Terms & Conditions

HistoIndex Ptd Ltd (“HI”), in partnership with a CLIA-certified laboratory (“PacificDx”), provides specialized laboratory testing services on samples and test reports based on tests selected (“Services”). PacificDx provides the services from its CLIA-approved, CAP-accredited laboratory located at 5 Mason, Irvine, CA 92618.

Intended Use

FibroSIGHT™ is a Laboratory-Developed Test (LDT) based on 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. It is based on an imaging methodology called Second Harmonic Generation (SHG) that allows sensitive detection of collagen fibers (excess of which leads to fibrosis) in liver biopsy samples. FibroSIGHT is not intended for direct consumer use or as a standalone diagnostic tool.

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 cleared or approved by the U.S. Food and Drug Administration (FDA). The FibroSIGHT™ test performance characteristics were determined by PacificDx. The test is for informational purposes only, intended to assist clinicians in making patient management decisions and should be interpreted alongside other clinical data and relevant treatment guidelines. It is not intended that

clinical diagnosis and patient management decisions be made using this test alone. 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.

Medical Disclaimer

FibroSIGHT provides imaging-based readouts of patient's liver biopsy samples to support clinical decision-making. It does not replace professional medical advice, diagnosis, or treatment. Healthcare professionals must exercise their independent judgement when interpreting results and making clinical decisions.

Ordering Process

- All samples submitted for testing must comply with PacificDx's guidelines for collection, handling, and shipping. Orders will be processed once all necessary information is received.
- PacificDx is not responsible for the quality or integrity of samples provided by the user.

Turnaround Time(s) ("TAT") as a guide only

All turnaround times for tests administered by PacificDx are provided as an indicative guide only and are based on PacificDx's experience of the time taken for the majority of such test results to be delivered. 'Business day' refers to Mondays-Fridays, 9am-5pm only, excluding Saturdays, Sundays, and public holidays.

Modifications of Terms

HistoIndex reserves the right to modify or update these Terms and Conditions at any time without prior notice. Continued use of FibroSIGHT constitutes acceptance of any changes.

Force Majeure

In the event of unforeseen circumstances beyond our control, including but not limited to acts of nature, governmental actions, or other events classified

as force majeure, HistoIndex shall not be held liable for any failure or delay in fulfilling our obligations. This force majeure clause is intended to provide protection against events that are unforeseeable and unavoidable. We commit to making reasonable efforts to mitigate the impact of such events on our services and will communicate promptly with affected parties regarding any necessary adjustments.