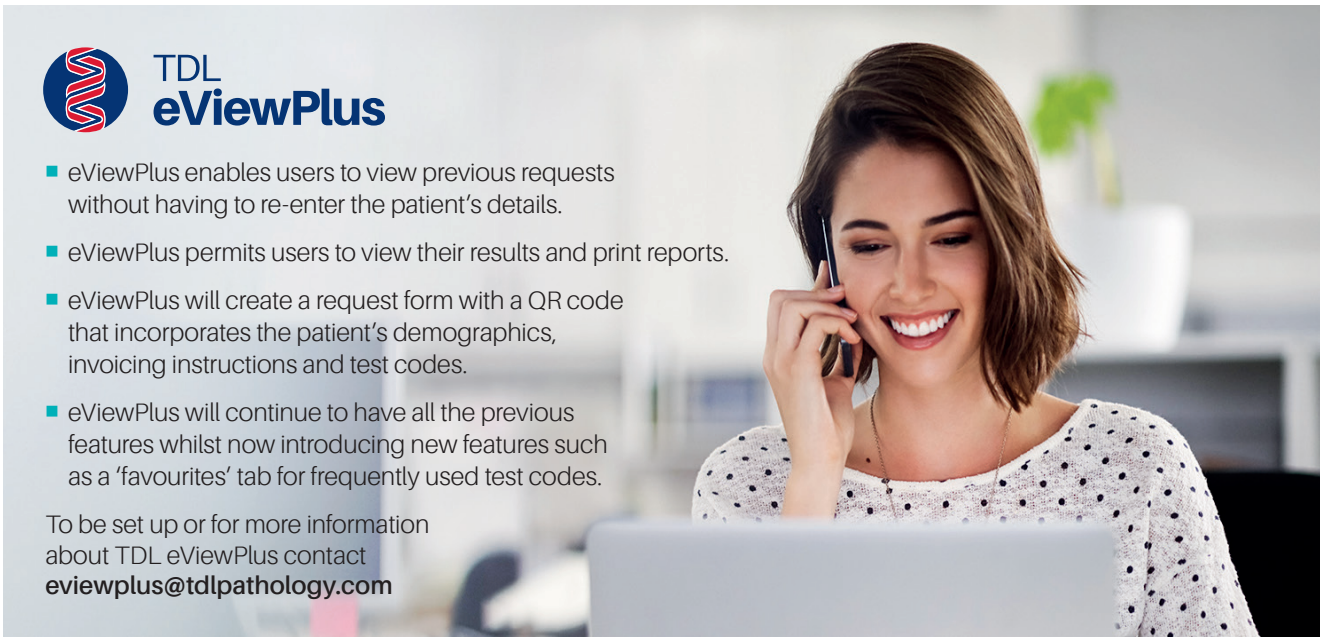
ALEX® Allergy Explorer rapidly tests for up to 300 allergens simultaneously and providing a comprehensive analysis, from a very small sample volume. The panel of allergens includes pollen, mites, cat and dog fur, insect venoms, moulds and yeasts, food and latex.

In addition a total IgE is included. The volume of sample required is small, but the process of testing allows for different allergenic components to be incorporated in the panel. Testing sensitivity to component allergenic determinates of food or other proteins which give a better indication of risk of anaphylaxis and how best to manage the patient with their allergic condition.

TEST	CODE	SAMPLE REQS	TAT
ALEX² Allergy Test NEW Small volume samples suitable for self-collection/postal samples	ALEX	(B) (Serum)	3-4 days

TDL eViewPlus UPDATE

TDL eViewPlus allows users to create request forms without the need for the set-up and cost of a linked practice management system. More importantly, eViewPlus significantly improves the speed and accuracy of data entry for the laboratory as the request forms are QR coded for scanned input compared to manual entry from paper forms.



- Secure log in and password
- QR code replicates information provided by the practice
- Allows for 100% accuracy for test codes and patient demographics
- Accepts all test codes: single tests and profiles
- Minimal equipment needed, use your standard printer
- Ability to request for new and existing patients
- Option to print sample labels
- There is no charge for this service

Calprotectin/QFIT Combined Test NEW

This is a combined sample collection using the QFIT sample collection kit for the two tests. Results are reported individually. The combined collection assay requires a change of Calprotectin assay, as follows:

Calprotectin: <50 ug/g

Not indicative of GI inflammation. Consider IBS, or quiescent IBD if this is a known patient.

