

 Western Health and Social Care Trust	Precision Diagnostic Laboratory
	Activation Date: 20/07/2026
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PDL/MAN/2	Edition Number 2

WHSCOT PRECISION DIAGNOSTIC LABORATORY

Laboratory Users' Manual

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This document represents the Laboratory User Manual of the Western Health & Social Care Trust Precision Diagnostic Laboratory. All procedures contained herein are mandatory.

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INTRODUCTION

Each request submitted and accepted by the Precision Diagnostic Laboratory (PDL) for examination is considered a Service Level Agreement. The Laboratory will endeavor to provide a suitable medical laboratory service for each request to ensure appropriate examination and result interpretation in line with BS EN ISO 15189:2022 Medical laboratories – Requirements for quality and competence.

LOCATION

The WHSCT Precision Diagnostic Laboratory (PDL) is located within the C-TRIC building on the Altnagelvin Hospital site in Derry/Londonderry.

Precision Diagnostic Laboratory address:

C-TRIC Building

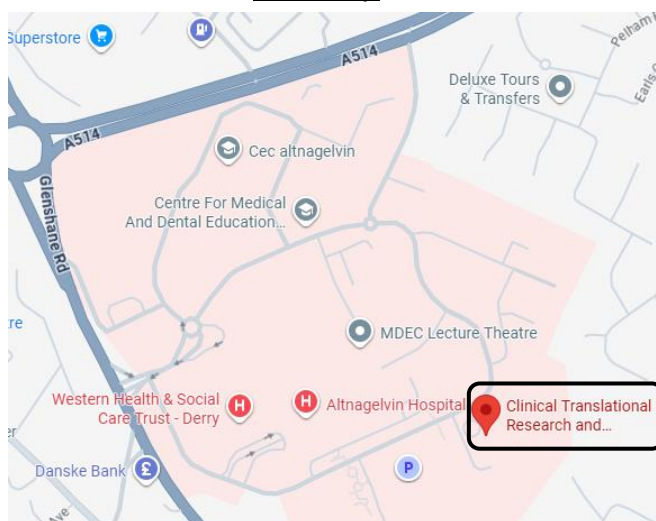
Western Health Social Care Trust

Altnagelvin Area Hospital site

Glenshane Road

Londonderry BT47 6SB

Site Map



Front of C-TRIC building



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LABORATORY HOURS

Normal working hours are Monday to Friday 9.00am - 5.00pm (Excluding Bank Holidays). If sample is to be received in late afternoon (>4pm) sample will be tested following day with no reduction in DNA stability within saliva collection device (stable for up to 60 days at room temperature 18-25°C).

LABORATORY CONTACT DETAILS

Name	Contact Details
Altnagelvin Hospital (Switchboard)	02871 345171
Dr Mark Lynch, Consultant Clinical Scientist (PDL Clinical Lead)	Ext 213806 Email: Mark.lynch@westerntrust.hscni.net
Vanessa Quinn (PDL Service Manager)	Ext 216638 Email: Vanessa.quinn@westerntrust.hscni.net
Mark Watson (PDL Section Lead/Laboratory Manager)	Ext 216629 Email: Mark.watson@westerntrust.hscni.net
PDL Specimen Reception	Ext 216641 Email: PDL@westerntrust.hscni.net

The Precision Diagnostic Laboratory welcomes feedback from health care professionals and patients on ways to improve the service. Please submit any feedback to the laboratory using the PDL User Survey Form [PDL/FORM/31] via PDL email address above (PDL@westerntrust.hscni.net).

REQUEST FORMS/SPECIMEN INFORMATION AND MINIMUM ACCEPTANCE CRITERIA

All request forms and samples must be clearly identified with a set of mandatory matching identifiers. Only a completed Request Form [PDL/FORM/22] will be accepted. Return the completed request form with the sample in accordance with the transfer method agreed with the service user. Copy of PDL sample request form can be found in appendix 1.

Note: Laboratory will follow NI Pathology Network Minimum Acceptance Criteria (MAC) Policy for the information provided on Request form and Sample collection kits for all sample requests.

