

Instructions for contract of Sanofi HRS

Lysosomal Storage Diseases Laboratory

National Taiwan University Hospital

The aims of the National Taiwan University Hospital (NTUH) lysosomal storage disease (LSD) laboratory are to bring diagnoses to patients to enhance their management and treatment.

Tests available for dried blood spot (DBS)

- Fabry disease
- Pompe Disease
- Gaucher Disease
- Mucopolysaccharidoses (MPSs): type I & II
- Measuring DBS Lyso-Gb3 (Fabry Disease), Lyso-GL1 (Gaucher Disease) and Lyso-SM (Niemann-Pick type A/B disease)

Tests available for dried blood spot (DBS)

Genetic confirmation of the following diseases

- Fabry disease
- Pompe Disease
- Gaucher Disease
- Mucopolysaccharidoses (MPSs): type I & II
- Niemann-Pick type A/B disease

Procedures

1. Fill in test request form on NTUH Lab Testing Service e-Platform according to the test request reference (page 9-10), **email NTUH to inform the shipping date**

Miss Teng, Chiao-ning: ntuh.lsdlab@gmail.com

cc. Dr. Hwu: hwuwlntu@ntu.edu.tw

2. Obtain informed consent from patients & physicians (Page 3-4)
3. Prepare samples and the package (Page 5-6)
4. Fill/Sign in the invoice form (Page 7-8)
5. Copy the invoice form and the Air Waybill and **email them to NTUH**
6. Send the package in room temperature which contains:
 - A. Samples
 - B. Test request form (printed from e-platform)
 - C. Inform consent form
 - D. Invoice form
8. Results will be sent through e-platform in 4 weeks

Informed Consent Form (For customs clearance)**To be completed by the patient/parent/guardian**

I understand that Lysosomal Storage Diseases are not common in our region and related diagnostic and monitoring tests are not performed in our places. Therefore I agree to have my blood and urine samples to be sent to National Taiwan University Hospital lysosomal storage disease laboratory for testing.

Printed name of the patient : _____

Signature of the patient/parent/guardian : _____

Date: _____/_____/_____

Day Month Year

知情同意書 (通關用)**由病人/家屬/監護人填寫**

我了解各溶小體儲積症在此地區並非為常見的疾病，因此無法提供相關的診斷或監測檢驗項目。我同意將本人的血液及尿液檢體送到臺大醫院生化遺傳研究室作檢測用途。

病人姓名 : _____

病人簽名 : _____

日期 : _____/_____/_____

日 月 年

To be completed by the Health Professional

We promise that we have informed this patient/parent/guardian regarding results and limitations of this test and get patient's informed consent before sample collection. We assure you that these human samples are not infected by HBV, HCV, HIV-1, or HIV-2 and the exportation of those samples is not restricted in my country.

Printed name of person who obtains consent : _____

Signature of person who obtains consent : _____

Affiliation: _____

Date: _____/_____/_____

Day

Month

Year

由醫療人員填寫

我們承諾已將本檢測結果和檢測限制告知病人/家屬/監護人，並在檢體採集前獲得患者的知情同意。我們保證，這些人類檢體未感染 HBV、HCV、HIV- 1 和 HIV-2，並且這些檢體的出口在我國不受限制。

醫療人員姓名：_____

醫療人員簽名：_____

醫療機構：_____

日期：_____/_____/_____

日

月

年

Prepare and send dried blood/urine spots

Prepare dried blood spots (DBS)

1. Blood sampling by either way (**blood clotting is not acceptable**)

- Venous blood with or without heparin
- Finger/heel prick with or without a heparin capillary tube

2. Apply blood to the center of the circle on a newborn screening card

- Mixed well blood sample
- Allow the blood to soak through the circle
- Fill all circles
- Do not apply blood twice to a same circle
- Do not apply to the other side of the circle

3. Dry the filter for 4 hours

- Avoid sun shine. Do not heat
- Filter can be dried overnight in an air conditioned room

4. Seal in a plastic bag and store frozen.

Sending dried blood

1. Put in a FedEx envelop

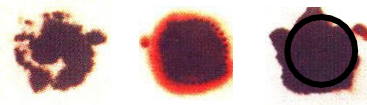
2. Can be sent at room temperature but need to **avoid heating of the samples**

3. Send by **International Priority**

Correct:



Incorrect:

