HelioLiver™
POWERED BY FULGENT GENETICS

Test Requisition Form

Please attach any relevant medical records and clinical information to the requisition form.

fulgent | INFORM DIAGNOSTICS™ A FULGENT GENETICS COMPANY

TEST NAME: HelioLiver Test (FT-TP01425)

PATIENT

LAST NAME* | FIRST NAME*

DATE OF BIRTH (MM/DD/YYYY)* | GENETIC SEX* ○ Male ○ Female ○ Unknown

MED REC#/PATIENT IDENTIFIER* | PHONE

EMAIL

I give permission to Fulgent Genetics to perform testing as described. By opting in below, I also give permission for his or her specimen and clinical information to be used in de-identified research at Fulgent and for publication, if appropriate. The patient's name or other personal identifying information will not be used in or linked to the results of any studies and publications. More information is available at www.fulgentgenetics.com/policies/privacy-policy.

By signing, I authorize Fulgent Genetics/Inform Diagnostics to contact me directly, and use the provided billing instructions to bill the indicated method and release medical information concerning the test to the assigned insurance company (if applicable).

☐ Opt in to research

☐ Check this box if you are a New York state resident and give permission for Fulgent to retain any remaining sample longer than 60 days after the completion of testing.

X _____ _____

PATIENT SIGNATURE (REQUIRED FOR BILLING) | **DATE (MM/DD/YYYY)**

ORDERING PROVIDER

FULGENT CLIENT ID*: _____

PROVIDER LAST NAME* | PROVIDER FIRST NAME*

NPI* | PHONE*

EMAIL*

INSTITUTION/PRACTICE NAME

INSTITUTION ADDRESS

CITY | STATE/PROVINCE | POSTAL CODE | COUNTRY

PRIMARY CONTACT NAME | PRIMARY CONTACT PHONE/EMAIL

I attest that I have fully informed the patient about the purpose, capabilities, and limitations of the ordered test. The patient has voluntarily given his or her full consent for the ordered test and a signed copy of this consent is available on file.

STATEMENT OF MEDICAL NECESSITY
By signing below, I, the ordering Medical Provider, confirm that testing is medically necessary and that test results may impact medical management for the patient.

X _____ _____

ORDERING PROVIDER SIGNATURE (REQUIRED) | **DATE (MM/DD/YYYY)**

SPECIMEN DETAILS

Please collect the following specimens for the patient:

- **Whole Blood:** 2 x 10mL PAXgene Blood ccfDNA
- **Serum:** 1 x 7.5mL BD Vacutainer SST Tube

SAMPLE COLLECTION DATE*: _____ (MM/DD/YYYY)

*Required Field

BILLING INFORMATION

Select one billing option and complete all information required in order to prevent a delay in the release of test results.

○ **OPTION 1:** Patient Self-Pay **OR** ○ **OPTION 2:** Institutional Billing

FULGENT BILLING ID*: _____

INSTITUTION/PAYOR FIRST & LAST NAME | ATTENTION TO

ADDRESS | CITY | STATE/PROVINCE | POSTAL CODE | COUNTRY

PHONE | FAX | EMAIL

○ **OPTION 3:** Insurance Billing — Please attach front and back of all insurance cards, ABN, medical criteria form.

ICD-10 CODE(S)* (PLEASE PRINT LEGIBLY AND ENTER ALL THAT APPLY) | REFERRAL/PRIOR AUTH

PRIMARY INSURANCE ID | INSURANCE NAME | STATE | GROUP | INSURANCE PHONE #

INSURANCE PLAN | NAME OF INSURED | RELATION TO PATIENT | DATE OF BIRTH (MM/DD/YYYY)

SECONDARY INSURANCE ID | INSURANCE NAME | STATE | GROUP | INSURANCE PHONE #

INSURANCE PLAN | NAME OF INSURED | RELATION TO PATIENT | DATE OF BIRTH (MM/DD/YYYY)

ICD-10 CODES

ICD-10 code(s) are required for laboratory services. The patient's medical record must support the diagnosis code(s) indicated by the physician. The information below has been provided for the physician's convenience and reference only. Fulgent/Inform Diagnostics makes no recommendation on the use of diagnosis code(s).