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Table 1 NI Pathology Network Minimum Acceptance Criteria

**MANDATORY LABORATORY REQUEST MINIMUM ACCEPTANCE CRITERIA
[MAC]**

Request Form	A. MANDATORY INFORMATION ON <u>LABORATORY REQUEST FORM</u>
Unique identifier Number ¹	YES
Patient Official First Name	YES
Surname	YES
Sex	YES
Date of Birth (DD/MM/YYYY)	YES
Date and Time of Sample Collection	YES
Requestor Name/Code	YES
Source (Ward/Clinic /GP)	YES

Sample Label	B. MANDATORY INFORMATION ON <u>SAMPLE LABEL</u>
Unique identifier Number ¹	YES
Patient Official First Name	YES
Surname	YES
Date of Birth (DD/MM/YYYY)	YES
Date and Time of Sample Collection	YES

¹The Health & Care Number must be used unless the patient is not registered with a General Practitioner in Northern Ireland (then use the local hospital numbering system)

Note: Requests missing mandatory identifiers will be rejected

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SPECIMEN REJECTION CRITERIA

The following requests/samples will be rejected by the Laboratory and a problem report will be issued:

- Illegible Requests
- Requests missing mandatory identifiers
- Request form and sample mismatches
- Samples collected into an incorrect sample collection type
- Samples too old for analysis

SPECIMEN TUBES /CONTAINERS

It is essential that the specimen is collected into the correct container to ensure accurate results. The following tubes are used:

Saliva Swab – ORAcollect.DNA | OCR-100 (DNA Genotek) - 1ml saliva collection tube containing DNA stabilization agent that preserves DNA within saliva for 60 days at room temperature.

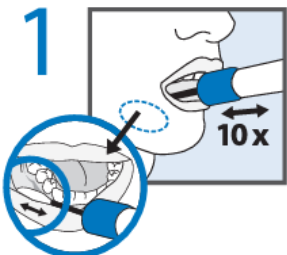


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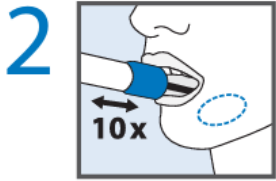
SAMPLE COLLECTION INSTRUCTIONS



EN ENGLISH
 User instructions



1



2



3



4



5

Read all instructions prior to collection.

Collection precautions:
 Ensure the sponge tip does NOT come into contact with any surface prior to collection.
 Donor should NOT eat, drink, smoke, or chew gum for 30 minutes before collecting oral sample.



Intended use: This product is designed for the collection and stabilization of DNA from human oral samples

Contents: 1 kit containing 1 mL stabilizing liquid

Warnings and precautions:
 Choking hazard. Caution should be used when inserting sponge into the mouth.
 Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See SDS at www.dnagenotek.com.
 Report any serious incident to DNA Genotek and the competent authority in your country.

Storage: 15°C ± 25°C (59°F ± 77°F)

Summary and explanation of the kit:
 ORAc collect™-DNA is a self-collection kit that provides the materials and instructions for collecting human oral samples.

Instructions for sample collection:

- Open package and remove collector without touching sponge tip. Place sponge as far back in the mouth as comfortable and rub along the lower gums (see close-up image) in a back and forth motion. Gently rub the gums 10 times. If possible, avoid rubbing the teeth.
- Gently repeat rubbing motion on the opposite side of the mouth along the lower gums for an additional 10 times.
- Hold the tube upright to prevent the stabilizing liquid inside the tube from spilling. Unscrew the blue cap from the collection tube without touching the sponge.
- Turn the cap upside down, insert the sponge into the tube and close cap tightly.
- Invert the capped tube and shake vigorously 15 times.

DNAgenotek™

REF OCR-100
 DNA Genotek Inc.
 3000 - 500 Palladium Drive
 Ottawa, ON, Canada K2V 1C2

Toll-free (North America):
 1.866.813.6354
 +1.613.723.5757
info@dnagenotek.com
www.dnagenotek.com

Patent (EN) Brevet (FR) Patente (ES)
 Patent (DE) Patent (NB) Patent (SV)
 Patent (DA) Patent (NL) Patent (CS)
www.dnagenotek.com/legalnotices

CE MD

Label legend:

	Catalog number
	CE marking
	UKCA marking
	Manufacturer
	Medical device
	Do not reuse
	Consult instructions for use
	Caution
	Use by
	Lot number
	European Authorized Representative
	Swiss Authorized Representative
	Unique Device Identifier
	Quantity of units per package
	Storage instructions