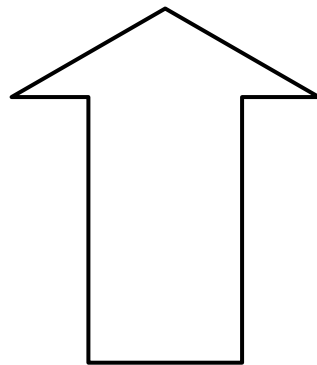


Label of package

Testing for lysosomal storage disease

Non-infectious

Store at 15~25°C



UP

Invoice form (Please fill in the QTY and calculate and sum the VALUE)

Commercial Invoice												
INTERNATIONAL CARRIER AIRBILL NUMBER	FedEx 	(NOTE: send 3 copies with each box. Each box should have its own set of attached documentation)										
DATE OF EXPORTATION				EXPORT REFERENCES (i.e., order no., invoice no., etc.)								
SHIPPER/EXPORTER SHIPPER:				CONSIGNEE (complete name and address) Wuh-Liang Hwu (Paul), M.D., Ph.D. Department of Medical Genetics Room 19004, 19F, Children's Hospital Building National Taiwan University Hospital No. 8 Chung Shan South Road Taipei 10041, Taiwan TEL: 02-23123456 ext 71939 FAX: 02-23314518 E-mail: hwwlntu@ntu.edu.tw ; ntuh.lsdlab@gmail.com								
									COUNTRY OF EXPORT			
									COUNTRY OF MANUFACTURE			
									COUNTRY OF ULTIMATE DESTINATION			
MARKS/ NOS.	NO. OF PKGS	TYPE OF PACKAGING	FULL DESCRIPTION OF GOODS	QTY	W	Unit of Measure	UNIT VALUE	TOTAL VALUE				
	1	Urine blood spot Urine spot	Human urine Dried blood on paper (Human) Dried urine on paper (Human)	— — —		tube Sheet Sheet	US\$ 1.00 US\$ 1.00 US\$ 1.00	US\$_ US\$ US\$____ US\$____				
	TOTAL NO. OF PKGS.					TOTAL WEIGHT		TOTAL INVOICE VALUE				
	1					—		US\$____				

THESE COMMODITIES ARE LICENSED FOR THE ULTIMATE DESTINATION SHOWN.
DIVERSION CONTRARY TO TAIWAN, R.O.C. LAW IS PROHIBITED

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

SIGNATURE OF SHIPPER/EXPORTER

DATE

Guide to fill in Air Waybill

FedEx. International Air Waybill
Express
For FedEx services worldwide. Packages up to 150 lbs. (68 kg), excluding dangerous goods.
Not all services and options are available to all destinations.

1. From / 寄自 Please print in English / 請用英文正確填寫
Sender's Name / 寄件人姓名
Date / 日期
Sender's FedEx Account Number / 寄件人之 FedEx 帳號
Phone / 電話
Company / 公司名稱
Address / 地址
City / 城市
Country / 國家
Postal Code / 郵遞區號
Email Address / 電子郵件地址
Internal Billing Reference / 您的內部帳務參考資訊

2. To / 寄往
Residential Delivery / 住宅遞送
Recipient's Name / 收件人姓名
Company / 公司名稱
Address / 地址
City / 城市
Country / 國家
Postal Code / 郵遞區號
Email Address / 電子郵件地址
Recipient's Tax ID Number for Customs Purposes / 收件人之稅務編號

3. Shipment Information / 託運貨品資料
Total Packages / 總件數
Total Weight / 總重量
kg
DIM
cm
Commodity Description / 商品說明
Harmonized Code / 海關稅則碼
Country of Manufacture / 原產地
Value for Customs / 海關申報值
Total Declared Value for Carriage / 託運申報總值
Specify Currency / 標明貨幣名稱
Total Value for Customs / 海關申報總值

4. Service / 服務
FedEx Intl. First
FedEx Intl. Priority
FedEx Intl. Economy

5. Packaging / 包裝方式
FedEx Envelope
FedEx Pak
FedEx Box
FedEx Tube
FedEx 10kg Box
FedEx 25kg Box
Other

6. Special Handling and Delivery Signature Options
HOLD at FedEx Location / 到站自取
SATURDAY Delivery / 星期六遞送
Direct Signature / 直接取得簽名
Indirect Signature / 間接取得簽名

7. Payment / 付款方式 Bill transportation charges to / 運費由下列支付:
Sender / 寄件人
Recipient / 收件人
Third Party / 第三方
Credit Card / 信用卡
Cash/Cheque / 現金/支票

