

FoundationOne Liquid CDx Ordering Instructions

➔ www.foundationmedicine.co.nz

Managing your Foundation Medicine account

- Please consider registering before you intend to place an order as it can take some days for a new account to be set up and login details supplied.
- You will be prompted to change your password every 6 months.
- If you forget your password go to the Ordering Portal login screen and click the "Forgot your password?" link to create a new one.

Registration: first time use only

1. Registration
 - Go to www.foundationmedicine.co.nz and click the "Order Now" button.
 - Click "Sign Up"
 - Complete the **Registration** steps
2. Next steps
 - Acknowledgement email will be sent (within 48h)
 - **Next steps** and confirmation email will follow

How to Order

1. Log in to the Online Ordering Portal
 - Log in with your Username (email address) and Password
2. Place the order
 - Click "ORDER NOW" and complete the fields. When the fields in each section have been completed correctly, the background will turn green.
 - *For lab partner (if you have to choose one), please select **IGENZ***
 - ADD a unique patient reference number
 - Select your chosen **test profile** (± PD-L1), and complete the Consent Section. You can download a consent form at this screen using the dropdown (English, Te Reo Māori or Chinese – simplified & traditional).
 - à **CONTINUE WITH ORDER**
 - Complete the patient information, diagnosis & specimen, and your contact information. If you want another clinician to be notified when the report is available click the slider 'add another person' to enter their details.
 - à **CONTINUE WITH ORDER**
 - Review the Order Summary, and select the payment method.
 - **Online Payment** generates an invoice to the payer. Add the payer details (*complete all fields*) and tick the box to confirm the details are correct.
 - à **SUBMIT ORDER**
 - Your order is confirmed. You will receive a confirmation email immediately to your nominated email address.
3. Please complete the next two steps:
 - **Download the test requisition form (TRF)** (attached to the confirmation email)
 - **Print and sign the TRF.** Foundation Medicine require a signed TRF to begin processing the sample.

The TRF is password protected. The order number, e.g. 01-2022-0000xxxx is the password.

4. Draw blood from the patient and fill the tubes in the F1Liquid CDx kit. Place the tubes in the kit box and send to FMI via FedEx.

Refer to Instructions for Specimen Collection and Shipping

Instructions for specimen collection and shipping

1. Unpack the contents of the courier parcel containing the **FoundationOne Liquid CDx** kit.

Contents:

- FoundationOne Liquid CDx test kit (pictured below left)
- Instructions: a) Ordering, b) Specimen Collection and Shipping
- Commercial Invoice: completion instructions
- International Air Waybill: completion instructions
- CDC Import Permit
- APHG Support for FoundationOne® CDx (if required)
- Purple FedEx Document Wallet




FoundationOne Liquid CDx kit contents list:

- Blood collection tubes & stickers (x2)
- inside a snap-lock plastic bag
- Refrigerant Bag & Foil Bubble Bag
- FoundationOne Liquid CDx specimen collection instructions
- Commercial invoice (3 copies)
- FedEx International Air Waybill (to be completed by sender)
- CDC Import Permit
- FedEx Express Large Clinical Pak
- FedEx NZ contact details (top of the box)

Ensure all of the contents are present before proceeding.

2. Check the **expiry date** of the kit - *displayed on the underside of the box, for example:*
3. Complete the following documentation as shown in the templates provided
 - a) FedEx International Air Waybill
 - b) Commercial Invoice

 **31-May-2023**

4. Blood draw (see Specimen Collection Instructions in the kit)

- Draw peripheral blood from the patient and fill the tubes provided in the FoundationOne Liquid CDx collection kit. Ensure you follow the specimen collection instructions.

(Only the tubes contained in the kit are acceptable for FoundationOne Liquid CDx testing).

- Label each tube using the included stickers and affix stickers to tubes (1 per tube).

NOTE: use US date format, i.e. MM/DD/YYYY.

For phlebotomy support, refer to document:

APHG Support for FoundationOne® Liquid CDx

5. Packing the samples for sending

- Place the labelled, filled tubes into the snap-lock bag, place between the folded refrigerant bag and put inside foil bubble bag.
- Place the bag with the samples in the box.
- Fold up the signed Test Requisition Form and place it in the box.
- Close the box.

6. Call FedEx for collection

Call the NZ 0800 number on the sticker on the outside of the box (0800 733-339).
The Information on the FedEx Air Waybill is required to arrange the FedEx pick-up.