Calprotectin: >50 ug/g

Calprotectin: 50–150 ug/g repeat calprotectin in 2 weeks (also consider other potential causes: infection, NSAIDS, GI malignancy, depending on the magnitude of the result and clinical context.)

Repeated Calprotectin result: 100–250 ug/g routine referral to gastroenterology. Calprotectin: >250 ug/g urgent referral to gastroenterology.

Tests for Elastase, helicobacter Pylori, EORD, PENT, etc, cannot be requested with QCAL – these specific investigations from stool samples need to be requested individually using separately labelled specimen containers.

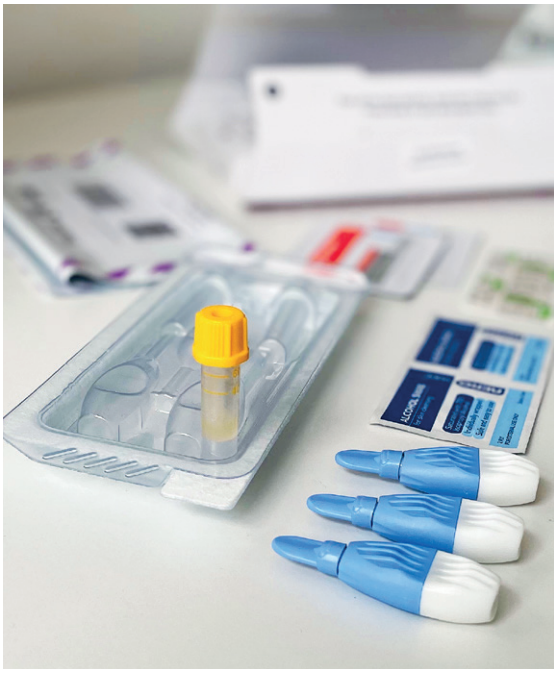
TEST	CODE	SAMPLE REQS	TAT
Calprotectin	**CALP**	**RF**	5 days
Quantitative Faecal Immunochemical Test (QFIT)	**QFIT**	**QFIT Kit**	1 day
QFIT/Calprotectin Profile (Combined) NEW	**QCAL**	**QFIT Kit**	5 days

Self-Collection Samples UPDATE

Self-collection is utilised extensively across areas such as sexual health screening, wellness services and hospital pre-operative screening. 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 pathology services. TDL kits are made up according to medical device manufacture (ISO13485:2016). Assays from self-collection blood samples have all undergone usability, stability and comparative venous/capillary review.

For tests that have undergone verification for self-collection, the entry will appear twice in the Laboratory Guide – with the shaded version highlighting that the test has been validated as a self-collect test (see page 131 of the Laboratory Guide for full more information about self-collection samples).



Below are examples to illustrate this for AMH and Vitamin D.

TEST	CODE	SAMPLE REQS	TAT
Antimullerian Hormone (AMH Plus)	**AMH**	B	4 hours
Antimullerian Hormone (AMH Plus) (Self-collect) See page 131 for more information	**AMH**	B (TDL Tiny)	1 day
Vitamin D (25-OH)	**VITD**	B	4 hours
Vitamin D (25-OH) (Self-collect) See page 131 for more information	**VITD**	B (TDL Tiny)	1 day

Orders for TDL Tinies™ (packs with instructions) can be provided to the practice to be sent out individually to patients, or supplied directly to doctors or healthcare companies.

This is not a patient self-referral service and it is not point of care testing. All testing is undertaken in the laboratory and results are always returned directly to the healthcare company or doctor, not to the patient. The range includes kits for self-collected blood samples with other self-collected samples types (urine, stool, swabs). A completed request form must be enclosed with the returned sample.

Recommendation

Most people are not experienced with collecting their own blood. Whilst it is possible to collect blood drops for two or three microtainers, the most successful outcomes are from samples collected by patients who read the instructions that are given in each pack, and who collect enough sample for one microtainer. Instructions for sample collection are enclosed in each pack.

For information and packs, please contact **UKCAkits@tdlpathology.com**

Self-Collection HPV Samples UPDATE

The Self-Collection HPV Test provides women with the option to self-collect a vaginal specimen for HPV testing. There is well documented high level of concordance between the HPV DNA results from self-collected and clinician-collected specimens.

