FibroSIGHT™

ANNEX: INSTRUCTIONS FOR TEST REQUISITION AND TISSUE SAMPLE PREPARATION AND SHIPMENT

For the Physician's Office:

1. **Fill in the Test Requisition Form**

   - Complete **SECTIONS 1-7** of the Test Requisition Form.
   - Select only one test by checking the corresponding box in SECTION 4.
   - Ensure that ordering physician and patient have signed SECTION 3 and 7, respectively.

2. **Complete the Letter of Medical Necessity checklist and have the physician sign this form**

3. **Send the ANNEX, the completed and signed Test Requisition Form (SECTIONS 1-7), Letter of Medical Necessity Checklist and copy of patient's insurance card, to the Pathology Lab**

   - Fax or email all pages of the Test Requisition, copy of patient's insurance card, Letter of Medical Necessity Checklist and this ANNEX to the pathology lab.
   - Email a copy of each to **fibrosight@pacificdx.com**

For the Pathology Lab:

1. **Print a copy of the Test Requisition Form, copy of patient's insurance card and Letter of Medical Necessity Checklist received**

2. **Prepare the Patient's Sample**

   - Prepare 5 unstained sections of 4-5 microns thickness from the patient's FFPE liver biopsy sample.
   - Fill in **SECTION 8** of the Requisition Form with sample information to **complete the form**.

3. **Pack the Sample Collection Kit**

The Sample Collection Kit comes with a clear slide box, bubble mailer, a pre-printed FedEx return label, and a 2in x 2in white seal.

   - Place the FFPE sections into the slide box, then place the slide box into the bubble mailer and seal the bubble mailer.
   - Place the completed Test Requisition Form, Letter of Medical Necessity Checklist, copies of the patient's insurance card and sealed bubble mailer into the Sample Collection Kit.

4. **Initiate a FedEx return shipment**

   - Paste the pre-printed FedEx return label on top of the existing FedEx label on the Sample Collection Kit.
   - Seal the Sample Collection Kit with the 2in x2in white seal.
   - Schedule a FedEx Express shipment to the following delivery address:

Pacific Dx
5 Mason, Irvine, CA 92618

TEST REQUISTION FORM (2 PAGES) FOLLOWS ON NEXT SHEET

FibroSIGHT™

TEST REQUISITION FORM

SECTION 1: Patient Information (Required)			
Name:			
Date of Birth: MM/DD/YYYY		Sex: ☐ M ☐ F	
Ethnicity:	☐ White ☐ Black ☐ Indian/Native ☐ Asian ☐ Hawaiian/Other Pacific Islander		☐ Prefer not to state
Address:			
City:	State:	ZIP:	
Phone:	Email:		

SECTION 2: Insurance Information (*Check one*) (Required)		
☐ **HMO, PPO, Commercial Insurance** – **provide front & back copy of insurance card**		
Patient Relationship to Policyholder: ☐ Self ☐ Other: ***If "Other", complete policyholder information below:***		
Policyholder's Information	Name:	
	Date of Birth: MM/DD/YYYY	Sex: ☐ M ☐ F
	Provider:	Policy #:
☐ **Medicare / Medicaid** – **provide front & back copy of insurance card**		
Subscriber ID:	Authorization #:	
☐ **Self Pay** – patient will be billed directly via mail		

SECTION 3: Ordering Physician Information (Required)		
Physician:		Practice:
City:	State:	ZIP:
Phone:	Fax:	Email:
*Select one method for final **FibroSIGHT™** report delivery:* ☐ Email ☐ Fax		
*Send additional copy of **FibroSIGHT™** report to: (email)*		

As the referring physician named above, I certify that (1) the information provided is complete and accurate to the best of my knowledge, (2) each test ordered herein is medically necessary and appropriate for the patient, is in the best interest of the patient, I have fully documented the basis for this determination in the patient's medical record, and the patient whose biopsy is being submitted for analysis has been informed of the benefits and limitations of the laboratory test(s) requested, has had the opportunity to have all questions answered adequately, and has given informed consent to perform FibroSIGHT™ testing, and (3) I have obtained any and all authorizations and consents from the patient or the patient's authorized representative necessary under HIPAA and state law to release protected health information, including that contained in this form, to PacificDx™ and its contractors and business partners for purposes of healthcare operations, treatment and payments.