7. Place the FedEx Air Waybill into the FedEx Document Wallet by lifting the purple panel.

- Make sure the front of the Air Waybill is visible through the clear panel.
- Include a completed Commercial Invoice form (all copies).
- Include a completed CDC Form – Importer's certification statement.
- Reseal the Wallet as per the instructions.
- Attach the wallet to the front of the FedEx Express Large Clinical Pak.

8. Place the following items into the FedEx Express Large Clinical Pak:

- A recent pathology report
- Foundation Liquid CDx box containing the blood sample
- Signed Test Requisition Form

Seal the courier pack securely.

9. Retain the Sender's Copy of the FedEx International Air Waybill for tracking purposes.

Patient consent

Prior to ordering a profile, the patient must provide consent for Foundation Medicine to conduct the comprehensive genomic profiling. It is optional to provide consent for Foundation Medicine to use their de-identified test results for genomic research.

Patient resources

Patients in New Zealand now have access to information about genomic profiling with FoundationOne by going to <http://www.mycancerisunique.co.nz>.

This website provides information and encourages a discussion regarding genomic profiling with their clinician to determine if it is a suitable option for them.

More information

Information for healthcare professionals, including relevant links and other resources, go to <https://foundationmedicine.co.nz>

Asia Pacific Healthcare Group support for FoundationOne® Liquid CDx

Asia Pacific Healthcare Group (APHG) laboratories now support **FoundationOne Liquid CDx** genomic profiling tests across New Zealand.

APHG Collection Centres will perform the blood draw and sendaway to Foundation Medicine.

INSTRUCTIONS FOR ONCOLOGY TREATMENT CENTRE

FoundationOne Liquid CDx kits must be used to transport the blood sample to the FMI laboratory in Boston. Treatment Centres can order kits directly from Roche by emailing: nz.rfm@roche.com.

Ensure each kit has not passed its expiry date before using

To order a **FoundationOne Liquid CDx** genomic profile visit the online **APAC Ordering Portal**. Go to www.foundationmedicine.co.nz and click on the **ORDER NOW** button to log in or sign up for an account.



Submitting the online order generates a **Test Requisition Form (TRF)**. The ordering physician **must** sign the TRF.

Ensure the patient signs the **Patient Consent Form**. Patient Consent templates are available in the Ordering Portal (English, Chinese - traditional and simplified, and Te Reo). File in the patient notes.

If the treatment centre cannot perform the blood draw and sendaway please refer to the following instructions.

ADVICE FOR PATIENTS

Staff at the chosen Collection Centre will perform the blood draw and send the sample to FMI for analysis using the **FoundationOne Liquid CDx** kit.

1. Make an appointment at a Collection Centre for the blood draw. (See the list on the next page.)
2. Advise Collection Centre staff that the blood draw is for a **FoundationOne Liquid CDx** test
3. Take the following items to the Collection Centre
 - **FoundationOne Liquid CDx kit**
 - **Signed Test Requisition Form**
 - **(Optional) Recent Pathology Report**
4. The Collection Centre will update the date of the blood draw on the TRF and send the blood to FMI for analysis

There is no charge to the patient for this service.

For questions and support, please contact:

Roche | Foundation Medicine: 0800 276 243 | www.foundationmedicine.co.nz | nz.rfm@roche.com

APAC Customer Services: 0800 880 177 | APAC.foundation@roche.com

APHG Collection Centres

Northland Pathology – <https://norpath.co.nz/collection-centres/>
Kaikohe, Kamo, Kensington, Kerikeri, Onerahi, Paihia, Whangarei

Labtests – <https://www.labtests.co.nz/collection-centres/>
Auckland, Waitemata, Counties Manukau, Waiheke

SCL Hamilton – <https://sclabs.co.nz/collection-centre/hamilton-collection-centre/>
Hamilton East

SCL Hawke's Bay – <https://www.hawkesbayscl.co.nz/collection-centres/>
Hastings, Havelock North, Napier, Taradale

Taranaki Pathology – <https://taranakipath.co.nz/collection-centres/>
New Plymouth, Stratford, Waitara, Hawera

Wellington SCL – <https://www.wellingtonscl.co.nz/collection-centres/>
Kapiti Coast, Lower Hutt, Porirua, Upper Hutt, Wairarapa, Wellington

Medlab South - <https://www.medlabsouth.co.nz/collection-centres/>
Marlborough, Nelson, South Canterbury

Canterbury SCL - <https://www.canterburyscl.co.nz/for-patients/collection-centres/>
Ashburton, Christchurch, Waimakariri

SCLabs - <https://sclabs.co.nz/collection-centres/>
Balclutha, Dunedin, Dunstan, Gore, Invercargill, Oamaru, Queenstown

FoundationOne® Comprehensive Genomic Profiling

Use: FoundationOne® Comprehensive Genomic Profiling results may help identify potential targeted therapies or treatment approaches available including clinical trials.