A NEGATIVE HPV result means that these high-risk subtypes HPV have not been detected and the patient is at extremely low risk of developing high-grade cervical disease/CIN2+ before their next routine visit.

A POSITIVE HPV result might indicate an increased risk of developing CIN/cervical cancer, and the report from the laboratory will provide a clear recommendation for follow-up/colposcopy.

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 individual high risk DNA subtypes
- Personal preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears
- Self-collection for HPV increases acceptability and coverage rate of cervical cancer prevention

Results will always be sent directly to the requesting clinician, clinic or healthcare organisation.

HPVY

Self-Collected HPV DNA with reporting of High Risk subtypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).

HPVZ

Self-Collected HPV DNA with **individual reporting** of all High Risk subtypes (16, 18, 31, 33, 45, 35, 39, 51, 52, 56, 58, 59, 66, 68, 26, 53, 69, 73, 82).

Triple Swab Female Profile NEW

- CT/GC Vaginal
- CT/GC Throat
- CT/GC Rectal

TEST	CODE	SAMPLE REQS	TAT
Triple Swab Female Profile NEW	**3SWA**	**PCR /**Aptima multisite swab x 3 (label by site)	2 days

Allergy Tests NEW

TEST	CODE	SAMPLE REQS	TAT
Allergy – Individual Allergens	ALLE	B	2 days
Allergy – 5 x Single Individual Allergens NEW	5AL	B	2 days
Allergy – 10 x Single Individual Allergens NEW	10AL	B	2 days

Allergy Profiles CHANGE

Allergy Profile 5 (Children's Panel)

CHANGE

Total IgE with individual IgE allergens for:

Cat Dander
Cod
Cow's Milk
Dog Dander
Dust Mite
Egg White
Egg Yolk
Hazelnut
Peanut
Silver Birch
Soya Bean
Timothy Grass
Wheat Flour

TAT: 2 days

5A

B

Atopic Dermatitis/Eczema Profile (14 allergens)

CHANGE

TOTAL IGE with individual IgE allergens for:

Cod fish
Cows Milk
Egg White
Soyabean
Peanut
Hazelnut
Shrimp
Wheat
Apple
Dust mite – dermatophagoides pteronyssinus
Cat Dander
Dog Dander
Timothy Grass
Common Silver Birch

TAT: 2 days

ALEC

B

Allergic Rhinitis/Asthma Profile

CHANGE

Total IgE with individual IgE allergens for:

Cat dander
Dog dander
Common Silver Birch
Timothy Grass
Dust Mite – Dermatophagoides pteronyssinus
Alternaria alternata
Aspergillius fumigatus
Caldosporium herbarum
Mugwort
London Plane
Peanut
Egg White
Cows Milk

TAT: 2 days

ALRN

B

Miscellaneous changes

- From 1st January 2023 **no hard copy results will be routinely sent by Royal Mail**. Please email **printcopy@tdlpathology.com** if you would like to receive hard copy, indicating the copy number required.
- QFIT is no longer included in the DL9M and DL9F Profiles.
- Vitamin C has been removed from the Vitamin Profiles (VITS and VIT2). Vitamin D is now included in both profiles.

Vitamin Profile 1

CHANGE

Vitamin A
Beta Carotene
Vitamin B1
Vitamin B2
Vitamin B6
Vitamin D (25-OH)
Vitamin E

TAT: 5 days

VITS

A B B [7]

Vitamin Profile 2

CHANGE

Vitamin A
Beta Carotene
Vitamin B1
Vitamin B2
Vitamin B3
Vitamin B6
Vitamin B9
(Red Cell Folate)
Vitamin B12 (Active)
Vitamin D (25-OH)
Vitamin E

TAT: 5 days

VIT2

A A A B B [7,13]

Hepatitis C Core Antigen (HCV Ag) UPDATE

The manufacture of Abbott Hep C Core Antigen (HCV Ag) has been reinstated. This is included in the Sexual Health Profiles. HCV Ag testing is also used as the confirmatory test for reactive HCV Antibodies.