15°C ± 25°C
 59°F ± 77°F

MADE IN US FROM FOREIGN AND DOMESTIC MATERIALS

Made in US from foreign and domestic materials

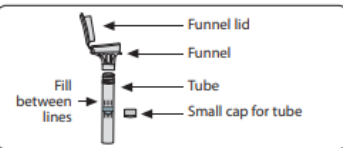
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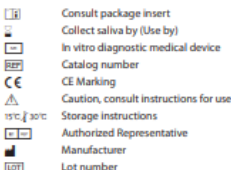
Saliva – Oragene | ON-600 (DNA Genotek) – 0.5ml saliva collection tube containing DNA stabilization agent that preserves DNA within saliva for 60 days at room temperature.





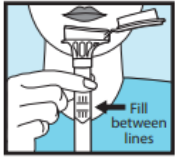
REF ON-500
REF ON-600

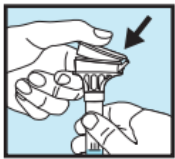


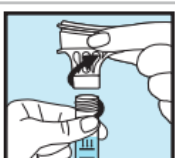
Collection precautions:
Do NOT eat, drink, smoke or chew gum for 30 minutes before giving your saliva sample.
Do NOT remove the plastic film from the funnel lid.
Do NOT spit above the top line on the tube (picture 1).
Intended use: For the collection of human DNA from saliva samples.
Contents: Kit contains stabilizing liquid.
Warnings and precautions: Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See MSDS at www.dnagenotek.com.
 Small cap may pose a choking hazard.
Storage: 15°C / 30°C
Summary and explanation of the kit:
 Oragene-ONE is a self-collection kit that provides the materials and instructions for collecting and stabilizing saliva specimens.
Label legend:


USER INSTRUCTIONS
Read all instructions prior to collection

Procedure:
Most people take between 2 and 5 minutes to deliver a saliva sample following steps 1 to 5.

- 

1 Spit a SMALL amount of saliva into the funnel. Gently tap the base of the tube on a flat surface to help the saliva move into the tube. Check that liquid saliva (not bubbles) level is between the lines as shown in picture #1.
- 

2 Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The tinted liquid in the lid will be released into the tube to mix with the saliva. Make sure that the lid is closed tightly.
- 

3 Hold the tube upright. Unscrew the funnel from the tube.
- 

4 Use the small cap to close the tube tightly.
- 

5 Shake the capped tube for 5 seconds. Discard or recycle the funnel.

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TRANSPORT OF SAMPLES TO LABORATORY

Altnagelvin Hospital based samples:

Hospital Porters: Samples may be sent to the Laboratory via Porters or other Hospital Staff. Sample should be left in Laboratory Specimen Reception Area.

GP Samples: Samples are transported to Laboratory via the normal Laboratory Transport Vans, Taxi or delivered in person as appropriate.

Note: Samples should be transported at RT unless as otherwise indicated.

AVAILABLE TESTS

PGx Panel Test

The following PGx test may be requested using a single saliva sample (acceptable collection devices found within PDL User Manual). The VeriDose Core Panel 2.0 running on the Agena MassARRAY system (Agena Biosciences) targets the most clinically relevant variants in 15 key genes implicated in drug metabolism pathways including 85 Tier 1 and Tier 2 variants according to Clinical Pharmacogenetics Implementation Consortium (CPIC) international guidelines (CPIC guidelines can be found here - <https://cpicpgx.org/genes-drugs/>). The results of this test allows prescribers to modify patient's prescriptions to reduce adverse drug reactions and improve quality of life. Full panel or components of the panel may be requested using sample request form and specific prescription medications may be queried to be investigated. Reports will be returned as a PDF or XML file as per agreement with the Purchaser.

Table 2 PGx profile tested on Veridose Core Panel 2.0.