Contraindications: None.

Warnings and Precautions: FoundationOne® profiling provides information about acquired genomic alterations in tissue samples. FoundationOne® profiling does not provide information about inherited genetic alterations. It is possible the profiles will not reveal the cause of your patient's disease or help identify possible treatments. These profiles do not examine every possible mutation or variant that may exist and not identify all mutations related to your patient's cancer. There is a small possibility of errors. Your patient may learn medical information about himself or herself that they did not expect, including learning of additional diagnoses or a change in their condition, which may or may not be treatable and may cause distress. **Please advise your patient that because genetic information is involved, it is possible that the results of these profiles could influence their ability to obtain life, disability or long-term care insurance.** For Healthcare Professional use only. More information, including the Technical Information and Specimen Guidelines, is available at www.foundationmedicine.co.nz.

COMMERCIAL INVOICE

INTERNATIONAL
AIR WAYBILL NO.

leave blank

NOTE: All shipments must be accompanied by a
FedEx International Air Waybill)

Please fill in the white boxes

<p>DATE</p> <p align="center">Add date</p> <p>SHIPPER (complete name, address, telephone, business registration No./ Customs/tax ID No. e.g. GST/RFC/VAAT/IN/EIN/ABN/SSN, or as locally required)</p> <p>Doctor's name Institution Full address (incl postcode) NEW ZEALAND Phone: Doctor's contact number</p>	<p>SHIPPER'S EXPORTER REFERENCES (i.e. order no., invoice)</p> <p>CONSIGNEE (complete name, address, telephone, business registration No./ Customs/tax ID No. e.g. GST/RFC/VAAT/IN/EIN/ABN/SSN, or as locally required)</p> <p>Attn: Accessioning Foundation Medicine, Inc. 150, Second Street, 1st Floor, Cambridge, 02141, MA, United States. Phone: +1-888-988-3639 Fax: +1-617-418-2290</p>
<p>COUNTRY OF EXPORT</p> <p align="center">NEW ZEALAND</p>	<p>IMPORTER - IF OTHER THAN CONSIGNEE (complete name, address and telephone)</p>
<p>REASON FOR EXPORT (e.g. personal gift, return for repair): Molecular Genomic Testing</p>	
<p>COUNTRY OF ULTIMATE DESTINATION: United States</p>	

COUNTRY OF ORIGIN	MARKS /NO'S	NO.OF PKGS	TYPE OF PACKAGING	FULL DESCRIPTION OF GOODS <small>To assist clearance times & reduce delay, the description should answer: What is it? What is it made of? What is it used for? What is it a component of? E.g Ladies 100% Silk Knitted Blouse</small>	HS CODE	QTY	UNIT OF MEASURE <small>e.g pieces, units, set</small>	WEIGHT (lb/kg)	UNIT VALUE (currency)	TOTAL VALUE
New Zealand		1		Non-Infectious Human Blood for Diagnostic Purpose	3002.90.5210	1	EA	0.4kgs	USD	\$ 30.44

	TOTAL PKGS							TOTAL WEIGHT	CURRENCY	TOTAL INVOICE VALUE
	1							0.4kgs	USD	30.44
								<p>Payment method</p> <p>L/C <input type="checkbox"/></p> <p>T/T <input type="checkbox"/></p> <p>Others <input type="checkbox"/></p> <p>Check if applicable</p>	<p>Incq Term</p> <p>FOE <input type="checkbox"/></p> <p>EXW <input type="checkbox"/></p> <p>CIF <input type="checkbox"/></p>	

I DECLARE ALL THE INFORMATION CONTAINED IN THE INVOICE TO BE TRUE AND CORRECT.

SIGNATURE OF SHIPPER/EXPORTER

SIGN HERE

DATE

Add date

FedEx EXPRESS International Air Waybill

For FedEx services worldwide. Packages up to 70 lbs (kg), including dangerous goods. Not all services and options are available in all destinations.