TDL Genetics

Next generation sequencing (NGS) NEW

Next generation sequencing (NGS) is a technology used to determine the genetic sequence of DNA or RNA, which provides confident insight into genetic variation associated with disease. NGS has the advantage of speed, high through-put and the ability to investigate many genes simultaneously. These include novel mutations associated with cancers and which help provide guidance towards optimal treatment options with the view to personalised medicine. NGS is provided through both Illumina and Ion Torrent sequencing.

The **NEW** Oncology NGS tests that are now available cover a vast range of genes and conditions within each test.

TEST	CODE	SAMPLE REQS	TAT
Leukaemia (Rapid Acute) DNA and RNA NGS Panel NEW	ALRP	A	3 days
Leukaemia/Lymphoma RNA Sequencing (Fusion Gene and SNV/Indel) Panel NEW	PHFP	A	2 weeks
Lysosomal Storage Disorders NGS Panel – full gene sequencing NEW Requires patient informed consent.	LSDS	A A [9]	4-6 weeks
Myeloid Gene Panel NEW Requires patient informed consent.	MVPS	A	2 weeks
Myeloproliferative Neoplasm NGS Screening Panel NEW Requires patient informed consent.	MPNS	A	1 week

Lysosomal Storage Disorders NGS Panel

This 55-gene custom next-generation sequencing (NGS) panel covers all known lysosomal storage diseases. These include:

- Fabry disease
- Gaucher disease
- Pompe disease
- Metachromatic leukodystrophy
- Mucopolysaccharidoses (all types)
- Fucosidosis
- Krabbe disease
- Tay-Sachs disease
- Sandhoff disease
- Danon disease
- Lysosomal acid lipase deficiency
- Niemann-Pick disease types A, B and C
- Lipfuscinoses
- Prosaposin deficiency
- Salla disease.

The panel detects both pathogenic SNP/indels and copy number variants (including whole exon insertions/deletions).

Sample type: 3ml EDTA blood sample

Turnaround time: 4-6 weeks.

Myeloid VariantPlex Gene NGS Panel

This is a 75-gene targeted NGS panel for acute myeloid leukaemia, myeloproliferative neoplasms and myelodysplastic syndromes. It also contains a number of targets that are useful for lymphoid malignancies (acute lymphoblastic leukaemia, ALL, and lymphoma).

Sample type: 3ml of peripheral blood or bone marrow in EDTA, CSF, pleural fluid or FFPE curls. For exact FFPE sample requirements please contact **molecular.haemonc@hslpathology.com**

Turnaround time: 14 days, although clinically urgent samples can be processed more quickly.

Leukaemia / Lymphoma RNA Sequencing (Fusion Gene and SNV / Indel) Panel [PHFP]

This NGS panel is designed to detect and identify fusions, point mutations and expression levels from RNA samples.

The panel covers targets in over 199 genes relating to lymphoid and myeloid malignancies. Molecular barcoded fragments enable accurate RNA abundance calculations. Both known and novel fusions can be identified. Fusions involving BCR and TCR loci, including IGH, IGK and IGL are targeted for RNA expression which allows for fusion calling when the fusion does not result in a chimeric transcript.

Sample type: 3ml of peripheral blood or bone marrow in EDTA, CSF, pleural fluid or FFPE curls. For exact FFPE sample requirements please contact **molecular.haemonc@hslpathology.com**

Turnaround time:14 days, although clinically urgent samples can be processed more quickly.

Myeloproliferative Neoplasm NGS Screening Panel DNA only) [MPNS]

The assay can be run in DNA-only mode for myeloproliferative neoplasm screening where the turnaround time is 7 days, and in DNA and RNA mode for acute leukaemia and other clinically urgent samples where the turnaround time is 3 days.

Sample type: 3ml EDTA peripheral blood or bone marrow aspirate sample.

Leukaemia (Rapid Acute) DNA and RNA NGS Panel [ALRP]

This NGS assay produces a comprehensive profile of variants (both DNA and RNA) from a single NGS run.
This assay can profile both DNA and RNA targets, and enables the sequencing of over 700 unique fusion transcripts.

The panel covers relevant targets for acute myeloid leukaemia, myelodyplastic syndromes and myeoproliferative neoplasms, including chronic myeloid leukaemia (CML), chronic myelomonocytic leukaemia (CMML) and juvenile myelomonocytic leukaemia (JMML).