Liver Disease
K70 Alcoholic liver disease
- K70.0 Alcoholic fatty liver
- K70.1 Alcoholic hepatitis
- K70.10 ..... without ascites
- K70.11 ..... with ascites
- K70.2 Alcoholic fibrosis and sclerosis of liver
- K70.3 Alcoholic cirrhosis of liver
- K70.30 ..... without ascites
- K70.31 ..... with ascites
- K70.4 Alcoholic hepatic failure
- K70.40 ..... without coma
- K70.41 ..... with coma
- K70.9 Alcoholic liver disease, unspecified

K71 Toxic liver disease
K72 Hepatic failure, not elsewhere classified
K73 Chronic hepatitis, not elsewhere classified
K74 Fibrosis and cirrhosis of liver
- K74.0 Hepatic fibrosis
- K74.00 ..... unspecified
- K74.01 ..... early fibrosis
- K74.02 ..... advanced fibrosis
- K74.1 Hepatic sclerosis
- K74.2 Hepatic fibrosis with hepatic sclerosis
- K74.3 Primary biliary cirrhosis
- K74.4 Secondary biliary cirrhosis
- K74.5 Biliary cirrhosis, unspecified
- K74.6 Other and unspecified cirrhosis of liver
- K74.60 Unspecified cirrhosis of liver
- K74.69 Other cirrhosis of liver

K75 Other inflammatory liver diseases
- K75.81 Nonalcoholic steatohepatitis (NASH)

K76 Other diseases of liver (Includes NAFLD but excludes NASH)
K77 Liver disorders in diseases classified elsewhere

Viral Hepatitis
B15 Acute hepatitis A
B16 Acute hepatitis B
B17 Other acute viral hepatitis
B18 Chronic viral hepatitis
- B18.0 Chronic viral hepatitis B with delta-agent
- B18.1 Chronic viral hepatitis B without delta-agent
- B18.2 Chronic viral hepatitis C
- B18.8 Other chronic viral hepatitis
- B18.9 Chronic viral hepatitis, unspecified

B19 Unspecified viral hepatitis

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HelioLiver™
POWERED BY FULGENT GENETICS

Certificate of Medical Necessity

fulgent

INFORM™ DIAGNOSTICS
A FULGENT GENETICS COMPANY

The HelioLiver™ test is a multi-analyte blood test that can detect the presence of hepatocellular carcinoma with an algorithm that evaluates DNA methylation patterns and protein tumor markers. It is intended to be used as surveillance for patients who are high-risk for liver cancer due to underlying chronic liver disease.

All Fields Required

PATIENT INFORMATION

NAME

DATE OF BIRTH (MM/DD/YYYY)

INSURANCE PAYER

INSURANCE ID

PROVIDER INFORMATION

ORDERING PHYSICIAN NAME

NPI

OFFICE ADDRESS

CITY | STATE/PROVINCE | POSTAL CODE | COUNTRY

OFFICE PHONE | OFFICE FAX

MEDICAL NOTES

CPT CODE
81479

DATE OF SPECIMEN COLLECTION (MM/DD/YYYY)

ICD-10 CODE(S)

SYMPTOMS / CLINICAL FINDINGS

☐ Cirrhosis ☐ Hepatitis B ☐ NAFLD ☐ NASH ☐ Fatty Liver Disease

☐ Other (Please List):

PRIOR HISTORY (CHECK ALL THAT APPLY)

☐ Hepatitis B (HBV) ☐ Hepatitis C (HCV) ☐ Alcohol ☐ Genetic Disorders

Clinical guidelines recommend the surveillance of high-risk individuals for HCC every 6 months. The HelioLiver™ test has been validated and proven to have higher sensitivity when detecting lesions in the liver than currently available blood tests, catching HCC in early stages where potentially curative options such as surgery and ablation are available. In addition to improving outcomes, these options are more cost-effective than later stage chemotherapy treatment.

This test has not been FDA cleared or approved. This test has been validated in accordance with the FDA's Guidance Document (Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA). Test results should always be interpreted by a trained medical professional in the context of the patient's medical history and other clinical data.

X
ORDERING PROVIDER NAME (REQUIRED)

X
ORDERING PROVIDER SIGNATURE (REQUIRED)

DATE (MM/DD/YYYY)

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