1 From **Please print and press hard.** Sender's FedEx Account Number **MM/DDDY** **Leave this field blank** ONLY

Date **MM/DDYY**

Sender's Name **Doctor's Full Name** Phone **Dr's contact no.**

Company **Institution Name**

Address **Address 1**

Address **Address 2**

City **City** State/Province **Province**

Country **New Zealand** ZIP/Postal Code **Postcode**

Email Address

Internal Billing Reference **MX39795** CHARGERS WILL APPEAR ON INVOICE

2 To Residential Delivery

Recipient's Name **ACCESSION-CUIPISCO** Phone **174182200**

Company **FOUNDATION MEDICINE**

Address

Address **150 SECOND STREET** City/Post **CAMBRIDGE MA**

Country/US ZIP/Postal Code **02144**

PACKAGE LABEL 815307783713 COMMERCIAL INVOICE LABEL 815307783713 DELIVERY RECORD LABEL 815307783713 DELIVERY REATTEMPT LABEL 815307783713

3 Shipment Information Total Weight **1** kg lbs **15 / 15 / 5** m dm

Recipient's Tax ID Number for Customs Purposes **65TRFQVATW/EN/AR/NT/IN/ OR AS LOCALLY REQUIRED**

Commodity Description **NON-INFECTIOUS HUMAN BLOOD EXEMPT SPECIMEN** **DIAGNOSTIC USE ONLY**

DETAILED REQUIREMENTS: NON-INFECTIOUS HUMAN BLOOD EXEMPT SPECIMEN DIAGNOSTIC USE ONLY

Country of Manufacture **US** Date to Customs **15 / 15 / 5**

Total Declared Value for Customs **0** No IED required, value \$500 or less per S.A. # Number. For U.S. Export only. Check One: No IED required, value exceeds \$500 or more per S.A. # Number. No IED required, enter exemption number.

No - Enter AES proof of filing number.

RRDA 0819

RETAIN THIS COPY FOR YOUR RECORDS.

Sender's Copy

0107/0500/0013688420/7

! The service order has changed in Section 4. Signature options have been added to Section 6. For Completion Instructions, and details on services and options, see back of fifth page.

FedEx Tracking Number **8153 0778 XXXX** Form ID No. **0402**

4 **Express Package Service**
NOTE: Service order has changed. Please select carefully.
 FedEx Intl. First FedEx Intl. Priority FedEx Intl. Economy

5 **Packaging**
 FedEx Envelope FedEx Pak FedEx Box FedEx Tube
 FedEx 10kg Box FedEx 25kg Box Other

6 **Special Handling and Delivery Signatures Options** Please mark applicable boxes for the FedEx Service Guide.
 HOLD AT FedEx Location SATURDAY Delivery
 Direct Signature Someone at recipient's address may sign for delivery.
 Indirect Signature Someone at recipient's address may sign for delivery.
 Signature by a neighboring address may sign for delivery.

7 **Payment** Complete payment options for both transportation charges and duties and taxes.
800 Transportation charges by: Recipient Third Party Credit Card Cash Check/Cheque
FedEx Account No. **3197-4261-1** FedEx Use Only

Bill duties and taxes by: Recipient Third Party
FedEx Account No. **319742611**

8 **Required Signature**
Use of the Air Waybill constitutes your agreement to the Conditions of Contract on the back of this Air Waybill, and you warrant that this document does not require a U.S. State Department License or other export-related goods. Credit Card, Third Party, and Cash payment options are available for signature. Signature by a neighboring address may sign for delivery. © 2010 FedEx Corporation. All rights reserved. FedEx, the FedEx logo, FedEx Express, FedEx Signature, FedEx Signature Service, and FedEx Signature Service are trademarks of FedEx Corporation. FedEx, the FedEx logo, FedEx Express, FedEx Signature, FedEx Signature Service, and FedEx Signature Service are registered trademarks of FedEx Corporation in the United States and in other countries. FedEx Signature Service is provided by FedEx Signature Service, a subsidiary of FedEx Corporation.

Sender's Signature: **SIGN HERE** **662**

For questions or to ship and track packages, go to fedex.com.
Or in the U.S. call 1.800.Go.FedEx 1.800.463.3338.
Terms and conditions of service may vary from country to country.
For a full version of the Conditions of Contract, go to fedex.com.

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