Sample type: 3ml EDTA peripheral blood or bone marrow aspirate sample.

eGFR calculation using CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) CHANGE

Glomerular filtration rate (GFR) is considered to be the best overall index of kidney function, and takes into account the variables of age, sex, body size and declines with age.

The National Kidney Foundation now recommends using the CKD-EPI Creatinine Equation to estimate GFR. Data was derived from a large diverse population, with and without kidney disease, using more rigorous statistical techniques. The recommendation for this change resulted from improvement in the performance of CKD-EPI especially reducing false positive results in women and the younger population, leading to more appropriate referrals to the renal services. The CKD-EPI equation also performs better in the elderly in early diagnosis of renal impairment.

Current guidance no longer advises adjusting eGFR for ethnicity due to unreliability in acute kidney injury. References to ethnicity have therefore been removed from reports. All creatinine-based equations for estimating GFR have some limitations. Exceptions to the use of eGFR include use of toxic drugs, in elderly patients over 75 years, and in patients with extreme of muscle mass where calculation of CrCl (Creatinine Clearance) is recommended. The British National Formulary (BNF) advises that in patients at both extremes of muscle mass (BMI of less than 18 kg/m^2 or greater than 40kg/m^2) the absolute GFR or CrCl (calculated from the C&G (Cockcroft & Gault) formula) should be used to adjust drug dosages.

https://bnf.nice.org.uk/guidance/prescribing-in-renal-impairment.html

https://www.sps.nhs.uk/articles/which-estimate-of-renal-function-should-be-used-when-dosing-patients-with-renal-impairment

Method for Creatinine – from Jaffe to Enzymatic CHANGE

Following NICE guidelines the Jaffe method for processing Creatinine has been replaced by the more sensitive method of enzymatic creatinine, preferable for lower level results. The renal function measurement of eGFR is calculated from the Creatinine value. Gold standard for measuring glomerular filtration is from plasma or urine, but calculated estimated glomerular filtration rate (eGFR) is an alternative that is calculated from the serum creatinine result. Changing from Jaffe to Enzymatic requires no change by the practice for sample type, or code.

Histopathology UPDATE

TDL's Histopathology service supports a full range of pathology sub-specialities and is now being undertaken as an in-house service.

To prevent tissue degeneration, it is advisable to collect histopathology samples in sample pot(s) containing preservative, usually formalin, to at least ten times the volume of the tissue sample (available from TDL Supplies). Use of preservative will ensure that the tissue architecture and microscopic appearances of specimens are preserved. Patient demographics, together with clinical and sample details need to be provided with the specimens. Testicular investigations for reproductive investigations are best submitted fixed in Bouins solution. Requests for products of conception require the patient's signed consent/instruction regarding sensitive disposal when the histopathology is complete. Please contact **020 7307 7380** or **020 7307 7373** for information or any query relating to histopathology.

Service email addresses – who to contact to make arrangements

addons@tdlpathology.com	To request additional tests from a sample already in the laboratory
andrology@tdlpathology.com	To arrange an appointment for semen analysis (telephone 020 7025 7940)
couriers@tdlpathology.com	Contact couriers as an alternative to online booking
endotest@tdlpathology.com NEW	From Jan 2023, information/orders for sample taking kits for Ziwig Endotest®
UKCAkits@tdlpathology.com UPDATE	Information for self-collection kits/service
printcopy@tdlpathology.com NEW	From Jan 2023, to request for printed copy of results
eviewplus@tdlpathology.com	From Jan 2023, to arrange a secure login/password for results look-up
finance@tdlpathology.com	To contact credit control for invoice related queries
homevisits@tdlpathology.com	To arrange a home visit for your London based patients
logo@tdlpathology.com	To set up your logo (GIF format) for emailed results
patientreception@tdlpathology.com	To email ahead for special arrangements for your patients
phlebotomy@tdlpathology.com	To email for special arrangements for patients when needed
supplies@tdlpathology.com	To order pathology supplies/postal packs for TDL samples, see page 10 and forms section at the back of the Laboratory Guide
tdl@tdlpathology.com	For general enquiries

TDL's Laboratory Guide 2023 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 will 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, The Halo Building, 1 Mabledon Place, London WC1H 9AX Tel: 020 7307 7373 Fax: 020 7307 7374
Email: tdl@tdlpathology.com Website: www.tdlpathology.com TAP5194/30-11-22/V2