PacificDx

FibroSIGHT™

PATIENT		PHYSICIAN	
Name:	Monfort, Gary	**Ordering Physician:**	Dr XXXXX YYYYY, MD
DOB:	1 Jan 1970	**Account Number:**	N/A
MRN:	XYZ6789123	**Practice/ Facility:**	Liver Health Medical Centre
Sex:	Male	**Report copied to:**	N/A
		Pathologist:	Dr XXXXX YYYYY Pathology Labs

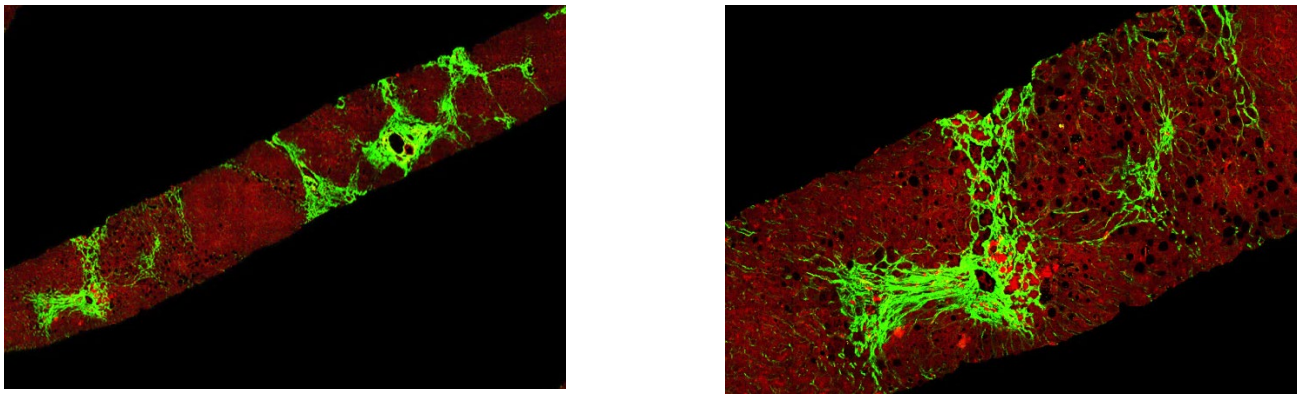
SPECIMEN DETAILS					
Accession ID:	CLNFS-001	**Report Date:**	01/09/2025	**Specimen ID:**	SP24-0000
Receipt Date:	12/23/2024	**Specimen Type:**	Unstained FFPE slides	**Biopsy Date:**	11/07/2024

CLINICAL INFORMATION	TREATMENT INFORMATION
Abnormal liver enzymes, percutaneous liver biopsy.	None

RESULTS

Fibrosis Assessment: FibroSIGHT™

Fibrosis Stage **3** *Range from 0 to 4*



FibroSIGHT™ imaging of liver biopsy

Left (Low magnification): Perisinusoidal, pericentral, peri-portal and bridging fibrosis. Right (High magnification): Perisinusoidal fibrosis. Green represents the SHG signal corresponding to fibrosis and red represents the TPEF signal corresponding to liver cellular morphology (refer to Test Methodology).

Liver fibrosis is consistent with stage F3 for this patient.
Prescription information for Rezdiffra (FDA, 2024). Fibrosis staging reference used is NASH CRN system, with range from 0 to 4 (Kleiner, et al., 2005).

Please see Comments for details of biopsy assessment.

COMMENTS

The sample is adequate for evaluation. Perisinusoidal fibrosis and portal/peri-portal fibrosis are present. Bridging fibrosis is observed.

TEST METHODOLOGY

FibroSIGHT™ is a proprietary digital pathology assessment platform owned by HistoIndex Pte. Ltd and designed for highly sensitive and consistent detection of fibrosis in liver biopsies without the use of exogenous stains or dyes. Utilizing Second Harmonic Generation (SHG) microscopy, FibroSIGHT™ enables high-resolution and consistent visualization of fibrillar collagen and pathological fibrosis in unstained FFPE liver biopsy sections, for consistent grading of fibrosis by the pathologist (Abdurrachim, 2024). The two-photon excitation fluorescence (TPEF) signal permits visualization of background liver architecture through endogenous tissue signals (Sun, et al., 2008). The NASH-CRN scoring system was used to score fibrosis with range from 0 to 4 (Kleiner, et al., 2005).

LIMITATIONS AND DISCLAIMERS

FibroSIGHT™ test is regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 for high-complexity testing. This test has not been approved by the U.S. Food and Drug Administration (FDA). The FibroSIGHT™ test performance characteristics were determined by PacificDx. The test is intended to assist clinicians in making patient management decisions and should be interpreted alongside other clinical data and relevant treatment guidelines. This test is conducted for clinical purposes only and should not be considered investigational or for research. Clinical validation has been established only for unstained FFPE liver biopsy sections of patients with metabolic-dysfunction associated steatohepatitis (MASH). This test is performed by PacificDx.

REPORTED BY

Name: **Signature:** **Date:**

PacificDx | Consulting Pathology
CLIA #05D2243972

REFERENCES

Abdurrachim, D. (2024). The utility of AI pathology as an aiding tool for pathologist fibrosis scoring in MASH. Journal of Hepatology, https://doi.org/10.1016/j.jhep.2024.11.032.

Kleiner, D. E., Brunt, E., Van Natta, M., Behling, C., Contos, M., Cummings, O., . . . Yeh, M. (2005). Design and validation of a histological scoring system for nonalcoholic fatty liver disease. Hepatology, 1313-1321.

Sun, W., Chang, S., Tai, D., Tan, N., Xiao, G., Tang, H., & Yu, H. (2008). Nonlinear optical microscopy: use of second harmonic generation and two-photon microscopy for automated quantitative liver fibrosis studies. Journal of biomedical optics, pp.064010-064010.

U.S. Food and Drug Administration (FDA). (2024). REZDIFFRA: HIGHLIGHTS OF PRESCRIBING INFORMATION. REZDIFFRA is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis(NASH) with moderate to advanced liver fibrosis (consistent with stage F2 to F3 fibrosis).