8. Required Signature / 要求簽名
Sender's Signature

Sender's Copy
The service order has changed in Section 4. Signature options have been added to Section 8. 請參閱 (4) 服務。增加快速遞送及保遞。請參閱 (8) 特別處理及遞送簽名選項。
For Completion Instructions, and details on services and options, see back of fifth page. 請參閱空運提單背面說明。請參閱空運提單第五頁背面說明。
FedEx Tracking Number / 貨件之追蹤號碼
Form ID No. / 表單號碼

- From** : Your information
- Shipment information** : Please fill in the sample type, QTY and the VALUE (Like invoice)
- Service** : Please check "FedEx Intl. Priority"
- Payment** : Please choose "Sender" or "Third Party"
- Bill duties and tax to** : Please choose "Sender" or "Third Party", if you forget to fill in this item, it may cause import delays.
➤ Please remember to fill in the Fedex account number.

Test Request Form

Patient Initials: _____ **Hospital Chart number:** _____
Gender: _____ **Birth date:** _____ (dd/mm/yyyy)
Sample collection date: _____ (e.g., 01/Jan/2018)
Physician Name: _____ **Email Address:** _____
Hospital Name: _____
NTUH Account code: _____

By enrolling in this program, I warrant I will neither seek nor accept payment (directly or indirectly) from a third party for the testing or related activities funded by Sanofi except that such other payment does not overlap the costs, expenses or efforts funded by Sanofi.

Clinical manifestations

- | | |
|---|---|
| ☐ Bone dysplasia | ☐ Cardiomyopathy |
| ☐ Bone fractures and thin cortex | ☐ Facial dysmorphism |
| ☐ Joint contracture | ☐ Mental retardation |
| ☐ Mild hepatosplenomegaly | ☐ Renal failure |
| ☐ Huge hepatosplenomegaly | ☐ Pain |
| ☐ Muscle weakness | ☐ Others: _____ |

Test list:

Fabry Disease

- ☐ Fabry Disease Enzyme Activity Test (DBS) – test code 000X0177
- ☐ Fabry Disease Lyso-Gb3 Test (DBS) – test code 000X0179
- ☐ *Fabry Disease GLA genetic test (DBS) – test code 000X0126

*Tick on this box indicates the agreement of automatic genetic analysis after an abnormal enzyme / biomarker test result, genetic test will not be performed if enzyme activity test or biomarker test is normal.

Pompe Disease

- ☐ Pompe Disease Enzyme Activity Test (DBS) – test code 000X0176
- ☐ Pompe Disease Glc4 Test (urine) – test code 000X0178
- ☐ *Pompe Disease GAA genetic test (DBS) – test code 000X0126

*Tick on this box indicates the agreement of automatic genetic analysis after an abnormal enzyme / biomarker test result, genetic test will not be performed if enzyme activity test or biomarker test is normal.

Gaucher Disease

- ☐ Gaucher Disease Enzyme Activity Test (DBS) – test code 000X0183
- ☐ Gaucher Disease Lyso-GL1 Test (DBS) – test code 000X0179
- ☐ *Gaucher Disease GBA genetic test (DBS) – test code 000X0126

*Tick on this box indicates the agreement of automatic genetic analysis after an abnormal enzyme / biomarker test result, genetic test will not be performed if enzyme activity test or biomarker test is normal.

MPS I&II

- ☐ MPSI Enzyme Activity Test (DBS) – test code 000X0186
- ☐ *MPSI IDUA genetic test (DBS) – test code 000X0126
- ☐ MPSII Enzyme Activity Test (DBS) – test code 000X0187
- ☐ *MPSII IDS genetic test (DBS) – test code 000X0126
- ☐ Urinary GAGs analysis (DUS) – test code 000X0188

*Tick on this box indicates the agreement of automatic genetic analysis after an abnormal enzyme / biomarker test result, genetic test will not be performed if enzyme activity test or biomarker test is normal

Niemann Pick Type A/B Disease

- ☐ Niemann-Pick Type A/B Disease Enzyme Activity Test (DBS) – test code 000X0183
- ☐ Niemann-Pick Type A/B Disease Lyso-SM Test (DBS) – test code 000X0179
- ☐ *Niemann-Pick Type A/B Disease genetic test (DBS) – test code 000X0243

*Tick on this box indicates the agreement of automatic genetic analysis after an abnormal enzyme / biomarker test result, genetic test will not be performed if enzyme activity test or biomarker test is normal