PHYSICIAN SIGNATURE (Required)_____ **DATE**_____

Name of Pathology Laboratory where patient's sample is stored:	**Address** of Pathology Laboratory:

SECTION 4: Laboratory Tests Ordered (Required, Please select <u>one</u> option below) *Only liver biopsy is accepted
☐ Fibrosis Assessment: **FibroSIGHT™** only
☐ Fibrosis Assessment: **FibroSIGHT™** and Histology Assessment: **Hematoxylin and Eosin** staining (CPT 88307+0754T)
☐ Fibrosis Assessment: **FibroSIGHT™** with **Masson's Trichrome** staining (CPT 88313+0757T) and Histology Assessment: **Hematoxylin and Eosin** staining (CPT 88307+0754T)

SECTION 5: ICD-10 Diagnosis Code (Required)	
☐ K75.81 (NASH)	☐ Other: _____

SECTION 6: Clinical History (If available)			
☐ VCTE FibroScan ____ kPa Date:	☐ FIB-4 _____ Date:	☐ NFS _____ Date:	☐ Other: _____ Date:

FibroSIGHT™

TEST REQUISITION FORM

SECTION 7: PATIENT'S CONSENT

I hereby consent to the use of deidentified leftover biospecimens collected for the purpose of this diagnostic test, and the deidentified diagnostic outcomes and other deidentified data to be used, at any time and without my additional informed consent or notification to me, for future research purposes, to the extent permissible under applicable law. I acknowledge that this consent is voluntary and understand that research may be about similar or different diseases or conditions, and may be performed by researchers at other organizations. I understand that no individually identifiable information will be collected and used for these research activities. I renounce any rights to such deidentified leftover biospecimens and related data (my "Sample") and assign to HistoIndex® any intellectual property rights that may be derived from Sample, whether derived now or in the future.

☐ **Yes** ☐ **No**

I authorize any physician or lab who has treated me or my dependent(s) to furnish any medical information requested. I understand that PacificDx™ may use the information included on this form and other information provided by me and/or my ordering provider or his/her designee to initiate preauthorization with my health plan as required. I understand a preauthorization approval does not guarantee full payment. In consideration of services rendered, I transfer and assign any benefits of insurance to PacificDx™.

I agree to provide information to assist PacificDx™ in determining insurance coverage for this test. I understand I may be responsible for any out-of-pocket expenses including co-payments and deductibles and payment for the test services provided. I understand I may be fully responsible for payment of my account if PacificDx™ is not a participant with my health plan, or my health plan does not fully reimburse my medical services.

PacificDx™ will work with your insurer to secure reimbursement for your test if available.

PATIENT SIGNATURE _____ **DATE** _____

SECTION 8 to be completed by the Pathology Lab*

SECTION 8: SAMPLE INFORMATION (Required)

***Quick Instructions for the Pathology Lab:**

- Upon receipt of this requisition form, print a copy of all pages received.
- Prepare the patient's liver biopsy sample: **5** unstained FFPE sections of 4-5 microns thickness.
- Fill in the information required below.
- Ship sample to PacificDx (5 Mason, Irvine, CA 92618). For details, refer to ANNEX with Instructions.

Specimen Identifier:

Liver Biopsy Collection Date: MM / DD / YYYY

Number of unstained FFPE sections:

Specimen Information provided by Pathology Staff:

Name: _____ Title: _____ Date: _____.

PLEASE COMPLETE ALL *REQUIRED SECTIONS* OF THE TEST REQUISITION FORM TO ENSURE FibroSIGHT™ TESTING IS PERFORMED AND REPORTED.

RECEIVING LAB USE ONLY

Specimen Received:

Date: MM / DD / YYYY
Time (24-hr): HH : MM

Comments:_____

_____

[Accession Label]