Gene Symbol	Gene Name	Drug Affected	Classes	Common Medications (Examples)
CYP2B6	cytochrome P450 family 2 subfamily B member 6	Antivirals, Antineoplastics, Anesthetics		Efavirenz, Nevirapine, Cyclophosphamide, Bupropion, Ketamine
CYP2C19	cytochrome P450 family 2 subfamily C member 19	Antiplatelets, Antidepressants, Antiepileptics	PPIs,	Clopidogrel, Omeprazole, Esomeprazole, Citalopram, Amitriptyline, Diazepam
CYP2C9	cytochrome P450 family 2 subfamily C member 9	NSAIDs, Anticoagulants, Antidiabetics		Warfarin, Ibuprofen, Celecoxib, Meloxicam, Glipizide, Tolbutamide
CYP2D6	cytochrome P450 family 2 subfamily D member 6	Antidepressants, Antipsychotics, Opioids,	Beta-	Codeine, Tramadol, Fluoxetine, Paroxetine, Nortriptyline, Metoprolol,

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		blockers	Risperidone
CYP3A4	cytochrome P450 family 3 subfamily A member 4	Statins, Immunosuppressants, Benzodiazepines, Antifungals, Anticancer agents	Simvastatin, Midazolam, Tacrolimus, Cyclosporine, Itraconazole, Erythromycin
CYP3A5	cytochrome P450 family 3 subfamily A member 5	Immunosuppressants, Antihypertensives, Anticancer agents	Tacrolimus, Cyclosporine, Nifedipine, Sunitinib
CYP4F2	cytochrome P450 family 3 subfamily F member 2	Vitamin K antagonists	Warfarin
DPYD	dihydropyrimidine dehydrogenase	Antimetabolite chemotherapies	5-Fluorouracil (5-FU), Capecitabine
HLA-A	human leukocyte antigen A	Antiepileptics	Carbamazepine
HLA-B	human leukocyte antigen B	Antiepileptics, Antiretrovirals	Carbamazepine, Phenytoin, Oxcarbazepine, Abacavir
NUDT15	Nudix Hydrolase 15	Thiopurines	Mercaptopurine, Azathioprine, Thioguanine
SLCO1B1	Solute carrier organic anion transporter family member 1B1	Statins	Simvastatin, Atorvastatin, Rosuvastatin
TPMT	Thiopurine S-methyltransferase	Thiopurines	Azathioprine, Mercaptopurine, Thioguanine
UGT1A1	Uridine Diphosphate Glucuronosyltransferase 1A1	Antineoplastics, Hormones	Irinotecan, Atazanavir, Ethinylestradiol, Bilirubin metabolism substrates
VKORC1	Vitamin K epoxide reductase complex subunit 1	Vitamin K antagonists	Warfarin, Acenocoumarol, Phenprocoumon

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TEST PROTOCOLS

Test protocols are available including:

- Manual DNA Extraction using Mag-Bind® Blood & Tissue DNA Kit CE IVD (Omega Biotek).
- Manual DNA Extraction using Prep-it L2P (DNA Genotek).
- Automated DNA Extraction using Roche MagNA Pure 24 System (Roche)
- Veridose Core 2.0 and CNV 2.0 Panels on the Agena MassARRAY Dx system (Agena Biosciences).

STABILITY OF SALIVA SAMPLES

Samples collected using the DNA GENOTEK OCR-100 saliva collection device are stable at room temperature for at least 60 days, we have verified stability internally for up to 120 days.

TURNAROUND TIMES (TAT)

Table 3 Turnaround Times (TAT) – For Tests performed in PDL.

Test/Profile	TAT (Routine)*
Pharmacogenomic (PGx) Panel	5 working days

*Increase in TAT will occur if incorrect type or number of samples and request forms, insufficient or illegible data.

UNCERTAINTY OF MEASUREMENT

Uncertainty of Measurement provides a quantitative assessment of the quality of a test result. Current international standards (ISO 15189) require laboratories to provide estimates of uncertainty of measurement. An estimate of measurement uncertainty provides an interval of values within which the true value is believed to lie with a stated probability and is therefore a quantitative indication of the reliability of a measurement.

Traceability and uncertainty are fundamental properties of all quantitative measurements. Because all measurements are made relative to a scale or defined standard, they are by definition *traceable* to this scale or standard. Traceability relates a measurement result to a stated metrological reference through an unbroken chain of calibrations or comparisons, each of which may contribute a stated level of uncertainty to the final test result. This unbroken chain of comparisons (leading back to a reference value) allows different laboratories to compare results and relate them to a common measuring scale.

If you require further information or explanation on any of aforementioned or require detailed estimates for any particular measurand please contact the Laboratory.

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CONSENT

For tests sent to the Laboratory: It is the responsibility of the requester to ensure that the patient has been informed of, and has consented to, any such tests as required.

Note: All testing requires consent, and the **[PDL/FORM/22]** Sample Request Form outlines that the requester should only sign the request form if “**consent has been obtained**”. In this regard it is the responsibility of the referring clinician to inform the patient:

- a) of the test to be performed
- b) genetic material will not be stored
- c) that results will be forwarded to their Consultant and GP

The Laboratory assumes that the provision of a sample implies that the referring clinician has obtained consent for testing.

CONFIDENTIALITY OF SERVICE USER INFORMATION

The Precision Diagnostic Laboratory adheres to the WHSCT Policy on the Data Protection Act 1998 and Protection of Personal Information, which outlines the legal requirement for both the Trust and its' staff to treat personal information confidentially and ensure all information is held securely.

COMMENTS/COMPLAINTS/COMPLIMENTS PROCEDURE

The Precision Diagnostic Laboratory adheres to the WHSCT Policy and procedure for the management of complaints and compliments. Copies of the policy are available upon request from the laboratory or via the Trust Intranet. We aim to provide high quality services. If you have a comment, compliment or complaint about one of our services, please let us know by contacting the laboratory via the contact details above (PDL@westerntrust.hscni.net).

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Appendix 1. PDL Sample Request Form

PATIENT DETAILS																	
<i>Enter details below or affix printed label</i> <i>Ensure matching patient details are attached to sample and are not covering sample barcode</i>																	
First name: Surname: H&C No: DOB: Address: Requested by: Hospital/GP: Ward/Clinic: Private Patient: Yes ☐ No ☐	For Laboratory Use Only Affix Laboratory ID Barcode																
CLINICAL DETAILS																	
Nature of Specimen: Saliva ☐ CAT 3 Patient: Yes ☐ No ☐ (If yes please specify)																	
Pharmacogenomic (PGx) Test Requested (Choose a test option): 1. Entire Gene Panel ☐ 2. Selected Panel <table border="1" style="display: inline-table; margin-left: 20px;"> <tr><td>☐</td><td>Cardiovascular</td></tr> <tr><td>☐</td><td>Pain Management</td></tr> <tr><td>☐</td><td>Mental Health</td></tr> </table>		☐	Cardiovascular	☐	Pain Management	☐	Mental Health										
☐	Cardiovascular																
☐	Pain Management																
☐	Mental Health																
3. Specific Requested Genes (Circle all required below) ☐																	
<table border="1" style="width: 100%; text-align: center;"> <tr> <td>CYP2B6</td><td>CYP2C19</td><td>CYP2C9</td><td>CYP2D6</td><td>CYP3A4</td><td>CYP3A5</td><td>CYP4F2</td><td>DPYD</td></tr> <tr> <td>HLA-A</td><td>HLA-B</td><td>NUDT15</td><td>SLCO1B1</td><td>TPMT</td><td>UGT1A1</td><td>VKORC1</td><td>2C Cluster</td></tr> </table>		CYP2B6	CYP2C19	CYP2C9	CYP2D6	CYP3A4	CYP3A5	CYP4F2	DPYD	HLA-A	HLA-B	NUDT15	SLCO1B1	TPMT	UGT1A1	VKORC1	2C Cluster
CYP2B6	CYP2C19	CYP2C9	CYP2D6	CYP3A4	CYP3A5	CYP4F2	DPYD										
HLA-A	HLA-B	NUDT15	SLCO1B1	TPMT	UGT1A1	VKORC1	2C Cluster										
Relevant Clinical Details (e.g. Prescription medication being queried): Signed: (Sign only if consent has been obtained) Collection Date: Collection Time:																	
LABORATORY INFORMATION																	
<table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> Precision Diagnostic Laboratory (WHSCT) C-TRIC Building Altnagelvin Hospital Glenshane Road Derry/Londonderry BT47 6SB </td> <td style="width: 50%; vertical-align: top;"> PDL Specimen Reception EXT: 216641 Email: PDL@westerntrust.hscni.net Refer to PDL User Manual found at https://westerntrust.hscni.net for sample requirements </td> </tr> </table>		Precision Diagnostic Laboratory (WHSCT) C-TRIC Building Altnagelvin Hospital Glenshane Road Derry/Londonderry BT47 6SB	PDL Specimen Reception EXT: 216641 Email: PDL@westerntrust.hscni.net Refer to PDL User Manual found at https://westerntrust.hscni.net for sample requirements														
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